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NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING TO ACCEPT COMMENTS ON THE NRC'S EVALUATION OF TRAINING AND EXPERIENCE REQUIREMENTS FOR DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS

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TUESDAY,

DECEMBER 11, 2018

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ROCKVILLE, MARYLAND

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The meeting convened in the Commissioners' Hearing Room at the Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, at 1:00 p.m., Joan Olmstead, NRC Facilitator, presiding.

NRC STAFF PRESENT:

JOAN OLMSTEAD, NRC Facilitator

SARAH LOPAS, Project Manager, Office of Nuclear Material Safety and Safeguards

MARYANN AYOADE, Health Physicist, Office of Nuclear Material Safety and Safeguards

CHRISTIAN EINBERG, Chief, Medical Safety and Events Assessment Branch, Office of Nuclear Material Safety and Safeguards

JENNIFER FISHER, Office of Nuclear Material Safety and Safeguards*

ALSO PRESENT:

JANICE CAMPBELL*

RALPH LIETO, St. Joseph Mercy Health System*

ARIA RAZMARIA*

JOE RUBIN, United Pharmacy Partners

JEFF NORENBERG, National Association of Nuclear Pharmacies

JOHN WITKOWSKI, United Pharmacy Partners*

*Present via teleconference

C O N T E N T S

P R O C E E D I N G S

1:04 p.m.

MS. OLMSTEAD: Good afternoon. Welcome to the Nuclear Regulatory Commission's webinar to accept comments for the staff evaluation of training and experience requirements for different categories of radiopharmaceuticals.

My name is Joan Olmstead. And I'll be facilitating today's meeting. I am joined here at the NRC's headquarters by Chris Einberg, who is staff of -- Chief of the Medical Safety and Events Assessment Branch.

And Sara Lopas, a member of the Medical Radiation Safety Team, and project manager for the NRC's training and experience evaluation. And Maryann Ayoade, who is a Health Physicist on the NRC's Medical Radiation Safety Team, and the technical lead on the training and experience evaluation.

This is a Category Three public meeting to encourage active participation and information exchange for the public. The NRC staff will provide information on our current evaluation efforts, and then solicit comments on what could be potential issues that should be considered in the Commission paper being prepared on this topic.

I'd like to go over some logistics before we start the meeting. Hopefully everyone has signed in and received copies of the handouts, the presentation slides, the August 18 training and experience information paper that was developed for the Commission, and the training and experience Federal Register Notice that was published on October 29, 2018.

If you haven't signed in, the sheets are near the handout table by the left entrance to this room. For those of you on the phone who haven't signed in, please contact Sarah Lopas to ensure that we have your contact information.

You can get Sarah's contact information from a slide that the NRC staff are about to present. And also from the public meeting announcement.

All web conferencing participants that wish to ask questions or give comments, can type them into the webinar if they would like. People on the teleconference line can also tell the Operator that they would like to ask questions or give comments by pressing star one on their telephones.

The Operator will be putting the teleconference on mute and form a queue for participants. I'll make sure to ask the Operator if there are people that have comments during our comment

period.

This meeting is being transcribed. So in order to get a clean transcript and minimize distractions during the meeting, we'll ask that you turn off or mute anything that rings, buzzes, beeps or alarms.

For folks on the phone, please put your phone on mute unless you're speaking. Please try to minimize loud side conversations. We'll try to have only one speaker at a time.

When speaking, please use the microphone so people on the phone can hear you. We have two standup microphones and one handheld microphone that I can bring to you if you would prefer to stay seated during your comments.

Restrooms are out this door, the one on the left door. And then when you go in the hallway, it's on the left. If we have to evacuate, please follow directions from the security officers.

Are there any questions about the logistics?

(No response.)

MS. OLMSTEAD: Okay. Next slide, please. After the welcome, Sarah Lopas will go into some more detailed information for the webinar participants.

And Maryann Ayoade will give a presentation about the current training and evaluation regulations, and NRC's evaluation process.

After that we'll have a comment period, which will also include seeking comments on particular questions that were raised in the Federal Register Notice.

We'll be taking a short, ten minute break beginning maybe between 2:00 and 2:15 p.m. When we break, we will ask that those of you participating remotely, stay on the phone line and stay logged into the webinar.

Chris Einberg, Chief of the Medical Safety and Event Assessment Branch will start us off with a short welcome and the purpose of today's meeting. I'll now hand the meeting over to Chris.

MR. EINBERG: Thank you Joan. Good afternoon everyone. Thank you for taking the time to attend today's meeting both in person and on the webinar.

Today's meeting is the second of the four comment acceptance meetings that the NRC will be conducting on our training and experience requirements evaluation.

The purpose of today's meeting is twofold.

First, to provide background information on the NRC Staff's planned evaluation of developing tailored training and experience requirements for administering different categories of radiopharmaceuticals, from which a written directive is required in accordance with our regulations in 10 CFR, Part 35.

Which are our regulations for the medical use of byproduct material in Subpart E, under Part 35, which covers unsealed byproduct material written directive required. And most importantly listen to and record your comments on the evaluation.

The comments we receive from the medical community, the agreement states, and other stakeholders, are critical to the NRC staff's decision in making -- to the NRC staff decision making on whether our existing training and experience requirements should be revised.

If you do not provide your comments today, we encourage you to participate in one of our future comment meetings in January. Or submit written comments using the Regulations.gov by January 29, 2019.

Later in the presentation we will cover how you can submit your written comments. And now I'll hand the presentation over to Sarah Lopas.

MS. LOPAS: Hi everybody. I'm going to

-- and so Chris's welcome, thank you for taking the time to be here today.

So for folks on the phone, if you aren't logged into the webinar that's okay. Because you can still access our slides. They are posted on our Meeting Notice.

So, if you go to Google and you Google NRC Public Meeting, the first result that will pop up will be the NRC's Public Meeting Schedule website. If you click on that link, it will take you to the meeting schedule webpage.

And one of the first couple of meetings listed is this meeting, the training and experience meeting. If you click on more, then scroll down, you'll see a link to our slides.

And also, if you were registered for the webinar, you should have gotten a reminder email at about 12:00 p.m. Eastern. And in that reminder email, there was a link to our slides as well.

So, also for logged into -- if you are logged into the webinar, I have uploaded a few handouts on the right-hand side of your webinar under the handout tab.

You can find the same handouts that we have here in the room. So that's our information paper that

we created for the Commission back in August 2018.

We also have the Federal Register Notice. And then we also have the slides for today. So you can download those onto your computer if you're on the webinar.

And of course folks here in the room, feel free to grab those copies here now or on your way out.

So, today we're going to be discussing the NRC's evaluation of our -- of training experience requirements for certain categories of radiopharmaceuticals. And so we're often going to refer to training and experience as T&E.

And then similarly, we will refer to authorized users, i.e., those physicians who are authorized to administer radiopharmaceuticals as AUs. So AUs and T&Es are what you'll hear for short a lot of times today.

As we mentioned, today's webinar is being transcribed by a court reporter. So, we will have a full transcript of today's meeting available for you in a couple of weeks in our Agency-wide Document Access and Management System, or ADAMS as I'm sure you're familiar with.

And I'll be posting a link to that transcript on our training and experience website.

So, all the information from the meeting we have on November 14, you know, an identical webinar on November 14, I've already posted that meeting summary and transcript, and slides from that meeting on that website. So the same thing will happen for this meeting and future meetings.

All the comments today are going to be captured on the T&E docket. So we'll be combing through the transcript and pulling out your comments and your questions for inclusion in our evaluation effort.

And if you speak a comment today, you don't necessarily need to repeat it again, then submit it written on the -- via regulations.gov. I mean, you can certainly if you want.

But, there is no difference. We treat the comments the same whether you speak them over the phone, or you submit them via the webinar and I read them aloud, or you stand up and use the microphone today. There's no difference.

So, we will be opening the phone lines after the NRC presentation for comments. And we'll be going to folks in the room for comments.

And as a reminder, the folks on the phone, you're in listen only. And you're just going to have to press star one to make a comment.

And so now I'm going to go to Maryann Ayoade. She's our health Physicist. And she's the technical lead on our project. And she'll give you some additional background on what we're doing here.

MS. AYOADE: Great. Thank you Sarah. So today I will be presenting information on an overview of the Regulations on training and experience for radiopharmaceuticals that require a written directive, some background information on the related stakeholder concerns that we have received thus far for this evaluation, and NRC's efforts on the evaluation this far.

So the current NRC Regulations on training and experience for radiopharmaceuticals requiring a written directive are under 10 CFR, Part 35, Subpart E.

These training and experience requirements provide three pathways that a physician maybe authorized to administer radiopharmaceuticals that require a written directive.

A physician can be authorized to administer these radiopharmaceuticals if they're certified by a medical specialty board whose certification process is recognized by the NRC or an agreement state.

A physician can also be authorized if they

satisfy the training and experience requirement via an alternate pathway, which includes the completion of seven hundred hours of training and experience. Including a minimum of two hundred hours of classroom and laboratory training in the relevant topic areas as listed in the Regulations. And, five hundred hours of supervised work experience in the relevant areas as listed in the Regulations.

And a physician can also be authorized if they are -- if they have been previously identified as an authorized user of NRC or agreement state license or permit.

For this training and experience evaluation is focused on the ultimate pathway. And NRC staff are looking into what tailored training and experience requirements for a limited authorization and limited administration of certain categories of radiopharmaceuticals would look like.

And that is what we will be referring to as a limited authorized user status. Next slide.

In Subpart E there are four sections that pertain to training and experience requirements. The first section is under 10 CFR 35.390.

And that is for the training for the use of all radiopharmaceuticals in Subpart E. All of which

require a written directive.

The second is under 10 CFR 35.392. And that is for training for oral administration of sodium iodide, iodide-131, requiring a written directive in quantities less than or equal to 33 millicuries.

The third is under 10 CFR 35.394, to train for oral administration of sodium iodide, iodide-131, requiring a written directive in quantities greater than 33 millicuries.

And the fourth section is under 10 CFR 35.396 for training for the parenteral administration of any radiopharmaceutical requiring a written directive.

And I want to point out that all of these sections are training and experience, including the pathway for experienced authorized users already listed on a license.

Also, all the Sections except 10 CFR 35.396 include training and experience under the board certification and alternate pathways. However, 10 CFR 35.396 is for training exclusively under the alternate pathway.

And it really is for the radiation oncologists that are looking to become authorized users. And they can do this by completing some

additional hours of training and experience.

I also want to point out that the alternate pathway under 10 CFR 35.392 and 394 is for the physician to successfully complete 80 hours of classroom and lab training that is relevant to the type of use for which they are seeking to be authorized.

Whereas the ultimate training pathway under 10 CFR 35.390 is for the physician to successfully complete seven hundred hours of training and experience, which includes two hundred hours of classroom and laboratory training. Next slide.

This slides some background information on stakeholder concerns with these related to these training and experience requirements.

Since the revision to the training and experience requirements in 2002 and again in 2005, stakeholders have raised concerns about the effects of some of the requirements of patient access to certain therapeutic pharmaceuticals.

Specifically, some stakeholders have asserted that the seven hundred hour requirement in 10 CFR 35.390 is overly burdensome for physicians who are not certified by medical specialty boards.

And that the extensive requirements have resulted in a shortage of authorized users. Which

thereby limits patient access to certain radiopharmaceuticals.

And so as a result, in 2015 and '16, in separate efforts, the NRC staff and the NRC's Advisory Committee on the Medical Uses of Isotopes, which is the ACMUI, independently reviewed the training and experience requirements for the medical uses authorized under Subpart E.

Specifically, the NRC staff reviewed the regulatory basis and comments that were received on past rulemakings that were related to the medical use of byproduct materials. And did not identify any new information that would call into question the basis of the existing requirements.

As a result, the NRC staff did not propose any changes to the regulation at that time. And the NRC staff is continuing to work with ACMUI on this ongoing training and experience evaluation effort. Next slide.

As part of the staff requirement's memorandum dated August 17, 2017, and that information is publically available in ADAMS in the hyperlink that's referenced on this slide.

The Commission directed the NRC staff to evaluate whether it makes sense to establish tailored

T&E requirements for different categories of radiopharmaceuticals.

To evaluate how those categories should be determined, such as by risks posed by groups of radionuclides, or by delivery method to determine what -- to evaluate what the appropriate training and experience requirements would be for each category.

And to evaluate whether the requirements should be based on hours of training and experience, or focus more on competency. Next slide.

In response to the Commission direction, the NRC staff solicited feedback from some medical and regulatory stakeholders in April and May 2018. That evaluation including the NRC staff analysis and the feedback that was received of the training and experience requirement in Subpart E of 10 CFR Part 35, that was documented in SECY-18-0084.

And the results of the evaluation concluded that it maybe be feasible to establish tailored training and experience requirements for different categories of radiopharmaceuticals. And to create a means of authorizing the administration of certain categories of radiopharmaceuticals, which is the limited authorized user status.

It also concluded that there are viable

options for creating a competency-based approach to demonstrate acceptable training and experience for a limited authorized user status.

But however, the staff needs to conduct more extensive outreach to stakeholders in the medical community, to the agreement states, and to other members of the public before making any recommendation to the Commission.

And this brings us to our current evaluation to date. So, I will now hand over back to Sarah, who will be discussing our current evaluation efforts, and how you can participate.

MS. LOPAS: Thank you Maryann. So, the end product of our evaluation is going to be a paper that we're going to send up to our five member Commission.

And that paper will either document our reasoning for recommending no changes to the T&E requirements, or if we do recommend changes to our T&E regulations, if we conclude that these changes are warranted, we will document our reasoning and our plan for rulemaking in what we call a rulemaking plan paper.

This is a simplified diagram on this slide. The information that we're going to consider in our development of a recommendation to the Commission on

whether changes to our existing T&E regulations are required.

The diagram -- this diagram illustrates why this comment period is so important. Because in a large part, the feedback that we receive on the questions that we've asked in the Federal Register, are going to inform our recommendation to the Commission.

So, other important feedback that will also come from our coordination with our co-regulators, the agreement states, and the NRC's ACMUI, the Advisory Committee on Medical Use of Isotopes.

In addition to the input that we received from the public, medical stakeholders, the agreement states, and the ACMUI, the NRC is going to examine the issue of patient access.

So our staff is going to determine -- is going to attempt to determine the number of current authorized users and their geographic distribution across the United States.

An authorized user and associated geographic location data is not quite easily and readily available, so we're spending the next month or so pulling that data together from our web-based licensing system, and putting that data set together.

So, staff is also going to be reviewing training and experience requirements in other countries, in an effort to benchmark the U.S. against international medical regulations.

And then the third piece that we're going to look at is, we're going to do a review of medical and radiation safety events to see if any of those have a nexus to training and experience.

And it's important to note that if staff does end up recommending a rulemaking, which we would again, document in a rulemaking plan, the Commission would then proceed to the vote on that rulemaking plan. And that would determine whether or not the staff would proceed with the Part 35 rulemaking effort.

If rulemaking is recommended and approved by the Commission, that would start the NRC's extensive rulemaking process. Which I'm sure you're all painfully familiar with, right?

So, I wanted to highlight that process information. Because I think it's important that everybody understands where we are at this point in time with this process.

And where we are is that we're still in the information gathering stage, to help us determine whether rulemaking is even warranted at this point in

time.

So, I hope -- I hope at this point folks have read it. But our Federal Register Notice was published on Monday, October 29.

And that Federal Register Notice can be accessed via the link on this slide. Or you can also Google the citation. Which is 83 FR 54380. And it will pop up at the top of the search results.

So the Federal Register Notice, it announced our public comment period, which ends on January 29, 2019. It announced the dates for these public meetings and webinars.

And I'm going to talk a little bit about the remaining meetings we have. But most importantly, the Federal Register Notice asked a series of questions on which we would like medical community, stakeholder input.

And I'm going to take a moment to just read through those questions right now. I'm just kind of going to buzz through them. And it's more to give everybody a context of what the information that we're looking for.

When we do get to the comment portion of the meeting momentarily, you know, I'm going to open it up for general comments. And everybody can make

their general statements.

And then depending on time, and interest, I will attempt to maybe walk us through some of the more specific areas, the more specific questions to see if I can draw out some additional information on top of maybe some of the general statements that we're going to get from folks today.

Okay. So, the first set of questions, extensively covers the crux of what we're evaluating. Whether the NRC should create a tailored training and experience requirements for certain categories of radiopharmaceuticals.

So, A1, are the current pathways for obtaining AU status reasonable and accessible? Are they adequate for protecting public health and safety?

A2, should the NRC develop a new tailored T&E pathway? What would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements?

A3, Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status?

A4, how should the requirements for this fundamental T&E be structured for a specific category

of radiopharmaceuticals?

The next set of questions focuses on the NRC's recognition of medical specialty boards. So the NRC procedure for recognizing these boards is located on our medical uses licensing toolkit website. Which I hope that folks are familiar with.

So, our first question is, what boards, other than those already recognized by the NRC, could be considered for recognition for medical uses under 10 CFR 35.300.

And the second question, B2, are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

The next set of questions, the third set of questions focuses on patient access to nuclear medicine.

C1, is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? And if so, is the shortage associated with the use of a specific radiopharmaceutical?

C2, are there certain geographic areas with an inadequate number of AUs?

C3, do current NRC regulations on AU T&E requirements unnecessarily limit patient access to

procedures involving radiopharmaceuticals?

And C4, Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine?

And the last set of questions was just asking for more general input or opinions on the NRC's regulation of training and experience in general.

So, the first question was, should the NRC regulate the T&E of physicians for medical uses? Second question, are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

And the third question, how can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the general public, patients, and human research subjects.

So those are the questions that we've asked in the FRN. And we are hoping to get some feedback on.

So how can you submit your comments or respond to these questions? Well, in addition to speaking during today's meeting, and during the additional meetings we have scheduled in January, which are January 10 and January 22, you can also just provide

written comments via regulations.gov.

And this link in this slide, the direct comment submission link, that will get you right to the comment submission portion of the T&E docket. And you can either upload a comment, you know, a Word document or a pdf, or kind of anything along those lines, or you can type directly in the text box.

I just want to note that at the NRC I have immediate access to those comments as they're like submitted via regulations.gov. But there is a little bit of a lag time due to processing we do here at the NRC, where you won't be able to see your comments immediately.

I won't get into the details. But, you won't see your comments immediately, but I will get them immediately. And we work to get them up there as quickly as we can, back up on regulations.gov.

So you should be able to see other folks comments up there as well. We -- right now I will be honest, we have only submitted -- we only have six comments up there.

We've only had six written comments submitted so far. But, I actually -- I have also posted on that T&E docket the transcript from the November 14 meeting as well, so.

If you encounter any issues with regulations.gov, just email me. And I can help you out.

And at the end of this public comment period, we will be compiling all the comments that we receive, both written and oral, and we'll be publishing them in one easily accessible comment reports.

And that comment report will not only, you know, lift out all the comments received, but it will also summarize the input that we receive. So, that comment report, that's going to be available on the NRC's T&E website.

And we are going to -- also, we'll make sure it's posted to the regulations.gov docket. And we will probably reference that heavily in our Commission paper.

And it's important to note that because this is in a rulemaking, that the purpose of collecting your comments is to help inform us. So, we aren't going to be responding to individual comments like you would kind of see in a rulemaking.

Or if anybody's seen how we respond to comments like in an environmental impact statement. It won't be like that. We're simply intaking comments at this point.

So we have two more public meetings, January 10 that's going to be -- January 10 and January 22.

January 10 is similar to this meeting where it's a webinar, but it's also in person. And that will be over in our Three White Flint building across the street on -- across Marinelli by the other Metro.

And then January 22 will just be one last chance. It will be a two-hour webinar again to just kind of capture any last comments.

And again, all those details are on our public meeting website.

So just briefly, I'll cover our next steps. After the comment period ends on the 29th of January, we're going to begin organizing and evaluating all the comments that we've heard from everybody.

And the NRC still will also, right now and into that period, we are working on conducting that additional research that I noted earlier. Doing that additional work involving, you know, looking at patient access, international bench marking to see what other countries are doing, and then assessing the medical and radiation safety events.

And then the ACMUI Subcommittee on training and experience will provide the NRC a report of their

findings and recommendations regarding the T&E requirements, sometime in the spring of 2019, like in March 2019.

And the NRC staff is going to consider that as well, their input as well in developing our draft recommendations.

And then both the agreement states and the ACMUI will have an opportunity to provide their comments on our draft Commission paper when we get that together. And the NRC will consider and incorporate their comments on our draft paper.

We'll incorporate that then into our final paper. And that final paper will be going up to the Commission in the fall of 2019.

So, for additional information, I just want to point out that we do have this website, our training and experience website. I'm doing my best to keep that updated with everything that you could possibly need on this effort.

So, the SECY papers, and anything that we publish or make publically available like our meeting summaries, and the transcripts, and all that good stuff.

The T&E docket, that's associated with regulations.gov. So that number, that NRC-2018-0230, that's the docket on regulations.gov.

Like I said, probably the best thing about that is you will see all the comments, all the written comments that everybody else has submitted, on regulations.gov. And that's probably the best place to go there.

And then of course Maryann and myself are your points of contact. I think if you have technical questions, I would please ask that you contact Maryann. And then if you have more process type questions, I can help you out with those.

And I think that's it. I think we can get into comments. We're kind of right on time more or less, 1:33.

So, I do want to remind that folks on the phone, so you can go ahead and press star one. I am going to start with comments in the room, because I do want to acknowledge the fact that there are some folks here in the room that did travel.

So I appreciate that you guys came out here to the NRC. So we'll start in the room. And we have to use microphones so that folks on the phone can hear and our court reporter can hear.

And if you can begin by introducing yourself, I mean, of stating your name clearly. If you have an affiliation that you would like to state,

you certainly can. You don't need to provide an affiliation.

And I think that's it. So we will just get started. Does anybody want to -- we can either run a mic to you, Joan can run a mic to you. Or you can use a -- use one of the stand mics.

Go ahead. Yeah. And folks on the phone, just go ahead and press star one. And we'll check in with you in just a moment.

And folks on the phone -- on the webinar as well, you can also submit a comment via the webinar using the question function. And I can read it aloud for you.

Okay.

MR. RUBIN: Good afternoon. I'm happy to go first. My name is Joe Rubin. I'm appearing on behalf of United Pharmacy Partners, and alliance of 83 independent commercial nuclear pharmacies and affiliate nonprofit academic medical center radiopharmacies across the country, which are focused on delivering prepared radiopharmaceuticals for diagnostic, molecular imaging, and therapeutic patient needs.

UPPI and affiliate pharmacies provide more than eight thousand unit dose prescriptions for

diagnostic imaging and radiotherapy every day.

John Witkowski is the President of UPPI, and he's on the phone to help address any questions that may come up in this discussion.

The two primary issues I'd like to address today, the first is the geographic distribution of AUs, and the impact that has on patient access to radiopharmaceuticals.

And second was how the NRC's regulatory approach can be transformed to ensure that public protection is maintained while expanding access to radiopharmaceuticals, by expanding the role of nuclear pharmacists.

Nuclear pharmacies play a vital role in the distribution and administration of alpha and beta emitter therapies to patients across the country. The training to become an authorized user as a nuclear pharmacist, is the same as the training for physicians.

The same seven hundred hour requirements. And NPs maybe listed on the radioactive materials license as the AU and radiation safety officer.

To help address the likely disparate geographic distribution of authorized users, which is having a detrimental effect on patient care, particularly in rural areas, UPPI urges the Commission

to consider enabling the teaming of onsite nuclear pharmacists and the specialist physician with limited hours of specific training.

This concept, which was previously submitted to the ACMUI committee, would enable the nuclear pharmacist and specialist physician team to fill the AU requirement as it pertains to radiation protection, patient care, and safety.

This would enable the specialist physician to handle the patient care aspects of treatment, and the radiopharmacist to handle the radiation safety aspects of the procedure.

The team would continue to ensure that the experience and training necessary of the AU is present for the administration of a radiotherapy of a particular procedure.

It would dramatically expand the service area for nuclear medical procedures utilizing alpha and beta emitters, protecting patients, and expanding patient opportunities.

So first, let me talk a little bit about the role of nuclear pharmacists. Nuclear pharmacists are trained authorized users, but generally have far more radiation safety responsibilities then physicians and others.

NPs have responsibility for creating doses, performing quality control of the radiopharmaceutical preparations, handling the radioactive waste of doses dispensed.

There are currently more than one thousand licensed authorized user nuclear pharmacists across the country. And unlike physicians, they are spread more broadly across rural markets.

Nuclear pharmacists are responsible for receiving and safe keeping of raw nuclear material such as molybdenum-99 generators, and converting the highly radioactive elutions into technetium-99.

Nuclear pharmacists must then draw the unit doses into the correct amount of technetium radioactivity required by the physician, or other radiopharmaceutical to make patient ready doses.

This step requires sophisticated analysis and understanding of the decay rate of the emitter, the time of day that the procedure will be administered, and the necessary amount of materials that must be available at the time the procedure is administered, to ensure that the patient receives the correct amount in the dose.

If the emitter has decayed too much at that time, the procedure maybe less effective. And if it

has not decayed enough, then the patient may receive a stronger dose of radiation then is necessary.

Further, nuclear pharmacies like UPPI members, generally create a number of doses in one central location, which are delivered across the geographic area.

For example, one UPPI member with labs in eastern and western Florida, distributes more than five hundred unit doses per day across Florida, from Gainesville to Miami and from Ocala to Fort Myers.

The nuclear pharmacists know and understand the nuclear safety challenges, preparing many hundreds of doses, and delivering them across such great distances. And how to handle any radiation safety concerns.

Let me talk a little bit about the shortage of authorized users. Antidotal and statistical evidence strongly supports the contention that there is a shortage of AUs in rural areas.

There appears to be no definitive answer as to whether or not there's a shortage of AUs, or if there's an uneven geographic distribution of AUs across the country. And if so, what that impact on patient care maybe.

And we appreciate that the NRC is going

to look very closely at that. However, antidotal evidence strongly suggests there is a strong regional disparity.

And this is having a major adverse effect on rural healthcare. For example, according to the National Rural Healthcare Association, there are critical shortages of physicians in rural communities across the country.

The patient to primary care physician ratio in rural areas is 39.8 physicians per 100 thousand people. Compared to 53.3 physicians per 100 thousand in urban areas.

In an emergency, rural patients must travel twice as far as urban residents to the closest hospital. The distribution disparity among specialists is even more acute.

While there are 263 specialists for every 100 thousand citizens in urban areas, that number drops to 30 specialists per 100 thousand residents in rural areas.

There's no reason to believe that the distribution of physician AUs is any different than the general distribution.

This assumption is supported by antidotal evidence as well, that clearly demonstrates there are

several areas of the country that face acute shortages of AUs. For example, testimony provided by Bayer to the ACMUI, describes in detail the difficulty it is facing in rural Michigan because of a shortage of AUs.

So, measuring the actual distribution again, we agree with the NRC and the American College of Radiology that there is a need to find trustworthy data about current active AU populations.

The UPPI has submitted to the NRC a Freedom of Information Act request to attempt to help ascertain the number, type, and training and locations of AUs. And we'd love to work with you on fulfilling that, and the process that you guys have undertaken.

So here's our partial solution at least, as I mentioned earlier. Allow AU nuclear pharmacists to work in direct concert with the limited trained physician specialists, oncologists, or other specialists in the administration of patient prepared doses.

Nuclear pharmacists are authorized users who arguably have more responsibility for radiation safety, handling, use, and transport, then anyone else in the system. They're also on call to rural areas that may not have AU locations as they deliver patient ready doses.

This availability gives them far great reach then the current system. Particularly if they are able to team with a limited trained specialist physician to provide patient care.

Enabling licensed, trained, responsible nuclear pharmacists to assist the limited trained specialist physician to administer patient ready doses of alpha and beta radiotherapies, would dramatically expand patient access.

In other words, instead of reducing the AU training for certain procedures, the Commission could maintain its current AU training standards. And expand the availability of AUs by enabling nuclear pharmacists to work with a limited trained specialist physician.

Accompanying our submission, are UPPI's comments from 2016 that first raised this suggestion. We will be submitting a more detailed comment later in this process.

We wanted to raise this proposal at this public meeting to give the NRC and other commentators an opportunity to ask questions, and consider this proposal, so that we may help address these questions as part of the RFI process.

Thank you. And with that, I'm happy to

take any questions.

MS. LOPAS: I have one question for you. Do you know -- this is Sarah Lopas. Do you know when you guys submitted that FOIA?

Because I'm looking at my coworker and --

MR. RUBIN: It was within the last two or three days.

MS. LOPAS: Okay. We'll get it soon then.

MR. RUBIN: Yes.

MS. LOPAS: All right, excellent. Thank you.

MR. RUBIN: Thank you. Thank you very much.

MS. LOPAS: Okay. Does anybody want to go next in the room? Or should I go to the phones?

Okay, I'm seeing some looking around in the room here. So, Candy, do we have anybody who's pressed star one on the phone?

OPERATOR: Yes. We do have John Witkowski. Your line is open.

MS. LOPAS: Okay.

MR. WITKOWSKI: Thank you. I'm the President of UPPI. And Joe Rubin offered our statement there.

The comment I wanted to add is that there

will be a growth of alpha and beta radiotherapeutic products in the future. That the regulations should consider expansion of these products becoming a greater portion of the therapies available to patients as time moves forward.

The process of having a nuclear pharmacist team with a limited trained authorized user medical specialist, such as a medical oncologist, is similar to a dual authorized user situation that has been familiar with the NRC in the past.

We think this is an opportunity to reach out to areas where patient populations can better be served, because alpha and beta therapies may require more than a single injection. So if we go for a course of -- and that's radium-223, for a course of therapy, it is six infusions.

And to have a patient from a rural area make six trips over many, many months to a location to receive the radiotherapy, when it could be done with a dual authorized user situation, would save the patient a lot of time and expense. And then there would be better follow up to patient care.

Thank you.

MS. LOPAS: Okay. Thank you very much. So a reminder for folks on the phone, press star-one. And I also

want to just let you know that you can submit a question or a comment to me using the question function on the webinar, and I can certainly read it aloud for you, if you would -- if you would feel more comfortable doing that.

Candy, do we have any other questions or comments on the -- on the phone?

OPERATOR: We are showing no questions at this time.

MS. LOPAS: Okay. Does anybody in the room want to make a general comment or statement?

Okay. All right, guys. I'm going to just walk us through some of these questions, and it might be radio silence and that's okay, but I'm going to try. I'm going to try here, and maybe we -- we end our meeting very early, depending on if we just really get no -- no input.

So here I just want to focus on some of the specific questions that the NRC asked in our Federal Register Notice, because we are looking at -- we would like to get some specific feedback on these questions. It is going to help us develop our paper for the Commission.

So here we have these questions about -- there's four general questions under tailored training

and experience requirements. And if you open up the FRN, the Federal Register notice, if you have that on -- with you now or if you're on the webinar, that's one of the handouts that I uploaded, we actually asked a whole bunch of subquestions underneath these questions.

So there really are a ton of questions that we could -- we could delve into here, but I'm wondering if anybody has any specific feedback. The last webinar we had, we got some feedback that -- that it would be difficult if the NRC created additional categories for radiopharmaceuticals, that if new -- we got one comment that said that if new radiopharmaceuticals came in and they didn't kind of fit precisely under our categories that then we'd have to figure out where they fit, and that could delay patient access to getting these new -- these new therapies.

So that was one comment that we got where somebody was against creating more specific categories for training and experience.

And I just want to add another point of thought, just kind of summary of what we heard in our last meeting maybe, and maybe it will jog some -- jog some comments. Somebody did give the point that they thought that some of the more patient-ready doses of

radiopharmaceuticals just really did not merit the 500 and 200 hours, so total 700 hours, and then that was adversely affecting patient access.

And then a converse point to that was that if we allow physicians to just kind of come in with a limited amount of training, like 80 hours or whatever it might be, that that wouldn't help advance the general field of -- of nuclear medicine in the United States, that the physician pointed out that nuclear medicine and the advancements and developments in this field of medicine are lagging behind other countries because -- for whatever reason. And that if we just kind of let these specialists come in and just kind of do one thing, and they only do the one thing, and they don't do any advancements in the field, that that wouldn't help the overall nuclear medicine field.

So those are some of the -- some of the things. I'm trying to -- a number of things in our last webinar on November 14th, but I don't know if that jogs any comments that folks would have, anybody wants to comment on creating specific categories?

Candy, is there anybody on the phone?

OPERATOR: Currently, we are showing no questions. Again, for questions or comments, press star-one.

MS. LOPAS: All right. Or you can submit a comment via the webinar.

We have the fourth question the slide, the fourth part of the questions that we had.

Question 5 here, this was the part that had all sorts of -- all sorts of subquestions, so if anybody has any thoughts on this one. We did get some input last time around, but there should be -- the radiopharmaceutical manufacturers should be able to provide preceptor attestation. We did get that input.

And feel free to jump up and use a mic. You look like you want to comment. All right. We've got a taker. I like it. I like it. Okay. And star-one on the phone, and we'll come back to you folks on the phone.

DR. NORENBERG: Hi. I'm Dr. Jeff Norenberg. I am the Chairman and the Executive Director of the National Association of Nuclear Pharmacies. We are a trade association. Our membership is exclusively comprised of nuclear pharmacies that provide the unit-dose, patient-ready radiopharmaceuticals that are used in diagnostic and therapeutic nuclear medicine, some 35,000 doses per day. About 10 million per -- patients per year are affected by the drugs that flow through the nuclear

pharmacies.

Our mission as a trade association is to identify and communicate the best practices in nuclear pharmacy that can ensure patients have access to safe and effective radiopharmaceuticals and thereby improve the quality of medicine that is delivered in the nuclear medicine departments by the customers who we serve.

So our feeling on this issue is that all avenues should be explored, that we should identify opportunities to provide greater access to patients, acknowledging the shortages of some of the specialists and practice settings that are often required, which do negatively impact patients and require the need to travel, as a previous commenter alluded to.

We are also aware that physicians can play a critical role, and there may be opportunities for enhanced training, additional competencies to be demonstrated, which would improve patient access. So I think were agnostic to -- at this point to the specific remedy, but we do think that patients should have access to the right drugs, the standard of care necessary to alleviate the suffering from the bad diseases that they suffer.

And we do believe that the current paradigm has shown us that there are limitations, and some of

it is scope of practice and maybe beyond the mandate of this group, but we want to make sure that we balance the needs to ensure public safety and the safety of the occupational workers who participate in these therapies.

So our participation today is really just to encourage the dialogue about learning more for specific categories of radiopharmaceuticals, specific routes of administration, unique practice setting requirements that can be identified and resolved through additional opportunities for training and education, leading to competencies that would allow a greater number of patients to receive these vital therapies.

And so I think there have been a number of important points made today, and through the written comments there are a lot of thoughtful questions being asked, and I'm glad to see that the NRC is revisiting this issue. I was a little bit -- our members I think were a little bit discouraged by the previous subcommittee dialogue that occurred -- not being broad enough, perhaps ignoring some inputs -- and we're glad to see that this is on the docket and getting a full public treatment, and we look forward to providing more specific information about the training and education

that can be provided.

As an aside, my full-time job is I am a professor of radiopharmaceutical sciences and the Director of Radiopharmaceutical Sciences at University of New Mexico.

We developed Nuclear Education Online, which is an education and training platform specifically to deliver authorized nuclear pharmacist training. We started in 2000. That program is a web-based program that provides 200 didactic hours, and then we have a -- we work in partnership with training sites, and we have promulgated a training guide which has task-specific, competency-driven exercises that can be effected in a practice setting, and we mentor the preceptors to deliver those 500 hours of tactical experience.

Over 25,000 students have participated in courses offered by Nuclear Education Online, not all nuclear pharmacists, but a lot of nuclear cardiologists. We do a lot of training for shippers and receivers of radioactive material, seeking to comply with DOT requirements for training and education. And in that way, the Nuclear Education Online has endeavored to provide a full suite of didactic and experiential components that can serve

a variety of different audiences.

And we believe that similar mechanisms can be brought to bear to overcome some of the obstacles that we encountered that led to the formation of Nuclear Education Online to address the needs of pharmacists, nuclear cardiologists, and other workers in this area.

Prior to 2000, this education and training was done exclusively onsite. At the University of New Mexico, we have trained over 300 nuclear pharmacists, but not everybody wants to go to New Mexico and spend the 700 hours. It's hard to imagine that people wouldn't love to go to New Mexico, but it is a hardship to transplant oneself and to move to that geography.

And so we tried to provide an anytime, anyplace, any base, any pace kind of an education platform that could overcome some of those geographic barriers. And, really, we see today more and more education is moving beyond bricks and mortar and getting into more of a just in time, you know, professional adult learning kind of environment. I don't want to throw too much pedagogy, you know, buzzwords at you, but there is a lot of science behind the efforts at online learning.

We have grown a lot in the 18 years since this program was launched. We have learned a lot about

the environment, and this has led to our graduates and certificate holders being accepted in virtually every jurisdiction, agreement states, NRC regions, et cetera.

And so we have a lot of faith and confidence in our ability to deliver those online and to validate the outcomes that the students' competencies demonstrate, and similar efforts could be brought to bear to overcome the training needs in this area.

And so I would just encourage everyone to have an open mind and think about not only historical data but also future opportunities that we have for education and training. And I think we all want the same thing; we all want patients to get those necessary therapies.

And whatever the education necessary, if it's 700 or 200 or 80, I'm confident that we can develop high-quality programming and educational opportunities that can satisfy those needs, and we can do it in a -- in a very facile way that can lead to a reproducible outcome and impart competencies that would satisfy the need to balance the protections of the public and the occupational workers with those needs of patient access.

So with that, I will stop talking and take any questions that I might have raised.

MS. LOPAS: That was great. Thank you. I appreciate that. Do you know how many folks -- I'm just curious how many folks you -- since you started that online training, how many folks have kind of -- do they graduate from your program, or how does that --

DR. NORENBERG: Yeah. We've had over 400 nuclear pharmacists, and we've had some 13 -- 1,300 or so radiation workers. We've done a lot of DOT because the frequency of training is every two years, and some employers would like it done every year to overcome any training requirements that DOT might interpret.

And then, probably about another 300 or so authorized nuclear cardiologists, COCAPs, sort of changed their model for the pre-qualifications for the exam. So we had a large bolus of those nuclear cardiologists that came through the program about five to seven years ago, but there still are some.

And then we provide ongoing opportunities for, you know, nuclear pharmacists. There is about -- as the previous speaker alluded to, there is over 1,000. We like to think there is about 1,700 nuclear pharmacists in the U.S., about 1,200 full-time, and every year there is about 100 or more turnover.

Pharmacy has a lot of practice

opportunities. People often move from one practice setting to another. And having the unique skills to work with aseptic processing, radiation safety, and specialized parenterals, a lot of nuclear pharmacists find opportunities to work in hospital or specialized infusion areas, and vice versa.

So we see pharmacists that come in and out of nuclear pharmacy throughout their career, and some of them, you know, may need to address the recentness of training requirements. And so we have done a lot of sort of refreshers where people come back and repeat the course because it has been 10 years since they worked in a nuclear pharmacy, or whatever.

And so we see, you know, 100 or so people coming into nuclear pharmacy or refreshing their training a year. And I -- I would guess that trend will continue as we see sort of the dynamics of the workforce and the aging population, that there will be a consistent need for slightly more than 100 nuclear pharmacists a year.

MS. LOPAS: All right. We've been doing -- Dr. Donna-Beth Howe and Maryann have been doing recent public meetings on our -- changes to our Part 35 regulations, which go into effect on January 22, 2019.

I'm trying to think of some of the questions that we have been getting about recentness of training, and so that's interesting to hear.

MS. AYOADE: Yeah. That's correct. I just wanted to correct for everybody on the record, it's January 14th for the NRC licensees, and for agreement states it's three years from that date, which would be January 14, 2022.

MS. LOPAS: All right. Thank you so much.

DR. NORENBERG: Thank you.

MS. LOPAS: All right. Candy, do we have anybody on the phone, any star-ones on the phone?

OPERATOR: We do. We have a question from Janice Campbell. Your line is open.

MS. CAMPBELL: Hello. Yes, I have a question. I am a medical physicist specializing in nuclear medicine, and, you know, one of my -- I guess I just want to clarify in my mind, you know, we currently have authorized users authorized to oversee diagnostic radiopharmaceuticals for imaging.

And as -- as I oversee these types of programs and do a lot of teaching, I think of those as sort of lower risk radionuclides, and it sounds like -- but, please, you know, clarify for me -- what we're looking at is changing the training and experience

requirements for the higher risk radionuclides, the ones that actually are for treatment.

And when I say "higher risk," I guess these are the ones that could, you know, cause harm, that a medical event could occur with.

And are we asking for these to be able to be administered in a special practice setting, you know, something like where they would have an independent, you know, license? One of the -- you know, a special license specifically for one radiopharmaceutical, and that specific or special doctor would -- or authorized user would oversee the staff and the safe use of just that radiopharmaceutical? Is that what we're kind of looking at?

MS. AYOADE: Yes. So we are evaluating the training and experience requirements for radiopharmaceuticals under Subpart E, which is for the 10 CFR 35.300. It is primarily therapy uses and for iodine -- iodine risks.

MS. CAMPBELL: So --

MS. AYOADE: I mean, greater than 30 -- 30 microcuries.

MS. CAMPBELL: Right. So, in essence, so what I'm saying is correct, we would be --

MS. AYOADE: Yes.

MS. CAMPBELL: -- requiring these authorized users to have less training than the lower risk diagnostic radiopharmaceuticals.

MS. AYOADE: If you -- yes, but we are just evaluating our current training and experience requirements. We are not putting out, you know, any -- anything yet.

MS. CAMPBELL: Right, right. No, but I just wanted to make sure that that was part of what we're looking at. And the reason is because there is not enough physician-authorized users in rural areas, and -- but these physicians would have to get their own license, correct?

MS. AYOADE: Yes. They would have to get their license to be able to practice in NRC states.

MS. CAMPBELL: I see. So they would have -- that would have to be part of their training, I would think. Okay. I just -- I just wanted to clarify, because earlier one of the speakers from UPPI was discussing a lot of the diagnostic doses that are delivered and the difficulty in the regions and geography, et cetera.

And so it made me start to think that we were talking about diagnostic doses as well that these authorized users would be able to, you know -- would

be overseeing. But it sounds like it's specifically just for the therapies.

MS. AYOADE: That's correct.

MS. CAMPBELL: Okay. Okay. Thank you very much.

MS. LOPAS: Thank you. Thank you for commenting.

OPERATOR: Thank you. Again, for questions or comments from the phone, it's star-one. We do have another question on the phone. Ralph Lieto, your line is open.

MR. LIETO: Thank you. I am a medical physicist and a former radiation safety officer, and my question is actually -- my first question actually goes back to questions 1 through 3. I thought I understood what the NRC was driving at when they used the term "current pathways for obtaining authorized user status."

But now I'm a little -- I think maybe the NRC might need to clarify that because -- and what the previous commenters were saying about nuclear pharmacists, is the intent of the NRC to look at pathways other than licensed physicians obtaining, say, any of the requirements of certain board certification, having certain qualifications, and completing that board

certification?

Or are you -- do you intend to make this open-ended? You would have pharmacists that they use providing this administration? Because I could see that this pathway is sort of an open-ended thing. You could have highly qualified nuclear medicine technologists, you know, providing an end-use status qualification that's not going to be a physician.

So could you clarify what you mean by "the current pathways"?

MS. AYOADE: This is Maryann Ayoade for NRC. When we say "the current pathways," we're looking at the current NRC requirements. So that is for physicians right now.

Now, as part of our evaluation, we are, you know, taking comments, and you have received comments, you know, several comments regarding taking a look at pathways for other than physicians. And so that's part of, you know, what we're -- we're going to be looking to use as part of our evaluation.

MS. LOPAS: Right. So I think the point is that we are welcome -- we are open to -- to all comments essentially, that we have heard that, that ANPs should be considered. So we're open. We're in this information-taking-in period. So that's

something that we are open to hearing as well for sure.

MR. LIETO: Okay. So my understanding, that this current pathway was pretty much an open-ended road by which any medical professional with the proper training and experience could become an AU to administer these Part 300 radiopharmaceuticals.

MS. AYOADE: Yes, that's correct.

MR. LIETO: Okay. My next question goes back to regarding number 5. And, again, you make a -- your clarification from NRC staff. These issues about the requirements for training and experience address the -- what I'll call the radiation safety aspects of the worker training and experience.

Is the intent of the NRC to also have some understanding that this must include the clinical patient care aspects and appropriateness of patient care? Which the NRC is pretty clear that they do not regulate.

So I'm trying to understand where the NRC has drawn the line between radiation training, safety, and -- radiation safety training and experience, and which it, obviously, it would be an appropriate way to regulate as opposed to the training and experience that is required by getting some type of clinical competency and appropriateness, and so forth, which

they are not supposed to be involved with.

MS. AYOADE: So I'm just -- I think I'm trying to understand exactly what your question is. But, again, with this question, just like we said before, we -- and I'm thinking you're referring to the work experience section. You know, we focus on radiation safety as it relates to some of our training, and there is always the talk of, you know, where we draw the line with impinging on the practice of medicine.

But, again, for these questions, we -- we want to hear, you know, from the public. We want to hear what you guys think in terms of what you want to see NRC doing for work experience and where we should draw the line. That's something we will consider based on the feedback that we get as we move forward in evaluating this current training and experience requirement.

MR. LIETO: Thank you.

MS. LOPAS: All right. Thank you. Candy, do we have anybody else on the phone?

OPERATOR: We're showing no questions at this time.

MS. LOPAS: Okay. Star-one for the folks on the phone, if anybody wants to make a comment in

response to anything that you've heard so far today, or talk about something new; that's great, too. Or you can send me something via the webinar software. That's fine, too.

Is there anybody in the room here that wants to make any additional comments? Yes, please.

DR. NORENBERG: All right. This is Jeff Norenberg. I'm speaking as an individual. Is that better? Sorry. Jeff Norenberg, speaking as an individual.

I wanted to fill in some context and perhaps help us understand some of the common features of licensed independent practitioners that are designated through the CFR and recognized by medical boards, pharmacy boards, TMS, and others.

The status of the license independent practitioner is granted by virtue of a professional degree and then a state licensure by a medical board or a pharmacy board. And I think that's different than what we see happening for technical personnel that go through a voluntary registration that don't have a national standardization of their training and experiential requirements. It's on a state-by-state basis.

And I think this has bearing on the

consideration of some of the issues that have come forward today. In many states, pharmacists are granted independent prescribing authority to administer vaccinations, do TB testing, birth control, hormonal contraception, and other things that benefit public health. And they do this after receiving training and education and demonstrating competency in a very specific category or task-specific practice setting.

In addition to the independent practitioner status that allows prescribing authority without monitoring, a number of states have pharmacist clinicians where pharmacists work under the supervision of a physician to administer the entire spectrum of therapies to diagnose and treat the chronic diseases that require intensive drug management, things like diabetes, HIV, hemophilia.

These are things that are treated per protocol that require intensive medication intervention. And as the medication experts that are duly professionally licensed and receive special training, pharmacists are identified as the best resource for many of these patients.

So I can't say today that I see the similar cadre available for therapy, but I could engage in their future state, that certainly radiopharmacists today

have the most experience handling radiopharmaceuticals. The volumes and the expertise and the manipulations that they do far exceed any other category of occupational operator in this paradigm we are discussing.

And I think, you know, back to my days doing therapy with investigational therapeutic radiopharmaceuticals, we have treated approximately 70 patients with investigational therapeutic radiopharmaceuticals, and oftentimes, you know, plumbing is really the key to getting the drug into the patient.

And there are -- there are some technical just staff's eye on this that experienced radiopharmacists bring that can overcome potential barriers. This is why most of nuclear medicine today is delivered as patient-ready doses that get administered directly to patients.

And so I could see a future state where patient-specific therapies with a dose that is prepared unique to a patient is delivered to a clinic, and then it really becomes a matter of getting it into the patient safely and avoiding untoward occupational exposure.

And those are the kinds of things that I think pharmacists have some unique capacity to do.

It's not to make treatment decisions, but it's, rather, to effect therapies that have been so directed under the written directive.

And so I could see that there are opportunities to overcome some of these barriers through that specialized training, and it should probably be drug or isotope-specific, practice setting-specific, and I think that that's a way where we have a track record of being able to ensure the safety of occupational workers and the public through the 10 million doses or so that travel through nuclear pharmacies today.

And so I see that there is a lot of different ways we could solve this. There is a bill in Congress right now to amend the Social Security Act and designate pharmacists as providers. That could have some bearing on the practice.

But I think from a radiation safety perspective and the health physicists patient control initiative, it is really about controlling exposures to the public, the occupational exposures, and making sure that we don't have untoward medical events that result in reportable errors.

And those are the kinds of things that I think we perhaps haven't recognized some of the unique

skills and depth of training that pharmacists have. So however we can solve this, and I'd like to see all powers brought to bear, physicians getting additional specialized training, technical staff improving their competencies, and other nuclear pharmacists and others, radiologists taking more interest in this practice setting.

So thank you for that opportunity to provide context. And if there's any questions, I'll --

MS. LOPAS: Candy, do we have anybody on the phone? Star-one on the phone.

OPERATOR: Thank you. Currently, we're showing no questions at this time.

MS. LOPAS: All right. Folks on the phone, star-one. I think since it's 2:16, the comments are kind of coming in slowly, we will not take a break. We will just kind of, you know, push forward, since we will likely be ending early. I don't think we need a break.

So star-one on the phone, and let's give folks a few more minutes. And then, in the room, just feel free to raise your hand or jump up. Yes, jump right up.

Okay. Let's see, does anybody have any input on our recognition medical specialty boards?

I don't know if there is anybody in the medical branch who wants to talk about anything that we're doing. No? I see heads shaking. Okay.

Okay. Let's see, and so the patient access issue, I can talk for just a moment on this because I'm working on this. So I will -- full disclosure, you know, right now we are limited with the data that the NRC has, and that data is of the NRC licensees, which is only 13 states. So, and there are limitations to the information that we could ask from our agreement states.

So the NRC is starting by looking at the facilities that are licensed to administer 300 drugs. We're mapping those for NRC licensed facilities, and we're also looking at the AUs associated with those licensees. So we will have that information for our 13 states where we are -- we are doing the licensing there.

So for the agreement states, we do not have that information, but that is kind of an evolving -- it's an evolving data set that we are working on. So we are looking at that carefully, but I do want to point out that that is a limitation we have.

But we -- we did get a question as to why we were asking this. We got a recent question asking,

"Well, don't you have that information at NRC? Why are you asking for that that input in the FRNs?" And we wanted to -- I mean, we are asking this because we want to hear, you know, specifically from folks that may be experiencing the impact. You know, if folks are being negatively impacted, and they think it has to do with our training and experience requirements, we want to hear that. So that's why we're asking these questions.

And, for instance, we do know that some stakeholders have given us information on this, like Bayer, and so we're encouraging -- we would like to hear more data from that end. So that's why we're asking about patient access.

Candy, can I check in on the phones? Star-one on the phone.

OPERATOR: Currently, there is no questions. And, again, yes, as a reminder, it's star-one.

MS. LOPAS: Okay. And then, so then this last set of questions, just to provide some context on this and then we'll check in for any more comments, you know, so the NRC in general has been looking at how they are -- how they should potentially transform their regulatory environment to continue to transform

the technology that is going on around us and the changes in our industry that we regulate. So this is kind of our -- our attempt at seeing if we could get any input or opinions from our stakeholders on maybe how we could continue to evolve and change as an agency when it comes to regulating the T&E of physicians for medical uses.

So, you know, we did hear a little bit about somebody -- I guess Mr. Lieto or Dr. Lieto mentioned about not impinging on the practice of medicine. So it is a fine line to walk.

So let me just check back in the room here, for the folks that traveled, anybody want to make any last comments? I'm getting silent looks here in the room.

And, Candy, can I check one last time on the phone?

OPERATOR: Yes. We do have Ralph Lieto. Your line is open.

MS. LOPAS: Hi, Ralph. Go ahead. Are you there? Ralph?

OPERATOR: Sir, your line is open, in case you might have muted your line. Again, Ralph, do we have you on the phone?

MR. LIETO: Sorry about that. Yes, I was muted. I just wanted to clarify on the point that you

made about collecting the data of users for Subpart E. Did you say you are only going to get it from the non-agreement states? Or that you are also going to include some of the agreement states?

MS. LOPAS: So right now the NRC, we only have non-agreement state data at our disposal immediately. There is a couple complicating factors. If we were to go out and ask the agreement states for all this data, it could be a pretty heavy lift, and we wouldn't need to apply for -- it's a little -- it's kind of, you know, government parlance, the Office of Management and Budget clearance information, collection clearance, and that's quite a process.

We are going to -- we are working with the Organization of Agreement States. We are in active discussions with them, and we may broach with them if there are states that maintain a database kind of similar to what we do. But if there are states that could kind of easily pull this information for us and give it to us, maybe even if it's just kind of raw and then we kind of sort through it, we will do our best.

So, but at the moment, the only data that we can get is NRC licensees. I don't know if -- Chris, if you have anything to add to that.

MR. EINBERG: That was a good summary.

MS. LOPAS: So, yeah, Ralph, more or less that -- that's the answer. Right now, we only have the 13 states of the licensees that we regulate.

MR. LIETO: So are you going to do any type of -- I imagine there is an issue that -- you realize that the largest state is going to be Michigan, and everything else is going to be basically extremely rural areas with few licensees.

MS. LOPAS: Right. I mean, I would imagine, I mean, there -- and we don't have -- we haven't pulled the map yet, you know, but we are -- we've got Michigan, Delaware, Vermont, Wyoming. Even though Wyoming is an agreement state, we still have their medical uses. Puerto Rico.

I mean, I think we're going to see that this tracks with physician access in general, right? I mean, you can't get brain surgery in a little teeny tiny town. You have to go to a major metropolitan city, right? I think it is going to be a little similar.

So I think you're right, and I will say that we struggle a little bit with what to do with the data that we are going to get, the maps that we're going to present. I mean, I think we kind of know what it's going to show us. So then the question will become, well, what -- what do we glean from those maps? So

it's a little tough, but -- I don't know if you have any additional thoughts on that.

MR. LIETO: Are you asking me?

MS. LOPAS: Yeah, I am. I am. I mean, there is -- I'm mean, that's kind of where --

MR. LIETO: You automatically collected the number of licensees that are in each state, and so forth. I kind of agree with one of the commenters before that -- or I think they -- they had asked a question like, don't you have that data already?

I think it's something that has been asked a number of times over the last probably two to three years. I would think at least the agreement states would be put on some kind of a request that they start to put this data together because there is obviously a demand for it. And I think it's kind of surprising that you don't have any idea on the number of licensees that are authorized for these high-risk radiopharmaceuticals.

I mean, it doesn't have to be, you know, exact, but at least some kind of a distribution, even by the states, who is authorized for this. And it's kind of surprising, that's all. And I think if the intent is not being able to do it in the timeframe of this comment period, I think the agreement states still

should be asked to start to generate that kind of data on a routine basis.

I think it -- I think it's quite important. You know, they're going to have future needs also. Just my thoughts.

MR. EINBERG: Thanks, Ralph. This is Chris Einberg. So we do collect that -- or we do collect data on the number of licensees on an annual basis. But we don't have the exact location of use for the licensees. So that has been the difference here.

You know, as far as, you know, collecting the information in the future, as Sarah pointed out, there is a lengthy Office of Management and Budget clearance process to start collecting that data. But that doesn't preclude us from starting the dialogue with the agreement states, which we have started, and we'll have actually a telecon with them on Thursday.

And this is an area of discussion that we plan on discussing with them on how best to collect this data and how -- or do they have this data available, so that we can help map out the authorized users at specific locations for these authorized users. So we're working, but it's a -- it's a work in progress.

MS. LOPAS: All right. We've got another comment here in the room. Star-one on the phone.

DR. NORENBERG: Hi. This is Jeff Norenberg with the National Association of Nuclear Pharmacies. I just want to comment on nomenclature for a moment. I think it's risky to accept the designation "high-risk radiopharmaceuticals" to create any sort of a nomenclature around that notion.

There are specific terminologies that the Institute for Medication Safe Practices uses to designate high-alert medications, high-risk medications, and others. And I think we ought to really be disciplined and stick to that 35.300 definition of radiopharmaceuticals requiring a written directive and avoid the common casual references to other terms that we might want to apply.

Thank you.

MR. EINBERG: Thank you.

MS. LOPAS: Okay. Candy, do we have any other comments on the phone?

OPERATOR: Yes. I have a question from Jenny. Your line is open.

MS. FISHER: Hello. This is Jenny Fisher from the NRC, and I just wanted to comment, to go back to when we were talking about the different states and to clarify that we're not just regulating the rural states, that we do have a couple of states -- Missouri,

Indiana, and Michigan -- and each one of those states have authorized users in the hundreds. So we're not just doing your limited access states as far as NRC regulations.

MS. LOPAS: Thanks, Jenny. That's helpful. Yeah. I couldn't think off the top of my head the 13 states that we -- we are looking at.

Okay. Candy, is there anybody else on the phone?

OPERATOR: We're showing no questions from the phone.

MS. LOPAS: Okay. All right. So I'm going to give folks just one more minute -- star-one -- to make any comments on the phone. And while I do that, I just want to close out with just a thought that we -- and I didn't mention this during our last webinar, but we do have meeting feedback forms. They're online, however. They -- if you go to our meeting notice after this meeting closes out, give it a couple hours, like if you go tomorrow, there will be a link for you to provide meeting feedback, and it's online now instead of our old paper and -- you know, paper, put it in the mail thing.

And I do remind folks, if you could, if you -- if you could just sign in, if you forgot to sign

in on your way in, that would be helpful for us for my meeting summary.

And our comment period closes January 29th. So if you are submitting those official written comments, we ask that you get them in by that date on regulations.gov. If you have any issues, again, you can just email me and I can take your comments as well and get them on the docket.

Candy, one last check? Comments on the phone? Questions on the phone?

OPERATOR: Thank you. And, again, as a reminder, star-one. I think we do have one in queue. Standby, please.

MS. LOPAS: Okay.

OPERATOR: We do have a question on the phone. We do not have a name recorded. So if you could press star-on, your line is open for your question. Go ahead, please.

DR. RAZMARIA: Hello? Can you hear me?

OPERATOR: Yes. Your line is open. Go ahead, sir. And your name, please?

DR. RAZMARIA: Hi. How are you? This is Aria Razmaria talking on behalf of nuclear medicine regulator issues. I just kind of thought that, kind of listening to the open public comments today, and

I cannot really --- can just offer my -- but I can, basically, just wanted to provide a comment as a physician in training and also in terms of what kind of scope of practice and how the future of nuclear medicine is going to be.

Again, I am really perplexed and asked myself, okay, why did I go to medical school where they have more than 10 years of training? And basically they are, you know, training in nuclear medicine in general, medicine in other areas, to be able to provide, you know, professional care of patients. And that's why I was listening to the comments today.

So respective of all of the providers that are contributing to patient care in terms of pharmacy technology -- but you kind of have to -- for myself, I think there is a clear delineation of practice. So we -- you heard about, you know, from -- a nuclear pharmacist being able to provide professional, you know, input to the clinic. But, again, what is -- from that point on, what is the clinical decision that is made based on? You know, what is the role of a physician?

Again, I don't -- I know I don't want to be --- I have really got to hold myself back and kind of listen to what you are talking about, and, you know,

have -- you know, just debate what the pros and cons are. And I kind of just think to myself, okay, you know, if one of my family members needs to have --- be in nuclear medicine study or anything, nuclear therapy, whom do I kind of go to, trust to?

And I kind of really -- kind of taken aback by some of the comments or, you know, asking, you know, that this is kind of public, you know, open forum where basically anyone can have these things, which is fine, which is correct, but, again, what is the quality of care that you are looking? What is the future of nuclear medicine?

Again, now, if you look outside borders, nuclear medicine in Europe, it has advanced significantly. All these therapies that we are currently talking about that are being able to be admitted to patients have been in the majority of cases coming from Europe, in countries that have a clear nuclear medicine delineation, scope of practice, who work on these therapies and develop in clinical trials and have brought it to fruition. And because of the regulatory framework in these countries, allowing this specialty to thrive and move forward. So I'm just really taken aback by comments made today, with all due respect to all of the teams and groups that are

working in the benefit of patients. And it's not about profit, about benefit, it's about patient care and quality of care.

And I will ask everybody in the audience, who would you like to send your loved ones to? Who wants to -- what do want to have your loved ones taken care of? Someone who has, you know, access of medicine who is trained in dealing with complications in different areas.

These new therapies are not just a simple injection. If you talk about new therapies, this has significant toxicities that come with it, like having chemotherapy administered by someone who is not trained in administering chemotherapies or newer therapies.

So it is not trivial, and I think the regulatory framework in the U.S. in the past has caused significant harm and detriment to the field of nuclear medicine. And the discussion that we are having today, everyone seems to want to have a part of the cake, but it is not about this. It's about patient care and the quality of care and some, you know -- some people that are dedicated to taking it forward, not about one pharmaceutical that is now the drug of the future, what other cancers can be treated with radiopharmaceuticals.

Again, with respect to all of the

participants that are taking care of patients and doing their best to provide professional care, but there is an area that, you know -- you know, who has just financial benefit and maximization of profit, which obviously industry is significantly interested in, but not losing, you know, the goal that we have, the quality of care, patient safety in mind.

It's not just radiation safety. It's just the clinical expertise in how that patient, what sequence of the therapy is indicated, which, you know, once a radiopharmaceutical therapy fails, what other option is there, in collaboration with oncology, with radiology, with other specialties that are interested.

So, again, I am surprised, I do really know that, you know, opening up all training requirements for, you know, the public. You know, I could just, you know, have, for example, my grocery store providing me my, you know, medicine that I need. So it's -- and there is expertise that goes with like pharmacies that can provide professional information about the medicines, the contraindications, or if there is observed side effects.

But there is an expertise that comes with the clinical practitioners that have read diagnostic studies, you know, and just are not focusing on one

treatment but know what the imaging aspects that their study looks at, what therapies are indicated in certain scenarios. What radiation dose is there, for that specific tumor burden is indicated.

So it is not simple. You know, I am -- just listening to the conversation, I am thinking if one of my loved ones needs access to nuclear medicine, whether the U.S. would be the right place to go or another -- go across country, go to Europe, and have it done by, you know, centers that specialize on these type of treatments.

And we won't be enhancing future of this type of treatments by opening up -- and specialized therapeutic treatments to, you know, public access.

So I know the concern, and I'm really surprised by how NRC is approaching this question with all the respect and all the -- you know, due respect in the field and that the federal agency has. I am kind of really surprised by the approach that is being taken.

It is -- it is not a simple -- there is a reason that medical specialties are present. There is a reason that the training program asks for those medical specialties. And all of this discussion and approach that NRC is taking undermines all reasoning

in terms of why these medical specialties are allowed, why there is a medical board of radiology, why there is a board of nuclear medicine.

So they have specific training requirements that, you know, involve the clinical expertise and knowledge that is needed for practicing that field. So it is -- the way I perceived this by NRC is opening up, you know, training to -- I mean, don't take me wrong, I am all open for patient access, but the patient access is just meaning, okay, opening up center for cardiothoracic surgery, and, you know, having family practitioners doing that.

And I am, as a nuclear medicine person, not able to understand what -- how to do surgery, so this is kind of expertise that a medical specialist would have developed to provide guidance. So I don't -- I just wanted to provide a comment. And I really have tried to hold myself back, but just wanted to have that thought in.

And then, just expecting that surprise, how NRC is approaching this and how it is basically really to detriment of a medical specialty.

Thank you.

MS. AYOADE: This is Maryann Ayoade with NRC. Thank you for your comments. We appreciate that.

Just to clarify, again, we are not -- you know, our intention with this evaluation is not because we are moving in any direction right now with making changes to our training and experience requirements.

We have had, you know, several public meetings. We have had different people coming in to talk to us about this topic. And so -- and so we have to do our due diligence and taking a look at our training and experience requirements as it relates to radiopharmaceuticals, and that's what we're doing here.

And in being open, you know, as part of, you know, what we try to do is we try to share with the public what we're doing. And so part of what we're doing right now is an evaluation process, as Sarah discussed as it relates to patient access, is we are -- we are hearing -- we are taking comments and we are working with the agreement states, and we are looking to see if there are any issues.

But this does not conclude or bring -- or say that we are concluding that there is going to be any changes to our regulations, and that we're acting upon it at this moment. We're, again, evaluating what we're doing.

And then I just had a question as it relates to -- I believe you talked about some of the different

countries and what they are doing. Do you -- I guess can you tell us some of the countries that you were referring to that have maybe different processes that we might be -- that we should be looking at?

DR. RAZMARIA: I can just refer to two main countries where these targeted therapies have been -- who have been pioneering this new targeted radiological therapies. One would be Germany, and the other is Australia. In those countries, you see that there is a clear line what requirements are needed in terms of training to be able.

And that has -- you know, there is a development -- atomic energy organization that is standardizing what training is needed to be able to practice nuclear medicine. And there is -- one of the countries that has the least command of kind of really minimal is the U.S. So we are lagging behind significantly in terms of, you know, delineating what in fact, training and experience requirements, and just really delineating the minimum.

So, and if any -- if anything, there is -- in the U.S., there is a need to increase the training and the clinical expertise. You are focusing so much on radiation safety but there is also the whole vast clinical expertise of using the radiopharmaceuticals

for therapeutic purposes.

So, again, the country -- you just need to look to Europe. You just need to open the Journal of Nuclear Medicine, and you can see that, you know, the majority of studies are coming from outside of U.S. And this is really kind of disheartening if you consider that nuclear medicine was in fact developed in the U.S.

So this is something that, again, there is a need for people who, you know, just not take, you know, discoveries from abroad and just use it here, but just come forward in developing new therapies for new cancers, new indications.

The U.S. has been historically kind of the leading edge of development, and we are just kind of lagging now behind in this area, because I kind of really believe because of the regulatory framework that hasn't really enabled the field of information to thrive.

So, again, putting all of the financial benefit to the side, looking at what the future will have, all of the areas of medicine move towards specialization in medicine. So just -- just opening up an area to kind of broad -- well, in our intent we have to always keep in mind patient access, obviously. But patient access to expertise therapy, not just --

just someone who is coming in, injecting a therapy and, okay, what are the complications, what are the contraindications, what other steps after the initial therapy are indicated?

So just forgetting about all of that, just having that unit dose available, injecting them, okay, we are done. That's not how patient care is done, so.

MS. LOPAS: All right. Thank you, Dr. Razmaria. That was -- that was very helpful, and I appreciate that you didn't -- I think you said you were trying to hold back, but I'm glad you didn't.

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

OPERATOR: We're showing no questions at this time.

MS. LOPAS: Okay. All right. Folks, I think -- unless anybody in the room has any last comments that they would want to make? Seeing none, Chris, do you want to close us? No? Okay. I will close us out then.

Okay. So our next meeting on here, if you feel like you want to come and spend some time with us again, would be January 10th, and that's the same time, 1:00 p.m. to 4:00 p.m., and it will be webinar and bridge line accessible as well. And then that last

webinar will be on January 22nd, and we will be in 2019. Can you believe it?

Okay. Thank you very much, everybody. And I will stay on the bridge line for our court reporter, but thank you, and this concludes our meeting on training and experience. Thanks.

(Whereupon, the above-entitled matter went off the record at 2:44 p.m.)