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# NUCLEAR REGULATORY COMMISSION

Title: Public Meeting To Accept Comments on the NRC's Evaluation of Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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UNITED STATES OF AMERICA

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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THURSDAY,

JANUARY 10, 2019

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PUBLIC MEETING

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The Public Meeting convened at 1:00 p.m., Sarah Lopas, Moderator, presiding.

PRESENT:

SARAH LOPAS, NMSS/MSST/MSEB

MARYANN AYOADE, NMSS/MSST/MSEB

CHRISTIAN EINBERG, NMSS/MSST/MSEB

DONNA-BETH HOWE, NMSS/MSST/MSEB

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P R O C E E D I N G S

(1:00 p.m.)

MODERATOR LOPAS: Hi, everybody. Good afternoon. Welcome to the NRC's Webinar and Public Meeting to Accept Comments on the staff's Evaluation of Training and Experience Requirements for Different Categories of Radiopharmaceuticals.

My name is Sarah Lopas and I am the project manager for the staff's evaluation, and I'm also going to be giving a portion of today's presentation, and facilitating.

I'm joined here by Maryann Ayoade who is a health physicist on the NRC's Medical Radiation Safety Team. And she is a technical lead on the training and experience evaluation.

And also with me is Chris Einberg. And Chris is the chief of the Medical Safety and Events Assessment Branch in the Office of Nuclear Material Safety and Safeguards.

So for folks that are here today, thank you for signing in. I appreciate that. You have those handouts. I also want to welcome the folks on the phone and joining us via the webinar.

And let's move on to the next slide here.

So today for our agenda Chris is going to give a quick welcome. I'm going to follow Chris with some leading information.

We are on Slide 3 right now for folks that may be following along on the slides, maybe not necessarily using the webinar.

Then Maryann and I will do the NRC presentation. And then we're going to open it up for your comments. And we'll answer your questions as we can. So there's plenty of time for comments. There's only a few people here in the room and there are about 20 or so of you on the phone. So thanks for calling in, we appreciate you.

All right. So I think at this point I will hand it over to Chris to give us our welcome.

MR. EINBERG: Okay, thank you, Sarah.

Good afternoon, everyone. Thank you for taking the time to attend today's meeting, the folks in person here at the NRC, and remotely via the bridge line in the webinar.

Today's meeting is the third of the four comment acceptance meetings that the NRC will be conducting in our training and experience requirements evaluations. The purpose of today's meeting is

twofold:

To provide background information on the NRC staff's planned evaluation of developing tailored training and experience requirements for administering different categories of radiopharmaceuticals for which a written directive is required in accordance with our regulations in 10 CFR Part 35, which are our regulations for Medical Use of Byproduct Material; and Subpart E under Part 35, which covers Unsealed Byproduct Material-Written Directive Required.

And most importantly, to listen to and record your comments on this evaluation.

The comments we receive from the medical community, the agreement states, and other stakeholders are critical to the NRC staff's 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 regulations.gov by January 29th, 2019.

Later in the presentation we will cover how you can submit your written comments.

And now I'll hand the presentation back

to Sarah Lopas.

MODERATOR LOPAS: Okay, just some quick general meeting information.

I do just want to note for the folks in the room the bathrooms are out the door to the left and kind of around. And if we have to evacuate for any reason, just follow us. We'll probably head out the way we came in, or there is also an emergency exit over just past the bathrooms. Follow us, yes. We've got you. Trust your regulators, we'll guide you.

So if you're on the phone and logged into the webinar, I do have some handouts uploaded for you, the same handouts that are here in the room. So that is the information paper that the staff published back in late August 2018, the Federal Register notice that opened up this 3-month comment period, and I also have today's slides. So you can download all of those from the handouts.

If you are on the phone and you are having issues with your webinar, our slides are posted on our public meeting notice. A link to our slides is included in the reminder email that went out at about 12:00 p.m. Eastern today. And the slides are also on the NRC's T&E Evaluation webpage. So there's a few places to

get to the slides if you want to follow along if you can't get into the webinar for some reason.

Let's see, what else do we have here? So today we're going to be referring to T&E a lot, training and experience. Authorized users will often be referred to as AUs. And today's meeting is being transcribed by a court reporter. They are on the phone with us. And we have, which I think was mentioned by Tara, our Operator, but we're recording this call as well just as a backup. But I just want to make sure everybody's aware of that.

So all of your comments today will be captured accurately by the court reporter. And comments that you speak today are given the same weight as comments that you submit written. And you can, you know, feel free, you don't have to resubmit your comments but you certainly can. So they all have the same weight.

All right. At this point we're going to go to Slide 7. And that's where I'm going to ask Maryann to take over for us.

MS. AYOADE: Great. Thank you, Sarah.

Today I will be presenting information on an overview of the regulations on training and

experience for radiopharmaceuticals requiring a written directive; some background on the related stakeholder concerns received for this evaluation; and NRC's efforts on the evaluation thus far.

So the current 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 may be authorized to administer radiopharmaceuticals that require a written directive.

A physician can be authorized to administer these radiopharmaceuticals if they are 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 requirements via an alternate pathway, which includes the completion of 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training in the relevant topic areas, as listed in the regulations, and 500 hours of supervised work experience in the relevant areas, as listed in the regulations.

I hope you guys can hear me better now. I'll try to speak up a little bit more.

A physician can also be authorized if they have been previously identified as an authorized user on an NRC or agreement state license or permit.

And so this training and experience evaluation is focused on the ultimate pathways. And the NRC staff are looking into what tailored training and experience requirements for 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.

So in Subpart E there are four sections that pertain to training and experience requirements. The first section is under 10 CFR 35.390 for 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 for training for oral administration of sodium iodide iodine 131 requiring a written directive in quantities less than or equal to 33 millicuries.

The third is under 10 CFR 35.394 for training for oral administration of sodium iodide

iodine 131 requiring a written directive in quantities greater than 33 millicuries.

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

So I want to point out that all these sections of training and experience, including the pathways for experienced authorized users already listed on the license, it includes the pathways for experienced authorized users that are already listed on the 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 pathways, and it is written 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 training pathway under 10 CFR 35.392 and .394 is for the physician to successfully complete 80 hours of classroom and lab training. And that is relevant to the type of uses for which they are seeking to be

authorized. Whereas the alternate training pathways under 10 CFR 390 is for the physician to successfully complete 700 hours of training and experience, which includes the 200 hours of classroom and laboratory training.

Next slide.

This slide provides some background information on stakeholder concerns received related to the training and experience requirements.

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

Specifically, some stakeholders have asserted that the 700-hour requirement in 10 CFR 35.390 is overly burdensome for physicians who are not certified by a medical specialty board, and that the extensive requirements have resulted in a shortage of authorized users, which thereby limits patients' access to radiopharmaceuticals.

As a result, in 2015 and '16, in separate efforts the NRC staff as well as the NRC's Advisory Committee on the Medical Uses of Isotopes, also known

as the ACMUI, independently reviewed the training and experience requirements for the medical uses authorized under Subpart E. Specifically, NRC staff reviewed the regulatory basis and the comments that were received on past rulemakings related to the medical use of byproduct materials, and did not identify any new information that would call into question the basis of this existing requirements.

As a result, the NRC staff did not propose any changes to the regulations at the time. And the NRC staff is continuing to work with the ACMUI in its ongoing training and experience evaluation efforts.

Next slide.

So as part of the Staff Requirements Memorandum dated August 17, 2017 -- and that is publicly available in ADAMS via the hyperlink that is referenced on this slide -- the Commission directed the NRC staff to evaluate whether it makes sense to establish tailored training and experience requirements for different categories of radiopharmaceuticals; evaluate how those categories should be determined, such as by risk, polled by T&E cards, or by delivery methods; to evaluate what the appropriate training and experience requirements should be for each category; and to evaluate whether

those requirements should be based on hours of training and experience or focused 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 of 2018. And that evaluation, including the NRC staff's analysis and feedback received of the training and experience requirements in Subpart E of 10 CFR Part 35 was documented in an NRC SECY paper, SECY-18-0084.

The result of the evaluation concluded that it may be feasible to establish tailored training and experience requirements with different categories of radiopharmaceuticals, and to create a means of authorizing the administration of certain categories of radiopharmaceuticals such as the Alimited authorized user@ status.

It also concluded that there are viable options for creating a competency-based approach to demonstrate acceptable training and experience requirements for a limited authorized user status. But, however, the staff does need to conduct more extensive outreach for stakeholders in the medical community, to the medical community, to the agreement

states, and to other members of the public before making any recommendations to the Commission.

And this is what brings us to our current evaluation today.

So now I will hand over back to Sarah who will discuss our current evaluation efforts and how you can participate.

MODERATOR LOPAS: Thanks, Maryann. And I just want to note that the SECY that Maryann was just talking about on Slide 11, that's one of the handouts that's attached to your webinar.

So next slide is Slide 12. And the end of evaluation will be a paper that we're going to send up to our 5-member Commission. In this paper they're going to document our reasoning recommending no changes to our current T&E regulations or, if we do recommend changes, we will lay out our reasoning for those changes and we will also add a rulemaking plan into that paper as well.

So this is a very simplified diagram of information that we're going to consider in our development of the recommendation to the Commission. The diagram illustrates why the comment period is so important. And that's because in large part the

feedback that we received is on -- that we received on those questions that we asked in the Federal Register notice is going to help us inform our recommendation to the Commission.

Other important feedback will come from our coordination with our co-regulator, the agreement states, and the Advisory Committee on the Medical Uses of Isotopes, ACMUI.

So in addition to the input that we received from the public and the medical stakeholders, the agreement states, and the ACMUI, the staff is also going to look at patient access. We've been working on mapping facilities where they offer 35.300 therapies in the United States. And right now we just have access to NRC licensees for that data. But we do plan to go out for a voluntary data request from the agreement states to ask them if they can provide us that information, if they have it, in kind of an easily accessible form as well.

We use a web-based licensing database system to maintain our licenses, so we are able to kind of pull that information from our WBL system to help us map that information. So working on that right now.

And the next thing that we're going to start

looking at is we're going to be looking at medical and radiation safety events to determine if any of those have a nexus to training and experience. So we're just starting that effort as well.

Then and we're also going to start working on reaching out to some international community to talk to them about what kind of regulations they have for training and experience.

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

And if rulemaking is recommended and approved by the Commission -- and then approved by the Commission, that would start the NRC's extensive rulemaking process. And I am highlighting this process because I think it's important so that everybody understands where we are in this process, you know, we're at the information gathering stage, you know, we're not in a rulemaking right now. This is, you know, before we even make a determination about rulemaking.

The next slide is Slide 13.

This is the Federal Register Notice slide. The Federal Register notice was published on Monday, October 29th. It can be accessed at this link here. You could just also do a Google search of 83 FR 54380. It's also, of course, attached to your webinar too as a handout. Easy enough.

So it announced the date of the federal -- of the comment period, which ends January 29. And it's talking about public meetings that we've had to date. We had one in November, one in December. We have this one today. And then we have one final webinar on January 22nd. That will be a morning webinar, 10:00 a.m. Eastern time, just to kind of change things up because we've been doing most of these in the afternoon.

But, yes, and that will be a webinar only, no, no in-person meeting just a webinar.

But most importantly, the Federal Register notice asked a series of questions that we were really interested in getting input on. So I'm just going to quickly read through these questions on the next few slides just so you can understand, get a general context of what we were, information that we were looking to gain from comments from everybody. And note that when we do open it up for comments we can go back through

these questions. So we're just going to read through them right now.

So Slide 14.

The first set of questions was asking about tailored training and experience requirements. So are the current pathways for obtaining AU status reasonable and accessible? And are they adequate for protecting public health and safety?

Should the NRC develop a new tailored T&E pathway? And what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? What would be those appropriate requirements?

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?

And how should the requirements for this fundamental community be structured for a specific category of radiopharmaceuticals?

On the next slide we have Section B, which is talking about the NRC's recognition of medical specialty boards.

And the current boards in our current

process is located on the NRC's Medical Toolkit Website.

But our questions are:

What boards other than those already recognized by the NRC could be considered for recognition for medical uses under 10 CFR 35.300?

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

Section C is getting to patient access again. And we have heard some comments on patient access.

So we've been asking, we ask is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical?

Are there certain geographic areas with an inadequate number of AUs?

Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals?

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

And then Section D was kind of asking

generally about the NRC's training and experience requirements overall. And these questions are broader:

Should the NRC regulate the T&E of physicians for medical uses?

Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

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

So those are the questions. Clearly, you know, we're not limited, your comments are not limited to just those questions. We are asking that written comments come in by January 29th, 2019. The easiest way to submit them is via regulations.gov.

This is the direct link to submit your comments, but if you go to regs.gov and you just type in ANRC-2018-0230" in the search bar it will pop right up and it says, "Comment now!" So you can either upload your comments with a .pdf or you can type directly in the text box. There's a couple ways to do it.

If you have any issues with submitting your

comments that way, feel free to just email me directly, or email Maryann. We will make sure it gets on the docket for you. That's not a problem.

All the comments that we do receive and our transcript are posted on regulations.gov, but there's a lag for those getting posted. It's a few days, so you won't see your comment immediately. It will take a few days for it to pop up. But rest assured we will receive it.

Our comments are also going to be posted to ADAMS, of course, our user-friendly Agency-wide Documents Access and Management System.

And we are, of course, going to consider all of your comments, and we're going to summarize them, and we're going to bin them and summarize them and organize them. We'll create kind of a comment report, comment summary report that we'll put out that will accompany our SECY paper. So, you know, this is not a rulemaking so we aren't going to be responding back to individual comments.

And then we have one more public comment meeting, which I mentioned. That's on the 22nd, January 22nd, 10:00 a.m. - 12:00 p.m. Eastern Time. And this is a webinar only.

Slide 20 are our next steps.

So the public comment period ends on January 29th, as I mentioned.

We're going to continue the evaluation of the comments as they come in. We're going to finish our work with our additional information regarding patient access and trying to map these facilities and figuring out how many AUs there are.

Conducting that additional research about international benchmarking, and looking at medical, medical events.

And then the ACMUI Subcommittee on Training and Experience is going to provide their report to us on March 8. So there will be a public teleconference on that report probably sometime later in March. So we will, we will notice that on our public meeting notice and send notice of that meeting on our medical listserv. So if you're not on our medical listserv, get on that.

So we'll be looking, looking forward to that input from the ACMUI.

And then later on in the process, after we come up with our draft paper, we will be providing that to the agreement states and the ACMUI for them to review the draft paper ahead of time and to provide

their input and comments on that paper.

We will take their comments in, you know, revise the paper as needed, and finalize it and give it to the Commission in the fall of 2019.

And so for more information you can, of course, contact myself or Maryann. I'm more kind of the project manager person. If you have more kind of process questions, that's for me. If you have more regulations type questions, technical questions, contact Maryann. She's our technical lead.

Our website, I am striving to maintain the website with, you know, our meeting summaries, links to the transcripts for past meetings, things like that. So that's the T&E website.

Of course the T&E docket on regulations.gov, that will, that will show everybody's comments, so you can see what people have submitted so far if you're interested in that.

And with that, that's the end of our presentation. So finished up pretty quickly, 1:25. I want to -- we'll start here with comments in the room. Everybody has to use a microphone. So I can run this mic to you if you want to use this mic, or you're welcome to use the podium mic if you'd like to use the podium.

Just turn it on.

And, so folks on the phone, just go ahead and press star-1 and that will let Tara know, our operator, that you're going to need your line unmuted.

And I'm just going to ask that everybody start by introducing yourself. If you have an affiliation, great. You don't need to state your affiliation. And just speak slowly and clearly and into a microphone so that everybody can hear you on the phone.

We're starting with a comment in the room.

MS. TOMLINSON: Cindy Tomlinson with ASTRO. Okay, sorry. Cindy Tomlinson with ASTRO. Can you, can you expand a little more on your work with the Agreement States to get some of the census data in terms of your timeline? So will that be done in time for the ACMUI to review it or do you mean to have it done in time for the paper to be done?

I'm just curious as to where you are, what the time frame is.

MODERATOR LOPAS: It will probably be, it will definitely not probably be in time to help out ACMUI. It's a voluntary request for data from the agreement states.

And this is Sarah Lopas speaking, for folks on the phone.

And we have a letter that we're preparing to go out right now. It's kind of stuck in the process because it requires Office of Management and Budget Review and it is closed. So we're stuck in the process. We probably won't get that letter out -- I mean who knows, right? -- once OMB opens back up I anticipate it might be three to four weeks after that that the letter would go out. And then typically we give the Agreement States about 45 to 60 days to respond to something like that. So it will be a little while.

MS. TOMLINSON: And so is your, is your intent then to have this data in time then for the paper to be sent up to the Commission?

MODERATOR LOPAS: Yeah. Oh, absolutely.

MS. TOMLINSON: Okay.

MODERATOR LOPAS: It will be in that, whatever data we get from the states we're going to, we're going to clean up and map and include it in the paper to the Commission, absolutely.

MS. TOMLINSON: And will that data be -- obviously it will be public because it will be in the memo to the Commission -- but will you make that data

public?

MODERATOR LOPAS: We will be making the maps public.

As far as any Excel files or anything like that that we get from the states, we had not planned to make that public.

MS. TOMLINSON: And by "maps" -- I'm sorry to --

MODERATOR LOPAS: Yeah sure. No. Yeah.

MS. TOMLINSON: I'm just trying to understand because this is something that we are, we're concerned about --

MODERATOR LOPAS: Yes.

MS. TOMLINSON: -- in terms of this argument that there aren't enough physicians.

MODERATOR LOPAS: Right.

MS. TOMLINSON: I'm trying to understand if there is something maybe we can do.

And so -- but so the maps are they going to be just, like, a map of the United States with some pin drops on there saying numbers?

MODERATOR LOPAS: So right now -- I'll tell you what we have for our maps that we've done so far for the NRC, for the non-agreement states. It's maps

of States. And it is literally just a pinpoint.

And what we are, you know, and what we are doing is for -- so we have main facility locations. And we -- we're going to put the number of 35.300 AUs. That number is going to be next to the dot. You will see at that particular location there might be five 35.300 AUs there.

There are some satellite locations associated with some of those licensees. We don't know how many 35.300 for those locations. We do know that that use is certified, that satellite location is authorized to use 35.300 materials, we just don't know how many AUs they might have at that particular location.

So, yeah, you're just going to see --

MS. TOMLINSON: Okay.

MODERATOR LOPAS: -- dots on a map.

MS. TOMLINSON: Thank you. So if it's, let's just say no likely source here in this area --

MODERATOR LOPAS: Yes.

MS. TOMLINSON: -- and it's INOVA, and you know that INOVA has, whatever, 10 authorized users under 35.390, but one of them might work in, you know, the Fairfax Hospital, one might be at Fair Oaks, and one

might be at wherever else, that's not going to be included? It's just going to be the big total --

MODERATOR LOPAS: Right.

MS. TOMLINSON: -- because of the way satellites work?

MODERATOR LOPAS: Right. Exactly.

We will have, we are going to put it over population data.

MS. TOMLINSON: Okay. You're using census data?

MODERATOR LOPAS: Yeah. So we have, unfortunately we only have 2010 data. Right? But it will kind of, it's kind of the map is sort of shaded to show population density.

MS. TOMLINSON: Okay, great. Thank you.

MODERATOR LOPAS: Yep.

MS. AYOADE: This is Maryann from the NRC.

Cindy, the question is to Cindy from ASTRO. If for some reason based on what we shared with you today you guys have, you know, any other information or things that you think might be useful to use, please feel free to share --

MS. TOMLINSON: Okay.

MS. AYOADE: -- with us. Thank you.

MODERATOR LOPAS: All right. Folks on the phone, touch star-1. We're going to go for another comment in the room here and then we'll open it up to the, we'll check in on the phones. So star-1 and get in line.

MR. GUASTELLA: This is on, correct?

Hi. Michael Guastella. I'm the Executive Director of the Council on Radionuclides and Radiopharmaceuticals. And I want to thank you for the opportunity today to provide public comment.

It is CORAR's position that the current 700 hours training and experience alternate pathway for physicians who want to become authorized users to safely administer patient-ready alpha, beta, and beta/gamma emitting isotopes, and we kind of refer to those as the non-imaging radiotherapy doses, and we believe the requirements right now are excessive.

In answer to one of the questions, Sarah, that you actually had put up a little while ago -- should the NRC develop a new tailored training and experience pathway for physicians? -- CORAR does believe that the NRC should develop a new tailored training and experience pathway for specialists such as medical oncologists, hematologists, and urologists.

The new pathway should provide the training and experience necessary to safely administer these non-imaging radiotherapies with consideration to several factors.

One, the limited role in handling these radionuclides which would be dispensed and delivered to them in patient-ready doses from licensed nuclear pharmacies, dispensed by nuclear pharmacists, licensed nuclear pharmacists. Or, as we're starting to see, received directly from the manufacturer in a patient-ready dose container.

The limited role does not include, if you will, the full range of activity in handling byproduct material such as molybdenum technetium generators; preparing, compounding, and dispensing radioactive drugs; administering a wide variety of radionuclides requiring written directives; interpreting nuclear medicine scans; learning about imaging equipment; understanding imaging quality and assurance; and other important clinical skills necessary to ensure safe and comprehensive care in the nuclear medicine department.

All these things roll into the 700 hours currently.

Other factors for consideration include

the radiological safety profiles or radiopharmaceuticals containing the alpha, beta, and beta/gamma emitting isotopes. These, again, are the non-imaging radiotherapy doses.

And, finally, physician experience and training in handling toxic, non-radioactive chemical therapies such as cytotoxic chemotherapy imaging.

And why is this important? At least from, from our perspective, interested medical oncologists, hematologists, and urologists who wish to become limited authorized users through a potential needs-tailored training experience pathway will have the opportunity to provide improved continuity care for their patients.

For example, this will be very important for an oncologist who wishes to closely monitor a patient's response to a non-imaging radiotherapy treatment and quickly treat any condition or complication. These clinical efforts would be hampered if the patient was required to travel for treatment due to an AU shortage in the geographic area where the patient lives, and where he or she is receiving ongoing cancer treatment.

Thank you very much.

MODERATOR LOPAS: Thank you.

Tara, can I check in on the phone, has anybody pressed star-1?

OPERATOR: Yes. We do have a comment or question from Scott.

Your line is open.

MR. DEGENHARDT: Yeah, thank you. My name is Scott Degenhardt. I am a nuclear medicine advanced associate here in Omaha, Nebraska. I am speaking as an individual. I know there's been several comments that have been submitted in the comments section, but I did want to bring this up to the group, too.

I am proposing that nuclear medicine advanced associates be considered for authorized user designation. And for those of you who are unfamiliar with the nuclear medicine advanced associates profession, or NMAA, we are credentialed, board certified mid-level providers in nuclear medicine. We do function under the supervision of a physician.

I guess for those of, for those of you who are a little unfamiliar with the program. So the program is a Master's level program which includes graduate level didactic course work and then also a 24-month clinical internship designed after a nuclear

medicine residency. The NMAA student during that 24-month internship learns under the guidance of a, you know, a nuclear medicine physician or a radiologist, very similar again to a nuclear medicine residency.

And with that being said, authorized user training and education will not be compromised. Upon the completion of the program the NMAA graduate meets all qualifications required under 10 CFR 35.390 to become authorized users.

So I guess that's just a very brief and condensed statement about what a nuclear medicine advanced associate is and our proposal. But I guess some key points are, is that throughout healthcare we have seen mid-level providers improve patient access, efficiency, healthcare costs, and overall patient care. And I believe the nuclear medicine advanced associate would be no different in the field of nuclear medicine. Again, we are mid-level providers, credentialed, and board certified.

The way our program is set up, again, we would be able to address current and future authorized user needs throughout the country. The didactic course work is done remotely, while the clinical internship is done locally at the facilities that the student is

practicing at. We wouldn't compromise the current training and education set forth by the NRC. And ultimately we could improve overall patient safety and care while addressing the authorized user needs.

So I guess at that I am free to answer any questions or receive any comments.

MS. AYOADE: Thank you, Scott. This is Maryann Ayoade from NRC. I just want to clarify again your comments.

So you're saying that NRC should consider nuclear medicine technologists to be approved as authorized users in our licenses. If that wasn't your comment, feel free to clarify.

But also just wanted to point out we have received some comments also for NRC to consider non-physicians to be listed as authorized, as authorized users. Specifically we received comments on the nuclear medicine technologists as well.

MR. DEGENHARDT: Yes. It's not nuclear medicine technologists, it would be the NMAAs, the nuclear medicine advanced associates, those who have undergone that, that program, that training and education. So not technologists but the, again, the nuclear medicine advanced associates.

MS. AYOADE: Okay, thank you.

MR. DEGENHARDT: Yes. No, thank you.

MODERATOR LOPAS: Okay. Tara, is there anybody else on the line? Star-2 for folks on the line.

And you can also, if you have a short comment or a question, feel free to submit it via the webinar question function. I can read it aloud for you if you would feel more comfortable typing something.

Is there anybody on the line, Tara?

OPERATOR: Yes. Richard, your line is open.

MR. SISKA: Hi. My name is Richard Siska. I am a nuclear medicine advanced associate and a radiation safety officer in Rolla, Missouri. And I'd like to kind of piggyback a little bit off what Scott has said.

And to clarify, maybe give us a little perspective on where the NMAA sits at the mid-level. It would be akin to a nurse practitioner as opposed to a nurse. So these are people that have undergone not only undergraduate work but have obtained a Master's Degree in graduate work and post-graduate certification through a certification board.

In my commenting, too, through the website

I'm attaching some documentation that may help further for your information-gathering process that also would include a content outline of the examination process that NMAAs must undergo following their being awarded the degree of Master's of Imaging Sciences.

What this does, I think, is twofold. First, it utilizes a group of professionals or upcoming professionals in the mid-level studies that are peer into nuclear medicine. So these people were nuclear medicine technologists in the beginning, so they've had all the physics training. They are familiar with the biochemistry of radiopharmaceuticals. They have had experience in hot labs. They have had experience in radiopharmacies because that's part of the training requirement. They understand the physics.

And although they're not physicists, they do a lot of basic training in a lot of the components that physicists would do, but just not to that extent.

Add onto that the extra components that a graduate degree person, someone who has had experience, not only the training of a nuclear medicine technologist, the years of experience as a nuclear medicine technologist, but then going back and receiving extra course work much akin to a residency

that a physician would receive, just on a smaller scale. And put that extra education and experience on top of that, and that's what a nuclear medicine advanced associate is.

So they would be able to provide a pure understanding of what radiopharmaceuticals are. And one of the previous comments had aligned it to, you know, chemotoxicity. And it's a good analogy but it's not quite the same thing because radioactivity, of course, is a different animal.

So, you know, keeping those types of people with those kind of experiences and that kind of education would prevent the NRC from having to change the requirements as far as training and experience, which I think, you know, when we look around and we're looking at accreditation agencies which are separate from the NRC, we're seeing stricter regulations on other radiation safety activities. So it's kind of counterintuitive to reduce training and experience on activities that are actually using radioactive therapies that are changing the biochemistry of someone internally and reducing the requirements of radiation safety and experience on that. So to me it's a little confusing.

But I just wanted to add that comment. Thank you.

MODERATOR LOPAS: All right. I appreciate that Mr. Siska. Thank you.

Tara, is there another commenter on the phone?

OPERATOR: Yes. David, your line is open.

MR. BURPEE: Hi. I'm Dave Burpee with Bayer Pharmaceuticals. I work with Xofigo. And this week the SNMMI issued an editorial in their journal. And I want to make a comment about how I strongly disagree with this editorial.

Its main initiative was to state that the NRC is taking on this initiative to raise money through increasing or having more authorized user licensing fees. In my experience there's no such thing as a AU licensing fee. Certainly there are monies from applications for amendments to grants but I've got to believe that that's an incredibly small fraction of the NRC's budget.

From my perspective this is all about improving patient care. And I applaud the NRC for reviewing and taking on this important need.

I manage ten states currently. And there

are tremendous AU availability difficulties that are restricting patient care with these important radiotherapies. In the last quarter alone I saw four cases where there was no authorized user for years at these four institutions, and that's just in the last quarter in my part of the country, okay.

There's many other authorized user problems in the case of the large cities and the rural areas. Many, many patients aren't in the right network to get treated at the local hospital. Many physician groups and hospital groups don't play in the same sandbox together and they compete. And, therefore, the patients are forced to travel to get treated versus going to their local hospital. We're talking hours of travel with men who are sick. And it's a pretty tough situation.

So this is rather ubiquitous. And I, again, applaud the NRC for taking this on.

In your mapping effort, I applaud that. I think it's going to be helpful. But if there's any way of understanding who is actually treating, that's one of the big problems. There might be authorized users at XYZ hospital but they're not treating for various reasons from -- and, again, similar situations

to overall prejudice about not wanting to use that type of therapy.

So good luck on that. And I wish you luck to help try to understand that because their license is good they may not actually be treating and, therefore, the community is not being served.

Seven hundred hours would limit all of these options, if that was the only criteria for defining an authorized user. So we applaud the effort to look further at options. And that's what this is all about is giving patients options to improve the patient care.

So, finally, we would like from Bayer's perspective to allow limited licenses for interested physicians competing with -- limited licensing for interested physicians after completing product-specific manufacturer-provided training. And this should improve patient care.

And we thank you again for the reference. I'm finished. Thank you.

MODERATOR LOPAS: Okay, thank you.

OPERATOR: We show no further questions or comments on the phone.

MODERATOR LOPAS: Okay, thank you, Tara.

We're going to hear from Chris.

MR. EINBERG: Yes. This is Chris Einberg. Thank you for bringing up the issue of how the NRC is funded. And just want to provide a little clarification there regarding that fact.

The NRC is not a self-funded agency. We are funded by the Congress with the requirement that we recover 90 percent of our budget through fees assessed to licensees and applicants. This money is returned to the U.S. Treasury, the General Fund, and therefore reimburses the taxpayers for services provided by the NRC civilian industry.

The fees do not directly benefit the agency. Furthermore, the NRC issues licenses to facilities and not individual physicians or authorized users as the commenter indicated. This allows physicians to be listed on the license and authorized users -- or, I'm sorry -- this allows physicians to be listed on a license and authorized to use radioactive material under that license.

Increasing the number of authorized user physicians at already NRC-licensed facilities does not affect the fees that the NRC receives. Although increasing the number of facilities would increase the

fees that the NRC receives, NRC would have a proportionate amount of additional work, in essence additional inspections, enforcement, licensing actions, including renewals and amendments.

The licensees are billed an application fee under 10 CFR Part 170 and an annual fee which factors in costs for material users, license renewals, amendments, and inspections, under 10 CFR Part 171. As such, the NRC does not have a direct incentive to add new licensees.

MODERATOR LOPAS: Thank you, Chris. I appreciate that clarification.

Okay, we're going to go back to the room here. Folks on the phone, again, you can press star-1 at any time and we'll check back in on the phone. But let's go to the room here.

MR. WITKOWSKI: John Witkowski, President of UPPI.

MODERATOR LOPAS: Would you please speak right into the microphone. Thank you.

MR. WITKOWSKI: We wanted to read a prepared statement for the training and authorizing of authorized users.

UPPI sincerely appreciates the Nuclear

Regulatory Commission re-engaging in efforts to determine how access to medical isotopes can be expanded and the Commission's outreach to seek diverse opinions on the training and education required for authorized users. We believe that this is a very important issue and that the NRC can help to expand access to vital medical tests and treatments while maintaining safety.

On behalf of UPPI's 83 independent commercial nuclear pharmacies, leading nonprofit academic medical center radiopharmacies across the country which are focused on delivering prepared radiopharmaceuticals, diagnostic molecular imaging, and therapeutic patient care needs, we are pleased to offer comments to assist the NRC in evaluating how to expand access to these vital services.

Specifically, UPPI urges the NRC to consider building upon and expanding successful dual authorized user programs by teaming of an authorized user nuclear pharmacist and a limited trained medical oncologist in alpha and beta radiotherapies. This would enable the expansion of the availability of treatments and ensure that a highly trained authorized user is present to ensure patient radiation safety.

Since the pharmacy community has played

an important role in ensuring patient safety, centralized nuclear pharmacies handle the preparation and dose burden for hospitals and diagnostic imaging centers by dispensing and delivering just-in-time radiopharmaceutical doses for patients in molecular imaging and therapy.

UPPI members dispense 8,000 patient-specific doses each day. The U.S. imaging community orders 50,000 patient doses daily. Across the country 300 nuclear pharmacies cover metro, suburban, and rural areas. Nuclear pharmacists have the responsibility to deliver these individually prescribed and calibrated patient-specific doses to the hospitals and imaging centers.

The expertise and dedication of the nuclear pharmacists in delivery safe patient procedures ensure the safe handling of the radioactive material since back in the 1970s when the Board of Pharmacy Specialties began its first specialty examination in nuclear pharmacy in 1978. At that time the industry created and adopted self-governance, safety, and handling standards and training. That training continues to develop and supplements the federal and state requirements that are also necessary for nuclear

pharmacist licensing.

We believe that there is a role for nuclear pharmacists to play in this case as well. And we sincerely appreciate the NRC considering utilizing nuclear pharmacists to expand access.

Expanding patient needs for radiotherapeutic use of alpha and beta measures is clear and will continue to grow. Not only does there appear to be a geographic imbalance of authorized users that disadvantages rural patient populations, but the prospect of new systemic radiotherapies and the new and more advanced effective treatment options has grown since the petition by pharmaceuticals in 2015 to reevaluate the access to such treatment.

New biological approaches to utilizing alpha and beta radionuclides continue to expand as new therapies for prostate, breast, and other cancers are developed. Administering these advanced treatments will create a need for more authorized users.

This will put more demand on the current roster of authorized users. And the NRC is smart in seeking to understand future demand and utilization of authorized users, anticipating when and how the demand for authorized users will increase, and

proactively assessing the current pathways for training and experience to meet future patient needs.

UPPI believes that an expanded alternative pathway for training and education in the radiotherapy utilization of alpha and beta measures is appropriate and necessary to allow patient access to these treatments, especially in rural areas. The radiopharmacy as partner between manufacturers and hospitals is the source of the majority of the patient doses for diagnostic imaging and therapy. Nuclear pharmacists have authorized user training and experience and authorized user nuclear pharmacists can deliver fair amounts of care.

The nuclear pharmacist authorized users possess 700 hours of training and education to satisfy the radiation safety and protection requirements for handling alpha and beta radiopharmaceuticals. Specifically, there are many similarities to physician AU training in regard to understanding the drugs, the physiological action, and patient outcomes, along with the patient and environmental safety in handling and use of radioactive material.

For example, the 200-hour formal training includes a myriad of topics related to radiation safety

as outlined in 10 CFR 35.55, Training for Nuclear Pharmacists, which includes radiation physics and instrumentation, radiation protection, chemistry of byproduct material for medical use, radiation biology, performing checks for proper operation of instruments.

There's another description here, but it's also to determine activity of dosages and, if appropriate, instruments used to measure alpha and beta emitting radionuclides, using administrative controls to avoid medical events in the administration of byproduct materials, using procedures to prevent and minimize radioactive contamination, and using proper decontamination procedures.

In other words, the training and experience expertise that a nuclear pharmacist receives to become authorized users is similar to the training received by physicians, and the Nuclear Safety Act section would be even more rigorous than the training that the physician receives.

Because nuclear pharmacists receive similar training as doctors with regards to nuclear safety that enable nuclear pharmacists to become authorized users, UPPI believes that there is a way for the NRC to expand access to radiopharmaceuticals

without sacrificing patient safety by establishing an alternative pathway for expansion of an authorized user who's administering alpha and beta radiotherapy through the use of team of authorized users. That will ensure the fully trained authorized user at one site to ensure patient and environmental safety and the safe handling of all nuclear materials, and will not sacrifice those requirements but would also significantly expand the number and reach of treatment options for patients.

This dispensing of the therapeutic doses by the nuclear pharmacist has already been established by the nuclear pharmacy working with the drug manufacturer. Specifically, there are approximately 1,200 practicing nuclear pharmacist authorized users through the U.S., and they are widely geographically distributed.

For example, UPPI has members in urban areas like New York and Philadelphia, but also has members that cover the whole state of Florida and significant parts of West Texas. This proposal would expand the reach of these therapies to rural and underserved areas where medical oncologists keep treatment sites. Patient care and compliance with successful therapeutic injections would be achieved.

UPPI envisions that the team established under the proposal would consider -- would consist of a nuclear pharmacist authorized user on site who would cover the radiation safety aspects of the procedure, while a limited trained medical oncologist authorized user, one that possesses lesser hours of training than 700, would be present for the injection or infusion of the therapy and the patient care and treatment.

A single course was developed years ago with limited training of physicians for nuclear cardiology. The training hours address radiation safety and protection of the patient. Under this dual authorized user proposal the onsite nuclear pharmacist would provide radiation safety and radiation protection while the limited trained authorized user medical oncologist would follow proper radiation safety procedures and would care for the patient during and after the dose administration.

UPPI believes a limited trained physician teamed with a nuclear pharmacist would satisfy the NRC's concern for safety and care of the patient in alpha and beta radiotheranostics.

Tailored T&E has already been successfully integrated in several practice areas, notably the use

of Y-90 microspheres in interventional radiology and with brachytherapy prostate implantation with radioactive seeds. UPPI has a number of members that engage in this process and would be pleased to work with the NRC to provide feedback to evaluate potential changes to training and education.

This successful engagement provides a good template for the NRC to evaluate as the Commission considers its proposal.

In conclusion, UPPI urges the NRC to consider implementing a dual authorized user approach for alpha and beta emitters that enables an authorized user nuclear pharmacist to team with a limited trained medical oncologist. This approach, which has already been utilized to provide some additional treatment options for patients would significantly expand the patient access to these important services without sacrificing patient safety or requiring a complex system of different training levels for the administration of different treatments. As the NRC has indicated they may already be contemplating.

We understand that this proposal could create training changes for an alternative pathway for training and education. And UPPI stands ready to work

with the NRC and other professionals to evaluate and fulfill those needs.

Thank you very much for your consideration to this alternative. We look forward to answering any questions that you may have.

MODERATOR LOPAS: All right, thank you very much.

Any questions? All right, thank you.

Tara, can I check in on the phone? If there's anyone on the phone, star-1 to make a comment or ask a question.

OPERATOR: Yes. We do have a comment or question from Johannes. Your line is open.

MODERATOR LOPAS: Hello. Are you there?

DR. CZERNIN: Johannes Czernin.

MODERATOR LOPAS: Hi. Can you speak up a little bit? And could you spell your name because it's a little unclear.

DR. CZERNIN: C-Z-E-R-N-I-N.

MODERATOR LOPAS: Okay.

DR. CZERNIN: Can you hear me?

MODERATOR LOPAS: Yes.

DR. CZERNIN: So my first comment would be that there is a complete mix-up between therapeutic

and diagnostic applications. When the gentleman talks about nuclear cardiology and the radiotherapy he completely mixed up.

But one issue is providing diagnostic services with the therapeutic services.

The second one, training to become a competent radiologic therapy or radionuclide therapy expert it usually takes about five years in civilized countries in Europe, Australia, Asia.

We have a situation here where pretty much everyone can start treatment. My question for the gentleman would be why wouldn't you propose that pharmacies can provide immunotherapy services if radiopharmacies can provide radionuclide therapy services?

The second question for the gentleman would be how would you deal with any radiation spill if you, for instance, start treating patients with incontinent patients, prostate cancer patients with nuclear tuned treatment in an oncology office? How would you do this? How is this done?

But the most important thing is this is like karaoke amateur hour. These are untrained people who try to start treating cancer patients. It's the

most grotesque proposal that I've ever heard.

And with that I'm shutting up. Thank you.

MODERATOR LOPAS: Okay, thank you.

All right, Tara, do we have another commenter on the phone?

OPERATOR: There are no other comments or questions on the phone at this time.

MODERATOR LOPAS: All right. If you will press star-1 or you can submit a question or comment on, on the webinar using the webinar software.

Do we have anybody else in the room that wants to speak right now? I can run the mic to you if you don't feel like necessarily getting up?

No? Okay.

All right. So I'm going to quickly maybe while we're waiting for folks if they want to make additional comments, I'm going to just run through I have done meeting summaries from the meetings that we've had in the past. We had one on November 14th and one on December 11th. And the NRC publishes meeting summaries within 30 days after each public meeting. So I'm just going to run through some of the opinions and ideas and comments that we heard during those previous meetings.

And as I mentioned in the presentation, if you go to regulations.gov and you search the NRC, it's going to be Docket Number U10, which is NRC-2018-0230, you can see the comments, the written comments that folks have submitted so far if you're interested in seeing what people are sending to us thus far.

So first of all, we have heard some strong opposition to any reduction in teaming requirements in 10 CFR 35.390; we've heard that the current requirements are appropriate, that they protect the safety of patients, the public, and practitioners; and we've also heard that new, new therapies that are coming down the pipeline are getting increasingly complex and so they would require even more training perhaps than, than maybe, you know, than maybe less.

We have heard that changing the regulations and requirements could just create confusion and complexity for licensees, for the NRC, and for agreement states.

We have heard that in opposition to reducing any T&E that we have to consider the physician's background in the fundamentals of radiation protection and radiation physics, and that training

in radiation sciences can't simply be counted in hours, especially if this is, if working with radioactive materials is not part of the physician's regular job duties.

So additional comments that we've heard is some commenters have strongly supported tailored team requirements, citing that we already do this for, for sodium iodide administration in 35.392 and .394. And commenters have supported doing this for potentially other categories and classes of drugs, radiopharmaceuticals.

They thought that, you know, for administration of radiopharmaceuticals that are relatively safe in their unit dose agents that they thought that 700 hours of training would be overly burdensome and not warranted.

Other comments we heard about, we heard some opposition again, and opposition was stated that if we lowered training and experience requirements or lessened them that we could adversely affect the field of nuclear medicine in general, that it wouldn't encourage people to dedicate, you know, their practice to that field. And potentially research and development would suffer.

I'm going to move on to our next meeting summary. Let's see.

We have heard many comments about patient access, and particularly in rural areas there's an issue. There was a note that, there's a shortage of physicians in general in rural areas and that, you know, we don't expect that there'd be any difference between the shortage of physicians and shortage of AUs. You know, there's probably similar shortage of AUs in rural areas, if not worse for AUs.

We have heard, and then we did hear in our last meeting there was some more strong opposition to kind of opening up the AU to non-physicians, that there was opposition to that.

I'm going -- I do have one comment here on the webinar. Okay, I did get a request for me to repeat the docket number for T&E. So the docket number, I'm going to pull it up on the, on the slides as well. But it is NRC-2018-0230. It's right here.

So if you go to regulations.gov and you search NRC-2018-0230 that will bring you to the regulations.gov docket where it will list all the comments that we received so far, written comments. And we also are posting transcripts as they become

available.

So star-1 on the phone. Does anybody, anybody in the room have any additional comments before we go back to the phone?

Sure.

MR. GUASTELLA: This is Michael Guastella again at CORAR. I think the question, I believe in the ACMUI report they did comment on the safety profile and history of the radiotherapy.

Has NRC taken into consideration that that safety profile, that broad safety profile includes individuals that have been grandfathered in prior to the 2002 final rule? I don't know if you've ever kind of taken a look at that. It may be too granular, but I think it's, it's something to consider.

Thank you.

MS. AYOADE: Yes. Thank you for your comment, question. We have not taken that into account but, as you said, it's something for us to consider.

MODERATOR LOPAS: Okay. All right, Tara, are there any comments on the phone?

OPERATOR: Vicki LaRue, your line is open.

MS. LaRUE: Thank you. My name is Vicki LaRue. I am a nuclear medicine advanced associate in

Denver, Colorado. And I just wanted to reiterate a couple of points that were made by my colleagues. And that is the goal of the nuclear medicine advanced associates, which is the nuclear medicine physician extender, is to extend the services and expertise of our nuclear medicine physicians and nuclear radiologists while ensuring that they retain control of complex clinical decisions.

And basically as a medical specialty in general, we are trained by these physicians to perform as they would perform in specific clinical scenarios.

So I just wanted to reiterate the fact that as physician extenders we are always working under the supervision of physician authorized users.

And that is my main goal. Thank you so much.

MODERATOR LOPAS: All right. Thank you, Vicki.

Star-1 on the phone. Tara, is there anybody else?

OPERATOR: Shaemus Gleason, your line is open.

MR. GLEASON: Thank you very much. And thank you to the NRC staff for allowing us to comment

on this recent proposal.

I'd like to just refer the staff back to a letter that Bayer sent to the NRC in response to this initiative 11 July, 2018. In the interests of time I'm not going to go through every point and subpoint in there but I just want to kind of talk a little bit about the appeal and how we spent a lot of time running an effort developing a distribution model that we feel is safe administration.

That distribution model is distributing a product that has limited injection site reactions and limited adverse events associated with the therapy. These patients are dosed every four weeks and are immediately releasable patients.

And in spite of all of this, and in spite of the fact that we have over 1,000 sites up and treating patients to this day, in the market research that we provided to the NRC it shows that one of the largest issues we have is availability of nuclear medicine physicians to do these therapies, and also hesitation on the patient's side that they don't want to go to another physician.

So taking these things into account we really appreciate the opportunity to comment on this.

And I just wanted to kind of share that and kind of refer you back to the documents on 11 July, 2018, which I think are, you know, eliminates a lot of these issues that were talked about today.

So thank you for your time.

MODERATOR LOPAS: Yes. That was Shane, was that your name? Sheamus?

MR. GLEASON: Yes, it's Sheamus Gleason. And I'm the head of Global Radiopharmaceutical Strategic Operations at Bayer.

MODERATOR LOPAS: Excellent. Excellent, thank you, Sheamus. I appreciate that.

MR. GLEASON: No problem. No problem.

OPERATOR: The next question or comment comes from Johannes. The line is open.

DR. CZERNIN: It's Johannes Czernin again.

I completely understand why industry is pushing for that. My comments to some other prior comments that were made about kind of the needs assessment are that we did the analyses and actually came up, using data from Europe, that you need about 150 theranostics centers in the United States, number one.

Secondly, if you talk about highly

specialized theranostics clinics, they are not different from highly specialized oncology centers or transplant centers. Nobody of sound mind would place them all over the country. This is not the best way to do medicine. Medicine should be left to well-trained experts.

And what is proposed here is a completely dumbing down of a very complex, interactive, collaborative effort among many disciplines to provide best patient care.

And, again, if you suggest the radiopharmacies can do that, then why not pharmacies doing chemotherapy.

That's it.

MODERATOR LOPAS: Okay. Thank you, Johannes.

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

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

MODERATOR LOPAS: Okay. All right, folks on the phone, star-1. We will go for a few minutes long. But this will not be your last chance to get in comments. Clearly we have another webinar January

22nd. That's a Tuesday. It's at 10:00 a.m. Eastern time, so it's early for folks not on the East Coast.

And we also, you know, we do encourage folks to submit comments, too, on the docket written. I mean, of course we have your comments transcribed today but it's always, it is nice to get written comments as well because it really allows us to carefully evaluate those, too. So those can be done by regulations.gov.

And if you have any issues on regulations.gov, please just email me. And I'll put my contact information up again.

So star-1 on the phone. Do we have any last comments here in the room?

All right. Donna-Beth Howe. Donna, I'll bring -- Dona-Beth, I'll bring the microphone to you.

DR. HOWE: This is Donna-Beth Howe with the Nuclear Regulatory Commission. And I would just like to get a little bit of clarification on some of the things we've heard today.

One is the proposal from UPI -- UPPI to have the authorized nuclear pharmacists working in coordination with a limited authorized user. I understand that commercial nuclear pharmacies distribute radiopharmaceuticals to rural areas. But

those are people transporting doses. Do you have enough nuclear pharmacists to send your nuclear pharmacists to each rural physician or location to be active in the dispensing and the administration of the radiopharmaceuticals?

MR. WITKOWSKI: To respond to your question, I think conceivably it's not going to be every medical oncologist in the country who's going to try to get limited authorized user status. The comments from the call is that we're not going to put up a radiotheranostics suite in the nuclear pharmacy and have the patient and doctor come there, but we're looking at the nuclear pharmacists. And, yes, we do have enough staff to be able -- of nuclear pharmacists to go onsite.

The therapies could be scheduled for a single day of the week and it could be scheduled all at the one time. But go to the site that would be licensed. And potentially it could be the suite within chemotherapy that could be licensed by the agreement state or the NRC.

And the team there, the doctor would inject the dose, take care of the patient. He would have an understanding of the radionuclide and all these

radiation safety aspects. And the nuclear pharmacist who would dispense the individual dose in the nuclear pharmacy without any complaint, and handle any type of radiation safety and contamination issues, is there to address that should it occur at the site.

Additionally, and in some areas, you could have a health physicist come to help in monitoring the patient. And obviously these patients would require health physicists in order to keep compliance with the regulations that the NRC requires on patient dose recording and disposal rates and such.

We believe that this is not going to be a widespread number of sites, that it will be areas that have not been served but could be reached. A nuclear pharmacist could, with the staff and our nuclear pharmacist then would go on site. They would probably take the does on site and work with the physician for the injection.

DR. HOWE: Thank you. And I have one question for the individual I think on the phone with the advanced degree for the technologists and the intermediate between the physicians and the technologists.

We currently have at the NRC a program that

is widespread which is the mobile nuclear medicine where you have a authorized user physician and the pharmaceutical goes out in a van and the technologist will help administer it at the site.

Your, the last commenter commented is that this advanced intermediate person would operate under the supervision of a physician authorized user. So could you possibly comment on how this would differ between what you're proposing and what we currently have for a mobile nuclear medicine type license?

MODERATOR LOPAS: Okay, Donna-Beth, let's see if any of the commenters -- so I believe that was Vicki spoke up about that. We also had I believe Scott.

And, Scott, if you'd jump back on the line, I'd love to have the spelling of your last name.

And we also have Richard Siska.

So I don't know if Vicki, Scott, or Richard would want to potentially respond to Dr. Howe. So, Tara, let me know if any, if either of those three press star-1 to respond.

OPERATOR: I do have Johannes, Scott, and Vicki who are waiting to speak. Which one would you like first?

MODERATOR LOPAS: We'll start with Scott

and go to Vicki, and then we can go to Johannes.

OPERATOR: And we just had Richard as well join.

MODERATOR LOPAS: All right.

OPERATOR: So, Scott, your line is open.

MR. DEGENHARDT: Yeah, thank you.

And I, I did hear most of that question. I apologize, but what our program or what our profession is, is again we started off as nuclear medicine technologists, highly trained nuclear medicine technologists who have advanced their education or our education to a, you know, to a mid-level status.

We, you know, we have the graduate level didactic course work. We have a clinical internship under a nuclear physician or radiologist, 24 months worth of education where we study in depth radiation protection, radiation biology, physics, in addition to just overall patient care to function as a mid-level provider, again, in this field.

Where we could benefit in the healthcare setting is I currently work for a oncology practice here in Omaha, and as our -- we have our radioactive materials license, we do radiotherapy, you know, with

Xofigo, a 1-minute administration, pretty cut and dry. You know, little time as far as the administration and the complexity of administration goes.

Now that we have seen the emergence of Lutathera here in the U.S., you know, it's a little bit more of a complex administration. You know, 45-minute injection. And that's tying up our authorized user and our physicians, you know, that entirety. And, you know, they're unavailable for other patient care, unavailable to dictate, you know, other studies during that time as their time is dedicated to that patient.

Where a mid-level provider could certainly benefit, you know, with an authorized user status or limited authorized user status, again functioning under the supervision of that, that physician, you know, they could be that onsite provider there with that patient to free up the physicians for other, other work, other patients to, you know, improve patient access and, honestly, improve overall patient care and safety.

I would like to hear what Vicki and Richard would have to say about that as well. But I hope that answers the question, and I appreciate the opportunity.

My name, again, Scott Degenhardt,

D-E-G-E-N-H-A-R-D-T.

MODERATOR LOPAS: I'm sorry, could you spell that one more time? I just missed that. I apologize, Scott.

MR. DEGENHARDT: No problem. Degenhardt is D-E-G-E-N-H-A-R-D-T.

MODERATOR LOPAS: Okay, excellent.

All right, thank you. Okay, let's go to, we'll go to, over to Vicki, then Richard. And, Johannes, I know you are on the line. So, Vicki, we'll hear from Vicki next.

Tara, is Vicki still on the line?

MS. LaRUE: Yes, I'm here.

OPERATOR: Vicki, your line is open.

MS. LaRUE: Okay. Can you all hear me?

MODERATOR LOPAS: We can, yes.

MS. LaRUE: Okay, great.

If I'm understanding the question correctly from Dr. Howe, I believe if in a mobile service where maybe an authorized user is listed on a diagnostic prescription and then the technologist, say, injects the tracer, that's very commonplace for any, for any nuclear medicine department or for any nuclear medicine radiopharmaceutical injection.

I think what we can do as physician extenders is under the supervision of the physician authorized user, and functioning as an authorized user, we extend the services of the therapeutic authorized user and be the physical proxy.

As staff had mentioned previously, this is logistically challenging for our authorized users, our therapeutic physicians to either leave the department, leave the reading room. And even if it's going across campus or going up to the 15th floor, this is kind of non-productive time for them if there isn't a clinical emergency. Naturally, the physicians take care of all the complex clinical decisions of this.

Thus, the physical proxy being the physician's extender, as we have been trained by these physicians, then we can hopefully take a little bit of burden off of them. And whether it's going up to the 15th floor or across campus or across town, then we can certainly extend the services of the nuclear medicine physician or nuclear radiologist by being a physical proxy and, again, being the physician extender. This is the model. We see it in almost every other medical specialty of physicians using extenders.

So hopefully that answers the question.

MODERATOR LOPAS: Thank you, Vicki.

And, Richard Siska, are you still on the line, Richard?

MR. SISKA: Yes, I am.

MODERATOR LOPAS: Anything to add?

MR. SISKA: I think, well, I think Vicki pretty much answered the question head on.

Just to give an analogy, when you go to your doctor's office now sometimes you won't see your physician, you're going to see a nurse practitioner. You might see a couple of different people. You might see a nurse's aide, a nurse, and then the nurse practitioner.

And what the nurse practitioner is is what Vicki explained is the proxy for the physician. So the physician does supervise but it's a broad scope of supervision. They don't have to be in the room. They may not be in the building. They may not even be in the same town. But they're working in a collaborative effort.

This is more of the design of what the nuclear medicine advanced associate is. The technologists do have authorized duties to inject radiopharmaceuticals under the license and supervision

of an authorized user, whereas the NMAA could do that as a proxy, like, Vicki mentioned, in a different location being placed on a license that is, for instance, in a rural area.

I'm in an area that is two hours from a pharmacy. I don't know if my pharmacies would have licensed pharmacists to come up and sit with patients on a daily or even, you know, weekly basis to do all the duties that a technologist, an NMAA, and a licensed pharmacist could do when you could have one person doing that that's already working in that facility.

So to me this is kind of the role that the NMAA was created for. And this would help expand our duties and keep that, you know, the job duties of nuclear medicine within the nuclear medicine realm. Because, as other pure nuclear medicine people, I kind of think it's been watered down over time. And just because things have happened in the past that have allowed other entities to come into nuclear medicine doesn't mean that they were great ideas.

So I, I just reiterate what Vicki and Scott have said.

MODERATOR LOPAS: All right. Thank you, Richard.

Donna-Beth, do you have any more questions? Okay.

All right, is Dr. Czernin still on the line, Tara?

OPERATOR: Yes. Your line is open?

DR. CZERNIN: Just a few comments.

First of all, I have great respect for all the training levels but it's not the Regulatory Commission's purview to decide who can practice what kind of medicine. These are therapeutic, not diagnostic. The highest volume of patients will be prostate cancer patients within two to three years. Okay.

Prostate cancer patients, 50 percent of them will be incontinent. If you treat them with radionuclides in an oncology office you will have contaminations resulting, very often shutdown of rooms for a certain time or period to decontaminate it.

So how are you going to manage that in the oncology office? It's not the work flow of an oncology office. It will take enormous amount of time. And oncologists, by the way, are not trained even if you make them authorized users, to know what they are doing with radioactive treatment. That's number one.

The second one is I have, again, great respect for all the comments, but treating patients for physicians is always productive time. You may come from that kind of radiology offices where you just look at images.

Nuclear medicine comes from internal medicine. And to say that we waste our time by treating physicians is again a complete misrepresentation of what we do in our jobs. So I would really, I really urge you to respect appropriate training, competence, and unique treatments for properly trained experts.

MODERATOR LOPAS: Okay, thank you.

All right, star-1 on the phone for any additional comments. And we will get started to close out.

I want to check back in the room if there are any additional comments in the room?

Okay, Tara, I'm going to check on the phone one last time for any additional comments.

OPERATOR: We do have two. We do have two commentators. Aria, your line is open.

DR. RAZMARIA: Hi. This is Aria Razmaria speaking on behalf of training in nuclear medicine.

I just wanted to raise the topic about

advanced nuclear medicine associates. It's important that physician extenders are going to be in future of nuclear medicine. But I think the discussion here is about authorized users under whom advanced nuclear medicine associates are going to be working. The changes that have been discussed here really are, you know, how the treatment -- the training requirements are going to look like for these providers.

If you look at the 10 CFR Part 35.300 it starts with Aphysicians who.@ But this discussion is about physicians and the requirements for their training.

And, again, the point was brought up that nuclear medicine advanced associates are going to be practicing under supervision of nuclear physicians or nuclear radiologists. But, again, the changes that are happening or being discussed are pointing out that, for example, a family medicine physician could obtain authorized user status, an ophthalmologist could be able to obtain authorized user status by just having 80 hours, two weeks of training.

So this is, again, this is going to be a lot of responsibility that's going to be transferred to nuclear medicine advanced associates. And the

authorized user might not be a nuclear physician or a nuclear radiologist.

So this is you're going to have to bear that in mind when you're kind of looking for therapies that are highly -- high side effect profiles, for example, nuclear therapies. Imagine the patient goes into a cardiac crisis. It's just then a matter of saying the dose at the bedside and have it injected like a Xofigo. By the way, Xofigo has other kind of consideration of -- intensive therapy planning, what succession of therapy, it's just not a matter of giving a dose but it's a lot of thinking and clinical consideration in terms of dosing and dosimetry.

But I can just imagine for nuclear therapy a patient goes into cardiac crisis, who's going to be there who -- are you going to have this authorized user linkage -- authorized user that has not, you know, come across a side effect profile of such therapies, radioligand therapies.

Just bear in mind the discussions here, there are two different topics, the importance of nuclear medicine advanced associate and their future role in nuclear medicine -- to dilute training for authorized user -- another word for physicians who are

going to be responsible directly for what therapies are being administered.

And, again, I don't want to be in the position of a nuclear medicine advanced associate that runs into a very dangerous complication and who has, for example, a family physician or an ophthalmologist or internal medicine specialist who has never seen such complications that these therapies can have and have to resort to look for help from someone who doesn't have that experience or that level of training.

So just bringing that to your attention. This is a discussion here you're having is about physicians who are going to be authorized users who have the responsibility, the ultimate responsibility what complications those therapies going to have. Thank you.

MODERATOR LOPAS: All right. Thank you, Dr. Razmaria.

Tara, there was another comment?

OPERATOR: David, your line is open.

MR. BURPEE: Hi. Thank you again.

And just to put some perspective to the physicians' good concerns about an authorized user and the extent of training that obviously they have compared

to other who might not have as much.

I want to just paint a picture about how the real world works in that in my ten states that I manage the authorized users write the written directive, consult with the patient, and that's really about all they do.

The team that they work with is just as responsible and does a great job. And there's been no problems whatsoever.

So a team consists, of course, of the radiation safety officers, the radiopharmacist who prepares unit doses, the certified nuclear med techs, the hospital clinic administrators who are responsible with the licenses, and the regulatory people. They, they certainly are an important part of the team that makes all this happen in a very efficient and compliant way.

Radium is being used widely in our patient centers. And even in the worst case scenarios it's very, very easy for them to handle. And they're certainly prepared and it's certainly a part of their license to be ready to be prepared for any kind of contingency, like a patient who might be incontinent.

For the radium, that's an interesting

situation in the product really isn't coming out in urine, one, and it doesn't go past the outer layer of dead cells on your skin. It's easily cleaned up with your radcons, and a piece of paper clearly takes care of any kind of situation. You can continue to use the room because the alpha doesn't go past the piece of paper.

So there's many levels here of concern. And I think it's important to understand which isotope and therapies we're talking about as we look at what kind of level of training and experience we need.

So thank you.

MODERATOR LOPAS: Okay, thank you. And that was David Burpee; correct?

MR. BURPEE: It is.

MODERATOR LOPAS: Okay, excellent.

Okay, star-1 on the phone. Tara, do we have any additional comments on the phone?

OPERATOR: Yes. We do have another comment from Johannes.

MODERATOR LOPAS: Okay.

DR. CZERNIN: Sorry for talking again. It is absolutely true that this is a team effort. I completely agree with the previous comments. The

question is only whether the commentator is aware that before the directive is scheduled or the order is scheduled a whole hour, 45 minutes in treatment centers is spent by designing the appropriate treatment, understanding whether it's appropriate, and delivering the correct treatment.

I also appreciate very much the informative comments on alpha radiation. That's, of course, helpful for me to understand. But please keep in mind theranostics clinics will then be run by authorized users who have no idea about lutetium within a relatively short time frame. And they have no idea about any other therapeutic isotopes, side effects, combination issues, and so on and so forth.

So picking Xofigo is pretty easy. But are you really then limiting authorized users to just doing Xofigo? Or wouldn't you, if your patients want to go to a place where people really know what they are doing, they are part of an integrated care team that manages the patient, and don't have a pseudo-authorized user just to make your, you know, make an argument that the treatment is now more accessible for patients.

How do you make the argument for transplant patients? How do you make the argument for major

surgery centers? How do you make the argument for chemo and immunotherapy? It's just really picking and choosing an argument for reasons that can only be probably commercial.

MODERATOR LOPAS: Okay, thank you, Dr. Czernin. Tara, do we have another comment on the phone?

OPERATOR: There are no other comments or questions at this time.

MODERATOR LOPAS: Okay. All right, going to do last call in the room for additional comments in the room? Okay, hearing none, we are going to, I think, close out the meeting. We will have another webinar January 22nd, 10:00 a.m. The registration information is on the NRC Public Meeting Website. If you Google ANRC public meetings@ the meeting schedule page pops right up and you should be able to find our January 22nd training and experience evaluation public meeting.

I want to thank everybody for participating today. We had really great comments and a dialog, and we appreciate everybody's taking their time to dial in to the webinar on the bridge line and for folks to come in person. We appreciate it.

So with that, have a great afternoon,

everybody. Thank you so much.

(Whereupon, the above-entitled matter went off the record at 2:37 p.m.