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NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING

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

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TUESDAY,

JANUARY 22, 2019

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The meeting was held via webinar at 10:00 a.m. Eastern Time.

PRESENTERS FROM THE NRC:

MARYANN AYOADE, NMSS, MSST, MSEB

SARAH LOPAS, NMSS, MSST, MSEB

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

(10:02 a.m.)

MS. LOPAS: Hi, everybody, good morning. Welcome to the Nuclear Regulatory Commission's webinar to accept comments on the Staff's evaluation of training and experience requirements for different categories of radiopharmaceuticals.

This is our last of four public meetings/webinars that we've had on this topic. And I want to remind everybody that our comment period ends a week from today on Tuesday, January 29th.

My name is Sarah Lopas and I'm a member of the NRC's Medical Radiation Safety Team, which is part of the Medical Safety and Events Assessment Branch in the NRC's Office of Nuclear Materials Safety and Safeguard.

I'm the project manager for the NRC's training experience evaluation and I'll be facilitating today's webinar and giving part of the presentation.

And here to help me out is Maryann Ayoade, who is a health physicist in the NRC's Medical Radiation Safety Team. And she is the technical lead on the training and experience evaluation. So Maryann will be giving part of the presentation as

well.

We have a short agenda for today's webinar. I'll just be going over some basic information about the webinar and then Maryann and I will go through 15 slides that will cover background information on the NRCs evaluation on training experience evaluations, we're going to discuss the Federal Register notice that was published on October 29 and then we're going to cover how you can provide your written comments by that January 29th deadline, if you would like to provide written comments.

Then we're going to open up the phone lines to take your comments and any kind of process-type questions you have. And you can also submit questions or comments via the webinar software. I'll keep an eye on that.

The purpose of today's webinar is twofold. It's to provide you background information on the staff's planned evaluation of developing tailored training and experience requirements for administering different categories of radiopharmaceuticals, for which a written directive is required.

And that's in accordance with your regulations in 10 CFR Part 35. And those are

regulations for medical use of byproduct material.

And specifically, under Subpart E, of Part 35, which covers unsealed byproduct material written directive required.

And most importantly, the reason why we're here is to listen to and record your comments on the evaluation. So, the comments that we received from the medical community, the agreement states and other stakeholders, are critical to our decision making on whether our existing training and experience requirements should be revised.

And so, if you don't provide comments today, orally over the phone, just please make sure you get them in. You get your written comments in by regulations.gov by January 29th. That due date.

And I'll be going over how you can do that a couple more slides from now.

So, for general webinar information today, I want to note that if you aren't logged into the webinar that's okay, there's a couple ways to get our slides. You can either go to our public meeting schedule web page and that provides-if you find today's meeting, which should be one of the top meetings listed-there's a link to our slides.

If you go to the NRC's T&E website, if

you just Google ''NRC training and experience evaluation,'' that will bring up our T&E website. And there's a link to today's slides if you scroll down the page and look for today's meeting as well.

So, there is a couple of ways to get to our slides if you're just listening in without the webinar.

Today we're going to be discussing our evaluation of training experience requirements for certain categories of radiopharmaceuticals. We're likely going to refer to them as, training experience, as T&E for short. And also, we tend to refer to authorized users, which are those physicians who are authorized to administer radiopharmaceuticals, as AUs.

So those are some terms that you'll hear today.

And today's webinar is being transcribed by a court reporter. And a full transcript of this webinar will be publicly available in about a week and a half or so. Or maybe we might try to get it turned around a little bit quicker before the comment deadline. I'll try to do that for you all.

And it's going to be available in the NRC's agencywide Documents Access and Management

System, that's ADAMS. And I'll be posting a link to this transcript on the NRC's training and experience website. It will also go up on regulations.gov too.

And you can find all of the transcripts that we have for our past three public meetings on that T&E website as well. And also on regulations.gov.

On regulations.gov, under our docket (NRC-2018-0230), there is a category called supporting documents. And that's where I've listed the meeting summaries and transcripts, if you're interested in what people have said during past meetings.

And I do want to say that all the comments that are spoken here today will make it on our docket since they are being transcribed. And that oral and written comments have equal weight. So if you don't, if you've spoken your mind today and you don't feel like typing it in or sending it by regulations.gov afterwards, that's perfectly fine because we will get it today.

So, right now everybody is in listen only mode. And as Cedric mentioned, when Maryann and I finish the presentation, that's when I'll be opening the phone lines. And all you have to do is press

star-1.

And I'll remind everybody that you do need to make sure that you introduce yourself and clearly state your name. And if it's a tricky name, maybe spell it out for our court reporter. That's vitally important so we know who is saying what.

So now I'm going to hand the presentation over to Maryann so she can talk about our T&E regulations and give you some background.

MS. AYOADE: Great, thank you, Sarah. Good morning, everyone.

Today I will be presenting information on an overview of the regulations on training and experience for radiopharmaceuticals requirement and directive, some background on the related stakeholder concerns received for this evaluation and the 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 written directives.

A physician can be authorized to

administer these radiopharmaceuticals if they are certified by a medical specialty board. This certification process is recognized by the NRC or an agreement state.

A physician can also be authorized if they've satisfied the training requirements via an ultimate pathway, which includes the completion of 700 hours of training and experience, including a minimum of 200 hours in classroom and laboratory training in relevant topic areas as listed in the regulation. And 500 hours of supervised work experience in the relevant areas as listed in the regulations.

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.

So, this training and experience evaluation is focused on the alternate 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 an admitted 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, 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, the training for oral administration of sodium iodide, I-131. Requiring a writing 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, I-131. Requiring the writing directive in quantities greater than 33 millicuries.

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

I want to point out that all of these sections of training and experience, include the pathways for an experienced authorized user that is already listed on a license. Also, all the sections, except for 10 CFR 35.396, include training and experience under the board certification and ultimate pathways.

However, 10 CFR 35.396 is for training exclusively under the ultimate pathways. And it is really for the radiation oncologist 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 ultimate training pathways, under 10 CFR 35.392 and 394, is for the physicians 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, ultimate training pathways, under 10 CFR 35.390, is for the physician to successfully complete 700 hours of training and experience, which includes 300 hours of classroom and laboratory training.

Next slide. So, this slide provides background information on stakeholder concerns that have been received 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 on patient access to

certain therapy related pharmaceuticals.

Specifically, some of the stakeholders have asserted that the 700 hour requirements in 10 CFR 35.390, is overly burdensome for physicians that 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 in 2016, in separate efforts to NRC Staff and 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 authorizes under Subpart E.

Specifically, the NRC Staff has reviewed the regulatory basis and comments received on past rulemaking related to the medical use of byproduct materials and did not identify any new information that will call into question the basis of the existing requirements.

As a result, the NRC Staff did not disclose any changes to the regulations at the time. And the NRC Staff is continuing to work with the ACMUI in this ongoing training and experience evaluation effort.

Next slide. 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. It also evaluates how this category should be determined.

So, such as the risk posed by radionuclides or by delivery method. It also evaluates what the training and experience requirements would be for each category and to evaluate whether those 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 obtained feedback from some medical and regulatory stakeholders in April and May of 2018.

That evaluation, including the NRC Staff analysis and the feedback that was received of the training and experience requirements in Subpart E of 10 CFR Part 35, was documented in an NRC SECY paper, which is the SECY-18-0084.

The results of that evaluation concluded that it may 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 accessible training and experience for a limited authorized user status. But, however, the Staff does need to conduct more extensive outreach to stakeholders in the medical community, to the agreement states and to other members of the public, before making a recommendation to the Commission.

And that is what brings us to our current evaluation to date. I will now hand it back over to Sarah, who will discuss our current evaluation efforts and how you can participate. Next slide.

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

And that paper is going to document the results of our evaluation. Which would either be

maybe recommending no changes or recommending some options for potential changes.

And, if we do recommend some options, we will also have to accompany that paper with a rulemaking plan.

On this slide, we're on Slide 11 now, this is a simplified diagram of the information that we're going to consider in our development of a recommendation to the Commission. The diagram illustrates why this comment period is so important to this effort because, in large part, the feedback that we receive on the questions that we've asked in our Federal Register notice, are going to inform our recommendation to the Commission.

And other important feedback will come from our coordination with our co-regulators, the Agreement States, and the NRC Advisory's Committee on the Medical Uses of Isotopes, ACMUI as Maryann had mentioned earlier.

In addition to the inputs we receive from--

(Technical interference)

MS. LOPAS: -- the Agreements States and the ACMUI, the NRC Staff is also examining the issue of patient access. So, we are currently attempting

to map NRC licensees that are licensed to use 10 CFR Part 35.300 materials.

These are licensee facilities that could potentially offer these therapeutic radiopharmaceuticals. So, we're going to be mapping those. And there will be a series of maps of the individual states for the data that we have.

The NRC only has access currently to non-agreement states - - our licensees. And those are about 13 states at the moment.

We are planning to issue a voluntary request for information to the Agreement States for their information on --

(Technical interference)

MS. LOPAS: -- for these therapies as well. So that would hopefully give us a little bit more complete of a picture of the --

(Technical interference)

MS. LOPAS: -- United States, depending on how many Agreement States are able to respond back to us and help us out with this data.

I will note that we are stuck a little bit right now with that request. That voluntary request to the Agreement States. It does need to be reviewed and approved by the Office of Management and

Budget.

And the Office of Management and Budget is closed due to the partial Government shutdown. So, at the moment, we're kind of stuck. But I would hope that that letter would go out to the Agreement States --

(Technical interference)

MS. LOPAS: -- maybe two to four weeks after the partial shutdown ends and --

(Technical interference)

MS. LOPAS: -- everything goes back up.

The other things that the staff is going to look at are - - we're reviewing our training and experience requirements in other countries in an effort to benchmark what other, what the international community is doing with regard to training and experience.

And then we also are reviewing - - doing an extensive review of recent medical events in our NMED database. The Nuclear Materials Events Database. NMED is our database that covers events with nuclear materials - - to see if any medical events have a nexus to training and experience.

So, we have to dig a little deeper into those events to see if we can get to a root cause of

training and experience. So, those are the two additional things that we're looking at. Three additional things we're looking at.

In addition to evaluating your comments --

(Technical interference)

MS. LOPAS: -- and what we hear from the ACMUI and the Agreement States.

So, it's important to --

(Technical interference)

MS. LOPAS: -- is to our regulations, that we would need to document, again, document that in a rule making plan. And then our Commission would the proceed to vote on that rulemaking plan.

And that would determine whether or not we would move forward with another Part 35 rulemaking effort. And if rulemaking is recommended and the Commission approves it, that would then start our extensive rulemaking process that many people are familiar with.

And I am highlighting where we are in this process so everybody understands where we are. And where we are is that we're still in the information gathering phase. We --

(Technical interference)

MS. LOPAS: -- kept in mind, you know, we're really at the beginning of this. And until we really get all, until the public comment period ends and we get everybody's comments in and we get a chance to really digest them and we hear from the agreement states --

(Technical interference)

MS. LOPAS: -- a path forward yet. So, I just wanted to highlight that.

Next slide, Slide 12, covers our Federal Register notice. So, that was published back on Monday, October 29th. The Federal Register notice can be accessed by this link.

And I also want to point out that there are some handouts attached to the webinar. So, if you click on the little handouts button on your webinar, you'll see, I believe, a copy of these slides that you can download if you want.

I have the SECY paper that Maryann referenced from last August --

(Technical interference)

MS. LOPAS: -- And I also have a copy of the Federal Register notice. So you can download all of those documents from the --

(Technical interference)

MS. LOPAS: -- webinar. So, the Federal Register announced the comment period. It ends on, a week from a today on Tuesday, January 29th.

And most importantly, the Federal Register notice asks a series of questions on which the NRC would like specific input on from the medical community.

So, I'm going to read through those questions in the next four slides just to give everybody some context of kind of the information that we're looking for.

But then, we will be opening it up to public comments after I'm done here in a couple of minutes. So, we can certainly walk through the questions later on or however we want to do it, so, don't worry, I'm just going to read through the comments now, or the questions now, to put some context into what we're looking to get.

So, Slide 13, here we are. Questions in the FRN.

So, Part A was asking about tailored training and experience. And these aren't all of our questions so that's why I do encourage you to read through the whole FRN, there's a lot of subparts to these questions --

(Technical interference)

MS. LOPAS: -- You can review the FRN that I've attached to the webinar and read through them maybe during the comment portion of today's meeting.

Question 1. Are the current pathways for obtaining AU status reasonable and accessible, are they adequate for protecting public health and safety?

Question 2. Should the NRC develop a new tailored T&E pathway? What would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements?

Question 3. 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?

Question 4. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals?

Slide 14 goes over the NRCs recognition of medical specialty force. And if you Google NRC medical licensee toolkit, these procedures for recognizing the medical specialty boards are on that medical licensee toolkit website. But, what boards,

other than those already recognized from the NRC, could be considered for recognition for medical uses under 10 CFR 35.300. And those other boards are, American, or the boards that we currently recognize are, American Board on Nuclear Medicine, American Board of Radiology, American Osteopathic Board of Radiology, Certification Board of Nuclear Endocrinology.

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

Slide 15 goes over the patient access --

(Technical interference)

MS. LOPAS: -- perspective of folks that may or may not be impacted by our regulations on patient access.

So, 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 we have gotten some feedback or questions about, why is the NRC asking --

(Technical interference)

MS. LOPAS: -- this? And I would answer that and say that, you know, we are interested in the perspective of folks that are out there doing this - what are the impacts that people are noticing with regard to patient access?

You know, we have heard from some physicians that, No, there is no patient access issue, there are plenty of AUs out there. And then we've heard from some other industry folks saying, yes, we're having hard time finding AUs.

So, that's the kind of feedback that we'd like to hear. And that's why we thought it was important to include in the FRN.

And then Slide 16 are questions, just general questions about the NRC's training and experience regulations as a whole. These are kind of in an effort to, for us to kind of maybe look transformatively at our medical regulations with regard to training and experience.

So, Question 1. 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 general public, patients, and human research subjects?

So, those are all the questions. And like I said, there's multiple sub-questions underneath each one of these questions, so I really encourage you to check out the Federal Register notice.

So, this slide just gives you the important details about submitting your written comments. So, like I mentioned, January 29th, one week from today at 11:59 p.m., the regs.gov portal will stop accepting comments.

So, how do you submit comments to regulations.gov? Well, you simply just go to www.regulations.gov and there's a search bar will popup right at the top and you just type in, NRC-2018-0230.

And that will just bring you right to the T&E page, docket page. And it's very self-explanatory on submitting comments.

This is also, that second bullet there on the side is just the direct link to submit comments, so that will get you there as well.

I do want to note that, let's see, last Friday regulations.gov, I think, went down for about half a day. You could not access anything on regulations.gov.

And it was related to the Government shutdown affecting a portion of the Environment Protection Agency, which actually manages regulations.gov. But it is back up and running.

It did come back up and running about, I don't know, half way through the day on Friday. And I've been told, I've been assured that it should remain up and running through the rest of the comment period, through January 29th.

Now, if you have any issues at all with submitting your comments by regulations.gov, if you go to log on and you can't get to it, it's shutdown for some reason, you can email your comments to me or Maryann. That is no problem, that's perfectly acceptable.

And that's going to be the work around if for some reason regulations.gov shutdowns anytime between now and January 29th. But I've been checking regulations.gov a few times a day, every day because I'm nervous about about it, and it's so far so good. Except for that one Friday. Or, I think it was Thursday that it actually went down.

So, my contact information and Maryann's contact information will be in the slide, the next slide, so you'll see that. But I just want to make sure that everybody knows that emailing your comments to me is a perfectly fine option if regulations.gov isn't working.

I do want to note that when you submit your comment on regulations.gov, you're not going to see it posted right away. It takes a few weeks.

But I will, I promise you that we are getting it so don't worry. It sends you a little confirmation that your comment has been received. And we receive them.

It just takes a, we have an internal administration, an admin type process where we have to pull it down off the regulations.gov, put it into our ADAMS system, so your comments will also be in ADAMS, and then we re-post it back on regulations.gov.

So that's why it takes a little bit longer.

At the end of the comment period, so we're going to be compiling all the comments, organizing them, reviewing them and we'll be summarizing them. And we'll be putting together a nice summary report that will be attached to the paper that we send to the Commission. And the summary report will summarize everything we've heard from everybody.

And I do want to note that because this is not a rulemaking, so we aren't going to responding individually to comments, the comments are simply to inform us. So we aren't going to be responding back to your comments.

Okay, next slide is Slide 18. These are just next steps, so this is just a basic outline.

So the comment period ends on January 29th. And then in February and March we're going to be evaluating your comments, reviewing that additional information that I talked about.

You know, conducting the patient access, doing the patient access maps, looking at international benchmarking and accepting medical and radiation safety events. We'll be looking forward to getting a draft report from the ACMUI subcommittee on T&E, so hopefully we'll get that in mid-February

or so.

I will encourage folks to check out the T&E website. And if you aren't signed up for the NRC's medical Listserv please do that as well. We will be having a public teleconference with the ACMUI to discuss their draft subcommittee report on T&E.

So that may really be of interest for many of you that has been on these webinars. So, keep an eye out for that. It will be on our website.

It will be on the NRC's public meeting website. It will be noted there. And also, a note will go out via our medical Listserv about when that's going to be happening and how you can participate in that.

And then, once we do our draft paper, the ACMUI and the agreement states will both get to review that draft paper and send us back their comments. There will be another ACMUI teleconference on their comments on our draft sometime in the summer.

So, again, you would just keep an eye out on the medical Listserv and the websites to see when that is going to happen.

And then we will finalize our paper and hopefully deliver it to the Commission sometime in the fall. The Fall of 2019. So that's our general

schedule.

So, for more information, next slide, Slide 19. I really encourage you to visit the T&E website there. Like I said, the regulations.gov page, that docket page, that shows everybody's comments that they've submitted to date.

So if you're interested in reading through some comments that people have sent in so far. I also have been posting the meeting summaries and transcripts there.

And then of course, if you have any questions, you can contact me at sarah.lopas@nrc.gov. As the PM I kind of can talk you through the more process type questions.

But I encourage you to reach out to Maryann Ayoade. She is the technical lead on the project, so regulation type questions or have some technical questions, she is who you should go to.

And that's it for our presentation. So, before we open up the phones, I just want to remind everybody that, again, we're being transcribed by the court reporter so we can accurate comments for our T&E docket, so please being by introducing yourself. Maybe spell your name if you think it's a tricky name. And speak clear.

You can press star-1 at any point, so just go ahead and press star-1 if you already want to jump in. And then you are also free to submit your questions and comments via the chat function or the question function on the webinar. I'll keep an eye on that. And I can certainly read those aloud for you.

So, star-1 on the phone. And I'll just go to Cedric, if you can just let us know if anybody pops on the line?

THE OPERATOR: Sure. And also, if you'd like to ask a question, please remember to un-mute your phone and record your name clearly when prompted.

MS. LOPAS: Star-1 for any questions or comments.

THE OPERATOR: I'm currently showing no questions in queue.

MS. LOPAS: All right, everybody, this is your last, this is your last time to shine in public, so, if you want to get on the line and tell us how you feel, this is it. Otherwise make sure you do submit your comments by regulations.gov. Your written comments that is, by January 29th.

So, just press star-1. Or if you're a little shy, you can type it into the webinar, and

I'll read it aloud.

THE OPERATOR: And our first question comes from Ben Greenspan. Your line is open.

DR. GREENSPAN: Thank you very much. My name is Dr. Ben Greenspan and I'm representing myself.

The bottom line of my comments is that I think the NRC should not make a separate category for authorized users for people who haven't gone through approved board certification process and should not reduce the requirements.

I think that physicians need to master not only the previously submitted curriculum submitted by the SNMMI, and I know there's also curriculum by the ACMUI, and the number of other features that I think I'll send in writing. I don't want to read all this here.

But I think it's important for authorized users to have the full range of competency no matter which agents they are using. And there's going to be a whole range of agents in the future with all sort of different types of features and characteristics and risk factors and so on.

And it's also important to understand the radiation safety aspects and logistics of how we receive these radiopharmaceuticals and how they

dispose of waste and all that.

I also wanted to say I do not know of any evidence that there is an insufficient number of authorized users. Nuclear medicine physicians are authorized users, many nuclear radiologists are authorized users and many radiation oncologists are authorized users.

And I don't think, as a patient access problem, I think the major issue here is that many medical oncologists are not referring patients for these procedures. And now they want to give them themselves without any training, and I think that's really unacceptable.

Another thing, another point I wanted to make is, that I think competency is a better way to provide documentation of expertise rather than the number of hours. And there are a number of ways to do that.

One is certification by the appropriate boards, with maintenance of certification. Another is accreditation of the programs that these people are involved with, the departments of nuclear medicine and radiation oncology or whatever.

And certification can be accomplished by board exams, such as from the ABNM or the ABR.

Accreditation can be accomplished, and that can be setup very easily.

And then you could also actually setup proficiency testing, which would really be a good way to assess the department and the qualifications and expertise of the physicians.

And with that I think I'll quit, and I'll send in some comments in writing. Thank you.

MS. LOPAS: All right, thank you, Dr. Greenspan, I appreciate you calling in.

DR. GREENSPAN: Thank you.

MS. LOPAS: Okay. Cedric, do you have anybody else on the line?

THE OPERATOR: Yes. The next question comes from Ralph Lieto. Your line is open.

MS. LOPAS: Ralph.

MR. LIETO: Yes, thank you. My name is Ralph Lieto, I'm representing myself. My question for NRC Staff, in light of this big shutdown and your proposed timeline that was in the slides, is this timeline taking into account the delays due to the shutdown or is the timeline is likely going to be shifted back a little bit?

Because it seems like, in light of this shutdown and then your attempts to get additional

information, it looks like it's overly optimistic.

MS. LOPAS: That's a good question, Ralph. This is Sarah Lopas.

So, this timeline doesn't account for the shutdown impacting us at all. At the moment, I don't see the partial shutdown affecting us. You know, the NRC is fully funded.

Like I said, the only thing that kind of is, that were being affected right now by the shutdown is the Office of Management and Budget needs to review our letter to the Agreement States for that voluntary information requests going out to them.

I don't anticipate that delay impacting our overall schedule to be honest. So, we will of course keep you posted.

The other thing that I think is minutia, that I don't think really applies to much, but the Office of the Federal Register is shutdown at the moment. It is affecting our, the only thing I can think of is it is affecting our ability, we have to register, we have to notice to the Federal Register when we're going to have an ACMUI public meeting, and I might check with, I have a lawyer here in the room.

We must notice in the Federal Register notice before we can have that meeting? I'm asking

somebody in our room.

MR. IRVIN: So, this is Ian Irvin with the Office of General Counsel. I got to admit, that's with another attorney --

MS. LOPAS: Okay. Yes.

MR. IRVIN: -- counsel, with what most be noticed in the Federal Register.

MS. LOPAS: Yes.

MR. IRVIN: But we have received some new guidance --

MS. LOPAS: Okay.

MR. IRVIN: -- about what we can publish in the Federal Register.

MS. LOPAS: Okay.

MR. IRVIN: And we're still reviewing it. We just received that.

MS. LOPAS: Yes. So, Ralph, I'll be honest, I have to, if for some reason we were -- we have to notice that ACMUI, A-C-M-U-I, public meeting, public teleconference, ideally 15 days ahead of the meeting.

You can, under extenuating circumstances, do it like ten days or so ahead and note it's because of shutdown or whatever.

MR. LIETO: Okay.

MS. LOPAS: If for some reason that backs up that meeting, that public teleconference, that might back us up a little bit. So, I can just say stay tuned. If there's a delay it would be a very minor delay. So, does that help?

MR. LIETO: Yes. I'm just really concerned in the data that's going to be obtained from just NRC states alone. Not that that data is problematic, but I think it's not going to provide a typical cross section of the AUs that are out there because of the potential states that are non-agreement.

So, I think it would be tremendously valuable for the NRC to obtain as much Agreement State information that they're willing to provide.

MS. LOPAS: Yes, I would agree with that. Yes. Okay, do you have any other additional questions or comments, Ralph?

MR. LIETO: Not at this time. I'm going to be providing written comments also. But I echo many of the comments that Dr. Greenspan provided in that I think the current T&E is an acceptable methodology for assuring that the AUs are, have appropriate training and experience.

I will make one anecdotal comment, and I

think that you have mentioned in your introductory about the investigation, deeper investigation of medical events in the NMED database. And I have a lot of, shall I say, take it with a large grain of salt that that's going to be of any value.

I think if you look at the ACMUI comments from their own reviews annually of the NMED events involving medical events. That the data there is inconsistent across the states. Including the NRC investigations.

And I was involved with these for about eight years with the ACMUI. And this was a big complaint that the information and investigation of these events are sometimes very superficial. And it's not standardized across the Agreement States themselves, even relative to the NRC.

And I have never seen a medical event reported, in the years that I have reviewed it, where training experience was identified as a major cause of a major contributing cause.

So, I am a little concerned that the NRC is going to, "delve deeper" to find out if there are medical events that have training and experience, when that isn't even not reported in the events to date. I would think that that would be a major thing

if an investigator found that in one of the states.

And even sort of anecdotally again, some of the most highly publicized medical events over the last 20 years that the NRC has been involved with, training and experience was never identified as a major cause.

So, with that I'll let other people comment. Thank you for your time.

MS. LOPAS: Yes, thank you. Okay, star-1 to make a comment or ask a question or you can also type a short comment or short question in your webinar using your webinar software.

Cedric, do we have anybody else on the line that would like to have their line open?

THE OPERATOR: Yes. The next question come from Jeffrey Siegel. Your line is open.

MR. SIEGEL: Good morning. Thank you for having this -- sorry?

MS. LOPAS: Good morning. Sorry.

MR. SIEGEL: Good morning. Thank you for having this webinar and inviting comments.

Just a brief history before I begin with my comments. I've submitted written comments on the website, and I'm waiting for them to appear. It's been two weeks. But I understand it takes a while.

Historically there was great reason for there to be lots of T&E for physicians because most agents were not supplied as a unit dosage, they had to be manipulated. And hundreds of millicuries and a wide variety of agents were given. And this was a new field.

And, the T&E requirements, from historical aspects, are not necessarily germane to today's supplied agents.

Also, as I understand it, T&E regulations, for medical use, are only for, if justified by radiation risk to patients. They have nothing to do with the practice of medicine.

So what I'd like to say is that, first of all, the FRN is talking about radiopharmaceuticals categories, I think that's wrong. I think it should be for specific radiopharmaceuticals. Because, within a given category, not all agents pose the same risk.

So, now for my comments. Currently physicians are not free to attend limited used authorization for any given radiopharmaceuticals, regardless of its safety profile, as they must contain full AU status pursuant to 35.390.

This of course is not true for limited

use authorization which is available for sodium iodide. Since a physician would undoubtedly choose the ultimately pathway pursuant to 392 or 394, since much fewer T&E AUs are required.

The pathways for obtaining AU status pursuant to 390 are therefore not reasonable since physician desiring limited AU status for another radiopharmaceutical, even if it possesses radiation safety risk than oral sodium iodide, are required to have the same T&E as physicians seeking full AU status.

Tailoring, therefore, should be based on use of this specific agent, not an entire category. As I said, since not all radiopharmaceuticals, in any given category, pose the same radiation risk.

And when we're talking about categories, how many are there? 390 has four dosage categories. The first two are all sodium iodide. Not categories at all, just specific agents.

The last two are for parenteral administration of any beta emitter or photon emitting radionuclide with a photon energy less than 150 keV or parenteral administration or other radiopharmaceutical.

Therefore, this authorization for a given

category only pertains to those two categories. And that's all that's currently codified.

So there are three choices. Specific radiopharmaceuticals in these last two categories should either be placed into their own requirements, such as a new codified 10 CFR 35.395, if their radiation safety profiles justify it or reduce T&E that is appropriate and sufficient to protect workers, the general public, patients, et cetera or, two, they should be regulated under 35.1000 or, lastly, they should remain lumped together as is.

Unless the first two choices are implemented, the ability to attain limited AU status is justified, would be entirely ruled out. NRC already believes limited AU status is justified, at least for oral sodium iodide.

NRC therefore needs to objectively, not suggestively, assess the associated risks for a given radiopharmaceuticals. Such an assessment should include, how is it supplied, its ease of administration, the intended administered activity, half-life and purity, radio contaminate levels, root of elimination from the body, waste disposal, potential dose to others, potential for internal contamination and patient release issues.

Unless this assessment is not done, it cannot be entirely regulated appropriately and the hours necessary for ensuring safety cannot be done.

Reducing T&E requirements for specific agents will undoubtedly increase the complexity of regulatory oversight. But when justified, should be of minor concern as it would be a more risk informed approach and is great benefits to patients and their treating physicians.

Restricting patients access to and ability to use an FDA approved and commercially available agent by imposing unwarranted and unduly burden to community regulations that may not be reflective of the radiation risks involved, is detrimental to them and their patients.

Conflicts with NRC guidelines of minimizing intrusion into medical judgement, as the medical use policy statements say, only when justified by radiation risks will such requirements be imposed, and such an approach is most assuredly not risk informed.

I thank you for listening to my comments. Thank you.

MS. LOPAS: All right, thank you, Mr. Siegel. All right, Cedric, do we have another

commenter on the line? Star-1 to get your line un-muted.

THE OPERATOR: Sure. Next question and comment comes from Michele Panichi. Thank you, your line is open.

MS. PANICHI: Good morning. How are you guys doing?

MS. LOPAS: Good morning. Great.

MS. PANICHI: So, I'm going to have to respectfully disagree with Dr. Siegel. I know Jeff very well. He's very respected and I respect his opinion.

However, I believe that we should not change our training T&E requirements. These are relatively dangerous radiopharmaceuticals that we're talking about. They have long half-life's, they're alpha and beta emitters.

And there's a reason why a written directive is required. We don't consider this, you know, a diagnostic 140 keV, six hour half-life kind of isotope.

Industry is pushing primarily to sell their products. That being said, they want industry people to proctor physicians for this. Big mistake.

As soon as you allow somebody other than

a current authorized user in that category to oversee, you're opening up a large can of worms.

In the previous webinar there was a pharmacist who said that pharmacists require an authorized nuclear needs 4,000 hours. Well, that's not quite an accurate statement.

If you read the training requirements for that, the 4,000 hours is to get a board certification exam acknowledged by the NRC.

And the idea is that a nuclear pharmacist can oversee radiation safety for an authorized user is also not feasible. If you want to talk about a shortage of physicians, there's a huge shortage of nuclear pharmacists.

I dare say, there is a whole lot less fewer nuclear pharmacists than there are authorized users.

I don't believe there is a shortage of authorized users out there. I believe that every radiologist, and that radiation oncologist, now they have the opportunity to become authorized users.

I believe the people, the physicians who are pushing this, the MDECs and sometimes the urologists, they're more self-serving than we would like to see in a physician group. They need, want

to keep their patients in their practice. It has nothing to do with the availability of an authorized user.

And that's about it. I will be also submitting my comments in writing. And that's about it. Thank you.

MS. LOPAS: All right, thank you. Okay, star-1 to have Cedric un-mute your line for you. star-1. Cedric, do we have somebody up next?

THE OPERATOR: Yes. We have a follow-up with Jeffrey Siegel. Your line is open.

MR. SIEGEL: Hi, since my name was mentioned I must respectfully disagree with Michelle, of course. Because, objectivity is what's required.

We can't just say, all agents are equally hazardous because they are not. And if we're going to follow that all radiation is risky, ALARA and LNT, which I believe is not true at all, then that would be true.

But I think we owe it to the patients and the physicians and the community and everybody, to have an objective assessment of each agent. And the level of risk it involves. Thanks.

MS. LOPAS: Okay, thank you, Dr. Siegel. Okay, star-1 to get in on the conversation. Cedric,

do we have anybody else in line?

THE OPERATOR: None currently.

MS. LOPAS: Okay. All right, everybody star-1. We will hang on for a few minutes, but I want to, let's see.

I'm going to go, I pulled up on the webinar some of the questions, the more detailed questions under A. Tailored training and experience requirements.

You know, Dr. Siegel had mentioned that he didn't think it was appropriate to categorize state radiopharmaceuticals that may be, such as by their type of radiation admission or characteristics because not all, may be drugs within those admission categories, are the same.

So, some other options that were suggested in the FRN was to characterize radiopharmaceuticals by similar delivery methods. Whether it's oral, parenteral.

Of course, the radiation characteristics or emission, alpha, beta, gamma, low-energy photon. Or similar preparation methods, such as patient ready doses or a combination of that.

So that's something that we're looking to get comments on. And, Cedric, you can just interrupt

me.

THE OPERATOR: Sure. We do have David Burpee that's on.

MS. LOPAS: Okay.

THE OPERATOR: Your line is open.

MR. Burpee: Good morning, everyone, thank you for this opportunity and for all the good comments.

As far as enough authorized users, I think the key word is really treating authorized users that have the ability to.

I witness, as I manage ten states for license and compliance for Xofigo, numerous scenarios where patients cannot be treated at even very large institutions, typically due to infighting between authorized users who could be treating.

There's a very large place in north Chicago with 400 beds for four years, fought between authorized users as to who could have the privileges at that institution, and therefore they didn't treat at all. That story is fairly ubiquitous. And it goes in many directions.

For example, another large group needed to have preceptorships and they solicited another group to do that and at the end of the day the other

group decided they were competition and wouldn't sign the attestation forms, and so no one was able to treat at those institutions.

The rural situation is acute in that there are not enough out there to help cover all these places. And therefore in general, all these scenarios require the men to travel. Men were sick and don't want to travel typically.

So, we do need to look at how we can have more options for being an authorized user.

I think something dawned on me recently that I think is germane to this in that, if you look at alpha emitters, there has never been any formal trading for authorized users with alpha emitters. They are very unique.

And Dr. Siegel's comments are right on the money, that there are certainly incredibly differently qualities to those products compared to all beta emitters and every other types of therapy that has been out there.

So, thanks for those considerations and for this time.

MS. LOPAS: Sure.

THE OPERATOR: Thank you. We have an additional comment with Ben Greenspan. Your line is

open.

DR. GREENSPAN: Thank you. This is Ben Greenspan. I am a nuclear medicine physician and radiologist and I wanted to make some comments regarding some of the comments we just had.

First of all, I think, while there may be different lists of various, of these therapeutic radiopharmaceuticals, they're still potentially dangerous. And I also think that many of them will be given in combination. So we may give alpha emitters and beta emitters with patients to various cancers.

And therefore, the alpha's user who is treating these patients really needs to know the full range of the basic science and clinical expertise to handle all this.

In terms of various physicians, I have great respect for the clinical abilities of medical oncologist, and urologists, but I don't think they should be treating these patients by themselves.

I don't think they have the requisite background in radiation sciences and, if they actually wanted to get it all and spend whatever time it took to come up to the same level as a nuclear medicine physicians and radiation oncologist, then

that's fine. But I doubt any of them would.

As far as authorized users and patient access, I'm not aware of too many places having these kinds of logistical issues with infighting. I guess some of them do but I don't think that's a huge issue.

In terms of rural areas, I don't think, I think patients realize they have to travel if they're in a rural area. For just about everything beyond simple things.

So, if they want coronary bypass surgery, they're not going to get it by the surgeon who does one a year, they're going to go to a major medical center and get one by an expert. And the same should be true for treating with radiopharmaceuticals.

They have potential risks if they're misused or there are problems. And these should be provided by experts who know what they're doing, and I think patients realize that. Thank you very much.

MS. LOPAS: Okay, thank you, Dr. Greenspan. Press star-1, again, if you want to get in on the conversation.

I do have one question from the webinar that I'm going to read aloud. So there was a question about whether or not the NRC has been conducting any outreach to the referring visits physician

communities, such as medical oncology, et cetera, for input on this.

And we did send out, back when the FRN first went out, we did send out the FRN and ask them to provide questions to about 100 different stakeholder groups. And so, a lot of the stakeholder groups included, let's see, kind of professional societies for urologists, for cardiologists, for medical oncology.

So, we did do some attempt at outreach in that matter. I don't know if any of those are support to be on our medical Listserv, but we did reach out to the professional societies. And hopefully that those groups put the word out to their membership that this is something that we are looking at.

We also, and I can't remember off hand right now, but we did publish short little advertisement type articles, less than one page or so, kind of in a number of journals. Not medical journals per say but kind of like newsletter monthly, sort of either online or printed newsletters, for a number of organizations just alerting them to these public meetings and our effort and our FRN questions.

We did do a fair amount of outreach to what we think would be those communities, those

referring physician communities. So, thank you for that question, that's a good one.

Because we, exactly, we'd like to hear from those folks as well. This is what they want to be getting into.

Okay, Cedric, do we have anybody else on the line?

THE OPERATOR: None currently in the queue.

MS. LOPAS: Okay. All right, star-1 or, again, submit a question or comment via the webinar, we're happy to go that route.

Maryann and I attended recently, just this past weekend, on Thursday through Saturday, Maryann and I attended the Society for Nuclear Medicine and Molecular Imaging, their mid-winter meeting, which was in Palm Springs, which was very nice. But we got a lot of good feedback from the folks attending that meeting.

And I know some of you are on the line that we saw there, so thank you for calling in and we're definitely looking forward to your written comments as well.

star-1. And, Cedric, just let me know is anybody pops on the line.

THE OPERATOR: Okay.

MS. LOPAS: So, Question 5 here on the tailored training and experience requirements.

Question 5 gets into, if we were to create tailored T&E categories, what should those specific requirements include for the classroom and lab training?

How many hours, what should be covered under that classroom and lab training, what topics?

The work experience, we asked exactly, we heard some comments about whether or not the pharmaceutical manufacturers should be able to provide the preceptor attestation. That's one of our questions we'd like feedback on.

And the competency, we have been hearing some feedback on competency that we, the NRC, should look into whether or not we could move our regs to evaluate competency rather than just straight hours of T&E. So, those are some of our questions in our Federal Register notice.

Also, some questions on who should establish and administer these curriculums on an examination. And also, how often should AU competency be periodically assessed?

We have been getting some questions on

recent myths of training and so that's important to think about too. Should it be a number of cases every year or so that the physician AUs are required to maintain their competency or are required to maintain that AU certification?

So these are all good things to think about.

THE OPERATOR: Excuse me, Sarah, we do have a question. Miguel de la Guardia, your line is open.

MR. DE LA GUARDIA: Hi, this is Miguel de la Guardia and I am the RSO at Cook Children's Medical Center in Fort Worth. And we are one of the major trading centers for neuroblastoma using iodine-131 MIBG.

First, I want to echo Jeffrey Siegel's comments. I think they're spot on.

But next I also want to concur with the comments of the lack of authorized users. There are plenty of authorized users for diagnostics but for therapy is very difficult.

Right now we only have two authorized users here that can actually administer diamygadia (phonetic). And sometimes it's very difficult to schedule these treatments based on their

availability.

And as far as rural areas, we are very keenly aware of that because we get patients from all over the place. If you go west of Fort Worth, where we are, there is nothing as far as being able to treat these patients until you get to Arizona or California. So, there is a critical shortage out there of physicians that can do therapies.

Now, I do know that nuclear medicine, we would like hold on to as much as we can, but prior experience shows that when other groups get involved, such as the endocrinologist or cardiology, which actually launched nuclear cardiology made, basically saved nuclear medicine in many respects, I think that having a pathway for other physicians to be able to do these treatments will be very helpful.

Especially now that most of the therapies can be obtained from a nuclear pharmacy as a unit dose and you don't have to manipulate the product onsite.

So I want to thank you for the opportunity to commenting and for sponsoring this webinar. Thank you.

MS. LOPAS: Yes, thank you.

THE OPERATOR: Still no further questions

or comments.

MS. LOPAS: Okay, thank you. Okay, and I will maybe, just to kind of spur some conversation, the last public meeting we had was on January 10th. And during that meeting we got some unique ideas submitted by a comment.

One was to allow to open up the AU status to non-physicians. So, including maybe authorized nuclear pharmacists. Also maybe including some advance trained technologist.

We specifically got comments from nuclear medicine advance associates who undergo, you know, who have been technologist for many, many years and then they go on to continue their training with two years of a master's program and then they do a nuclear medicine kind of internship or they kind of, they kind of call it analogous to a residency. They offered up, they thought that potentially they could be considered for AU status.

So, we, at the NRC, even though our questions in FRN are kind of very specific, we are open to hearing any ideas on how, if we do think, you know, if you do think that's there's a patient access issue on how we can improve that situation.

So, that would include providing us

comments on whether you think it would be a good idea to allow certain categories of folks practicing in this medicine field to become AUs. Right now, in the Part 35 regulations an authorized user is only defined, can only be a physician, a dentist or a podiatrist.

So obviously the majority of our AUs are physicians. And so, we did get some comments that maybe we should consider expanding that definition of authorized user.

So, star-1 to provide any additional oral comments.

THE OPERATOR: We do have an additional comment with Michelle Panichi. Your line is open.

MS. PANICHI: Oh my goodness.

(Laughter)

MS. PANICHI: This is a tough one. So, let us not forget these are prescription medications. So, they have to be prescribed by a physician.

As much as I would like to say, as a nuclear med tech, that I am equally qualified as a nuclear medicine physician, I am not.

I also have the honor of being the RSO at nuclear pharmacies, and I can confidentially tell you that the majority of nuclear pharmacists that I have

met should not be prescribing these medications. Remember, this is not just administering.

I have no problem with a nuclear med tech administering a radiotherapy, with an authorized user in place. A lot of times it is simply passing a pill, injecting a patient.

But that's not what requires the AU status, it's the prescribing of these medications. And they are prescription drugs.

So, an NMAA or a nuclear med tech, even a nuclear pharmacist, they're not in the practice of prescribing pharmaceuticals. Thanks.

MS. LOPAS: Yes, thank you.

THE OPERATOR: Another addition question or comment comes from Ralph Lieto. Your line is open.

MR. LIETO: Thank you. I also would like to echo Michelle's comments that I think that these suggestions of non-physicians becoming authorized users basically would turn the NRCs whole regulatory framework upside down.

If you allowed this for therapeutic radiopharmaceuticals, you are opening up a literal Pandora's Box where you could have other specialists, you could have an RSO making a case that they oversee

all this and probably supervises as much as the AU does, the operations of radiation safety in these aspects, making a case for them to be the "AU."

Which I think is absolutely abhorrent as a medical physicist and radiation safety officer. I think that, like I said, this is just a very, very bad thought process for suggesting this.

And if the NRC would be considering this, you basically would undermine the whole intent of having a physician involved with not only the therapeutic aspect of it, but also the diagnostic imaging aspect of it.

As Michelle pointed out, the AU is not just involved with overseeing the administration, but supervising all aspects of receipt, patient assessment, administration and follow-up. And they are the best persons for this.

And I think my objections as a technologist and a nuclear pharmacist would be, a pun intended, just a set of nuclear land mines for the NRC.

I do have another comment that, regarding your previous slide. I think it was on Item 5 where you, the NRC uses the word competency.

I think this has some different

connotations to different groups. The ACMUI, over the years, has addressed this several times in the definition, or excuse me, the description of the preceptor attestation.

And I think NRC should stay away from that term because competency is more than just an assessment of the understanding and having a requisite knowledge to perform the supervisory aspects of the radiopharmaceuticals that the applicant is applying for.

It's maybe just a, maybe a pet peeve of whatever, but I think competency, as used in this slide, is not what you're really trying to evaluate. I think what you want to know is, did the training and experience that the individuals get can reassess that that training and experience contains the requisites body of knowledge that they need to function independently in supervising these types of radiopharmaceuticals. Thank you for the comment.

MS. LOPAS: Okay, thank you.

THE OPERATOR: We have a follow-up with Miguel. Your line is open.

MR. DE LA GUARDIA: Thank you for taking my follow-up. I'm not sure if I was clear on my comments.

I am a nuclear medicine technologist, but I am not in favor of nuclear medicine technologists prescribing. That is not part of our scope of practice.

Also, similarly, I think in almost every state here in the United States, pharmacist are not allowed to prescribe most medications. So, that would require a change completely in pharmacy practice.

I know in some other countries, pharmacist can prescribe, but commonly that's not true here in the United States. So, when I was talking about authorized user, I'm talking about physician authorized users. Thank you.

MS. LOPAS: Yes, thank you, Miguel. And I didn't mean to imply that you were suggesting that, I was just stating that in our previous meeting on January 10th, we had received some comments along those lines about potentially, the NRC should potentially consider opening up AU status to some non-physicians. So, understood. Understood.

THE OPERATOR: Thank you. And the next question, comment comes from Scott Degenhardt. Your line is open.

MR. DEGENHARDT: Yes, thank you. Yes,

my name is Scott Degenhardt. I am actually a nuclear medicine advance associate speaking on behalf of myself here.

I just want to clarify what a nuclear medicine advance associate is. While one time, at one time we were technologists, we're actually mid-level providers in the field of nuclear medicine.

Again, yes, we were technologists at one point, but we have gone through a two to three year additional schooling at the master's level where we have didactic course work, but we also undergo a 24 month internship under the supervision of a physician, most under a radiologist or a nuclear physician.

Where we, at the end of the program, are actually, we meet all training requirements for what is currently asked of, of an authorized user. So, we wouldn't, you know, if the NRC would consider the nuclear medicine advance associate for authorized user status, we wouldn't be compromising training and education, the current training and education requirements.

But I guess I just wanted to clarify that we are not technologist, we're actually mid-level providers in the field of nuclear medicine. Almost

every other field in the healthcare industry has mid-level providers that do prescribe drugs, under the supervision of a physician. And that's the model that we were proposing there.

The nuclear medicine advance associate would be working under the supervision of an authorized user, again, just as that physician extender alongside them.

I guess, any other questions I'm happy to answer but I just wanted to clarify that. Thank you.

MS. LOPAS: Yes, thank you, Scott. Thank you for that clarification.

THE OPERATOR: Our next question or comment comes from Ben Greenspan. Your line is open.

DR. GREENSPAN: Thank you. This is Ben Greenspan again, I'm a nuclear medicine physician and radiologist and I wanted to make some comments.

First of all, I agree with Ralph Lieto's comments. Regarding Scott's comments just now, I agree pretty much.

I mean, these NMAAs, the Nuclear Medicine Advanced Associates, are technologists who have had an extra two plus years of training and are certainly expert in radiation safety. And in other aspects of dealing with radiopharmaceuticals.

But they're not physicians. And if they were given AU status, they still have to, I would think they'd still have to work under an authorized user, under a physician. And I don't see how that adds anything.

I think they could certainly help with the process of treating a patient, and they could certainly give the radiopharmaceuticals, most of which would be given parenteral, but they still have to work under an authorized user, i.e. under a physician. And I think that would be most appropriate.

On the other hand, I really do think that's a very good program and I'd like to see it expand and have more technologists, nuclear medicine technologists, go into those programs. I think it helps the field.

Mid-level providers, as these people are seen throughout medicine now and they are physician extenders, and I think they would help nuclear medicine practice. Including in radionuclide therapy. Thank you.

MS. LOPAS: All right, thank you.

THE OPERATOR: Thank you. And our next question, comment comes from Rachel Semon. Your line

is open.

MS. SEMON: Thank you. Can you hear me okay?

MS. LOPAS: Yes, we can.

MS. SEMON: Okay, great. I appreciate the opportunity to comment. I'm really not going to comment one way or the other as to which direction this should go, in terms of T&E, but I did want to, for the record, provide some feedback regarding pharmacy and the practice of pharmacy and that there certainly is precedent outside of the nuclear medicine, or the nuclear medicine world, where pharmacist do have provider status.

It is quite often you will see this actually in medical oncology. There is board certifications based on specialty. So, I am a board certified nuclear pharmacist.

I could say today I would not be comfortable being in a AU, a full AU, overseeing patient management. It's certainly something to consider moving forward. Perhaps in conjunction within the nuclear medicine department.

And we talk about potential shortage of AUs. And what I know that I have seen historically, is that the current RVU model tends to provide some

barrier to a nuclear medicine physician being torn between the requirements of reading images, the diagnostic portion versus having to spend 30 minutes to an hour with a patient for therapy.

And so, perhaps there is something here that could help facilitate patient access and ease the requirements of time spent, et cetera, in the future.

But just for the record, I wanted to say that provider status is not, there is a precedent for provider status outside of nuclear medicine, particularly in medical oncology. And there are pharmacists who have limited prescribing rights as well.

Typically, it is under the supervision of a physician. So I think there is some room here. Maybe not immediately, but not to be close minded with that. That's it, thank you so much.

MS. LOPAS: Great, thank you. And, Cedric, do we have anybody else? star-1 if you want to get in on the conversation, get your comments transcribed to go on the record.

THE OPERATOR: None currently in the queue, but, again, press star-1.

MS. LOPAS: So, this is Sarah again. And

so, I will say that, related to that comment that we just heard, we have had some comments submitted that the NRC should be open to the idea of, maybe not necessarily making an authorized nuclear pharmacist an AU, but maybe some sort of requirement or new regulatory requirement for an alternate, an alternate pathway of having a limited authorized user physician teamed with a authorized nuclear pharmacist.

That authorized nuclear pharmacist undergo extensive training and, per our requirements, also require 700 hours of T&E, become an authorized nuclear pharmacist.

So, if you teamed an authorized nuclear pharmacist with perhaps a limited trained authorized user physician, that you would still be meeting the spirit of those 700 hours of training and experience. Because you'd have those two individuals working together.

So that was one comment that we received on the January 10th meeting. That's a little bit different from just suggesting that authorized nuclear pharmacists should be considered for AU status.

Okay, we're going to -- anybody else on the line, Cedric?

THE OPERATOR: Yes. Ralph Lieto, your line is open.

MS. LOPAS: Okay, Ralph.

MR. LIETO: Yes, Sarah. I'm glad you brought that subject up. I had heard about this but I was wondering if this was something the NRC was seriously going to consider or not.

Again, I think this is something that would basically set the licensee up for a lot of potential problems. Because, it's my understanding of this proposal that you would have a centralized nuclear pharmacist teamed with a limited AU that would be onsite, something to that nature.

And to me this is matched with two chiefs with no Indians.

I think that these types of situations you need, with therapeutic radiopharmaceuticals, a person that's signing the written directive needs to be in AU. And that AU has to be responsible for the proper management of that radiopharmaceutical, to that patient.

This dual AU, that would be fine as long as everything goes great, but what happens if something goes wrong, okay, and there's a medical event or there's a problem with the patient or the

assay at the site.

You can't have this dual AU geographically separated and expect that it's not just going to create further problems. And especially from the aspect of supervision, which is something that the NRC takes quite seriously. And not just in the diagnostic side but even more so on the therapeutic side.

And I think this dual AU is, again, just fraught with all kinds of potential problems that's going to place the licensee, who's going to be the management, in a lot more potential problems of trying to resolve this.

Because the nuclear pharmacist is going to be offsite at, and operating under a different license than the administration. Just so many things that add up to, that this is just a very, very poor idea.

MS. LOPAS: Okay. Yes, and I think to clarify, now, I haven't received the written comments on this, on this particular idea yet. They have not been submitted yet.

But just from hearing from public meetings, I think the idea that they're proposing is that the authorized nuclear pharmacist would travel

to the limited AU position site for a day of treatments, right. So they would be paired together physically, during an administration.

So, that's just a clarification from what I recall from the January 10th meeting. But yes, if you have any follow-up on that, Ralph, go right ahead.

MR. LIETO: I would just say that, if you have an AU that's onsite to administer it, then you wouldn't need the nuclear pharmacist to be present.

MS. LOPAS: Right.

MR. LIETO: I think it just, again, I think it kind of goes back that, what are you trying to sell here. And it is not anything that is going to improve the radiation safety management supervision at the site where the, where all the work is going to be done.

MS. LOPAS: Okay, thank you, Ralph. Does anybody else have a comment? star-1 or feel free to type one via the webinar software, I can read it aloud.

Okay, I'm just going to give it another minute or so. I do appreciate everybody calling in today and taking the time.

And I know that many of you have called in for a number of these meetings. So, I really

appreciate you guys taking the time to do and it means a lot to the NRC. And we do really, we're going to really examine everybody's input.

Whether you've spoken on one of these meetings or, and/or when you send it in, send in the written, your written comments.

And I just want to remind folks, you have until January 29th, end of that day, to get your comments in. That's a week from today. It's a Tuesday.

Try to use regulations.gov if you can. And if you're encountering any difficulties or at all concerned, I'm happy to take your comments via email. And, again, my email is in the slides here. It's sarah.lopas@nrc.gov. So either myself or Maryann will take your comments via email, that's fine too.

And, I don't know, Cedric, can I check in on the phone one last time?

THE OPERATOR: No questions or comments.

MS. LOPAS: Okay. I think that's it. And Dr. Siegel, I will say, I think you had noted that you're waiting for your comments to get up on regs.gov.

They are in ADAMS and I did see them come through in my email, I think on Friday. So they

should be on regulations.gov shortly.

But there is a number of kind of rulemakings and other efforts going on at the agency and we only have a few administrative staff that kind of handle the processing of all the comments that we receive from the public on all of our projects. So, I apologize for the delay, I know that's difficult. But I'm going to reach out to our folks and see if they can expedite some of the processing on regs.gov.

So, Maryann, do you have any follow-ups?

MS. AYOADE: Yes, Sarah, I was waiting for everybody to provide their comments. Just to add to and clarify Ralph Lieto's comment on competency. Thank you for bringing that up.

I just wanted to, as you have recognized the sensitivity with the word competency and the misunderstanding that it could come about from that. And so, with the new rule, I just wanted to point out that with attestation statement, it replaced the text that used to formally say, attestation demonstrate that the individual has achieved a level of competency to function independently.

That has been replaced with, the individual has demonstrated the ability to function independently to procure the radiation safety related

duties. So thank you for bringing that up.

Now, when this evaluation started, it was still with the former regulations. The new rule become effective last Monday, January 14th, at the NRC licensees.

And so, just a, I just wanted to bring it to your awareness that you recognized that. And thank you for bringing that up.

MS. LOPAS: Okay, thanks, Maryann. And on the NRC's medical toolkit licensee, or medical licensee toolkit website, Maryann, I think there is a page that's dedicated to the Part 35 rule changes that just went into effect, is that right?

MS. AYOADE: That's correct. And if you even just go to, if you Google the 10 CFR 35 regulations, they are now updated with the new rule. So, if you can't find it in our medical use toolkit, if you just Google 10 CFR 35 to get into the new rule, it's updated with the new rule.

MS. LOPAS: Right. And I think the slides from some public meetings that we had on the Part 35, the new rule changes, those are also on the medical licensee toolkit website I believe.

So those are available for people to pull up the PDF of slides if they just want to see an

overview. Although it's about a 96 slide overview, but it's an overview.

Okay. Cedric, do we have any other final comments on the line?

THE OPERATOR: No questions in queue.

MS. LOPAS: Okay. All right, Maryann, is there anything else?

MS. AYOADE: No, that's it.

MS. LOPAS: Okay. All right, everybody, January 29th, deadline to get your comments in. But Maryann and I are here for your questions and comments before, and after that date obviously. Please keep checking out our website that I have the slide up on right now for any updates.

And if you are signed up to receive our medical Listserv emails that's great. If not, do that. I suggest doing that because that's a good way to stay informed of all the NRC's medical regulations and news and all that good stuff.

All right, thank you so much for your time today and that will be the end of our meeting.

THE OPERATOR: Thank you, and that concludes today's conference. You may all disconnect at this time. Speakers, you may standby for post-conference.

(Whereupon, the above-entitled matter went off the record at 11:35 a.m.)