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# NUCLEAR REGULATORY COMMISSION

Title: Public Meeting to Accept Comments on the NRC's Evaluation of Training and Experience Requirements for Administering 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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WEDNESDAY,

NOVEMBER 14, 2018

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The meeting was conducted via teleconference, at 1:00 p.m., Sarah Lopas, Office of Nuclear Material Safety and Safeguards, presiding.

NRC STAFF PRESENT:

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

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

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

ALSO PRESENT:

DAVID CROWLEY, Radioactive Material Branch Manager, North Carolina Department of Health and Human Services

MUNIR GHESANI, MD, FACNM, FACR, Society of Nuclear Medicine and Molecular Imaging

RALPH LIETO, St. Joseph Mercy Health System

AMIN MIRHADI, MD, Cedars-Sinai Medical Center

ARIA RAZMARIA, MD, UCLA Medical Center

JEFFRY SIEGEL

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P R O C E E D I N G S

1:02 p.m.

MS. LOPAS: (presiding) Hi, everybody. Good afternoon.

Welcome to the NRC's webinar to accept comments on the Staff Evaluation of Training and Experience Requirements for Different Categories of Radiopharmaceuticals.

My name is Sarah Lopas, and I am a member of the NRC's Medical Radiation Safety Team, which is part of the Medical Safety and Events Assessment Branch and the NRC's Office of Nuclear Material Safety and Safeguards.

I'm the Project Manager for the NRC's training and experience evaluation, and I'll be facilitating today's webinar and, also, giving part of the NRC's presentation.

I'm joined here at NRC's Headquarters by my manager, Chris Einberg, who is the Chief of the Medical Safety and Events Assessment Branch. Also joining us remotely via phone is another member of the Medical Radiation Safety Team and the technical lead on the training and experience evaluation, Maryann Ayoade. Maryann will be helping me with today's presentation.

We have a short agenda for today's webinar. In just a moment, my Branch Chief Chris will start us out with a welcome and the purpose of today's meeting. And then, myself and Maryann will go through about 15 slides that will cover background information on the NRC's evaluation, and we will discuss The Federal Register notice that was published on October 29th and the questions that were contained in that Federal Register notice. And we will cover how you can also provide written comments by the January 29th comment deadline, if you would like to submit written comments.

Then, we're going to go to the phone lines. We'll open them up one by one, and we'll take your comments on the record.

And now, I'm going to ask Chris Einberg, Chief of the Medical Safety and Events Assessment Branch in the NRC's Office of Nuclear Material Safety and Safeguards, to give a short welcome.

MR. EINBERG: Okay. Thank you, Sarah.

Good afternoon, everyone. Thank you for taking the time to attend today's webinar, which will be the first of four comment acceptance meetings that the NRC will be conducting on our training and experience requirements evaluation.

The purpose of today's meeting is twofold:

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 materials in Subpart E under Part 35, which covers unsealed byproduct material, written directive required.

And most importantly, to listen to and record your comments on the evaluation. The comments that we receive from the medical community today, the Agreement States, and the 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 the future comment meetings in December and January or submit written comments using regulations.gov by the January 29th, 2019 comment due date. Later in the presentation, we will cover how you can submit your written comments.

And now, I'll hand the conversation back to Sarah, who is going to provide some basic information about today's webinar.

Sarah?

MS. LOPAS: Thanks, Chris.

So, if there's anybody on the bridge line that doesn't have the webinar up and running, or doesn't have the slides in front of them, I just want to let you know that you can go to the NRC's public meeting website and you can find that by just Googling or going to some other internet search. "NRC public meeting," search that term and kind of the first thing that pops up is our website, our public meeting notice website.

There, if you click on that link you pull down, you'll find the meeting notice for this meeting. If you click on "more" under that meeting notice and look a little bit further, there is a link to the slides. It will be a PDF file of what we're using today. So, that's just a quick notice for everybody on the phone, on the bridge line.

So, today we're going to be discussing the NRC's evaluation of training and experience requirements for certain categories of radiopharmaceuticals. We're going to often refer to training and experience as "T&E" for short. And we will often refer to authorized users -- that is, those physicians who are authorized to administer radiopharmaceuticals -- as "AUs".

Today's webinar is being transcribed by a court reporter. And as Cedric, our operator, had mentioned, this phone line is also being recorded. So, we're having a double-fail option here.

So, the full transcript of this webinar is going to be publicly available in a few weeks, and it will be on our NRC's Agencywide Documents Access and Management System, or ADAMS, as we call it. And I'll also be posting a link of that transcript to the NRC's Training and Experience website, as well as posting it to the docket website for T&E on regulations.gov.

All of the comments that you make today will be captured on the docket. So, I'll be combing through the transcript and pulling out your comments for inclusion in our evaluation effort. So, if you speak today, you do not need to then separately provide those written comments on regulations.gov. And because it will be captured in the transcript, we will have it on the record. And it's important to note that the full comments and written comments carry the same weight. There's no preferred way to submit your comments.

We'll be opening the phone lines for comments after the NRC presentation concludes.

Everyone is in listen-only mode at the moment. But, when it comes time to make a comment, you're just going to press *1 on your phone pad. That's *1. And that will let Cedric, who is the operator, know that you'll need your line unmuted.

And now, I'm going to hand the presentation over to my colleague, Health Physicist Maryann Ayoade, so she can review the NRC's current T&E regulations and talk about why the NRC is conducting this evaluation.

Maryann?

MS. AYOADE: Great. Thank you, Sarah.

Today, I will be presenting information on an overview of the regulations on training and experience requirements for radiopharmaceuticals requiring a written directive; some background information on the related stakeholder concerns received, and the NRC's efforts on the evaluation thus far.

The current regulations on training and experience for radiopharmaceuticals requiring a written directive are under 10 CFR Part 35, Subpart E. And these training and experience requirements provide two pathways that a physician may be authorized to administer radiopharmaceuticals that require a

written directive.

The first pathway is that 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, to satisfy the training and experience requirements, by an alternate pathway, which includes 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 regulation, and 500 hours of supervised work experience in the relevant areas, as listed in the regulation.

And a third path is that 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.

This training and experience evaluation is focused on the alternate pathway, 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.

In Subpart E there are four sections that pertain to training and experience requirements. The first is under 10 CFR 35.390, which is for training for the use of already pharmaceuticals in Subpart E, all of which require a written directive.

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

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

And the fourth is in 10 CFR 35.396, which is for training for parenteral administration of any radiopharmaceutical requiring a written directive.

All of this sections of training and experience include the pathway for experienced authorized users already listed on a license. All of these sections, except 10 CFR 35.396, include training and experience under the board certification and alternate pathways.

And so, I want to point out that 10 CFR 35.396 is for training that is exclusively under

the alternate pathways for radiation oncologists to become authorized users by completing additional hours of training and experience.

I also want to point out that the alternate training pathways under 10 CFR 35.392 and .394 are for the physician to successfully complete 80 hours of classroom and lab training that is relevant to the type of use for which they are seeking to be authorized. Whereas, the alternative pathway under 10 CFR 35.390 is for the physicians who successfully complete 700 hours of training and experience, which includes 200 hours of classroom and lab training.

Next slide.

This slide provides some background information on stakeholder concerns received related to training and experience requirements. So, 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 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 patient access to radiopharmaceuticals.

As a result, in 2015 and 2017, in separate efforts, the NRC staff and the NRC's Advisory Committee on the Medical Uses of Isotopes, also known as ACMUI, independently reviewed the training and experience requirements for the medical uses authorized under Subpart E.

Specifically, NRC staff 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 would call into question the basis of the existing requirements.

As a result, the NRC staff did not propose any changes to the regulations at the time. The NRC staff is continuing to work with the ACMUI in its 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; there is a hyperlink reference here - the Commission directed the NRC staff to evaluate whether it makes sense to establish tailored training

and experience requirements for different categories of radiopharmaceuticals; how those categories should be determined, such as by risk code, by use of radionuclides, or by delivery method; what the appropriate training and experience requirements would be for each category, and whether those requirements should be based on hours of training and experience or more focused 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. That evaluation, including the NRC staff analysis and the feedback received of the training and experience requirements in Subpart E of 10 CFR Part 35, is documented in SECY-18-0084.

And 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, such as the limited authorized user status.

The evaluation also concluded that there are viable options for creating a competency-based

approach to demonstrate acceptable training and experience for limited authorized user status. However, the staff needs to conduct more extensive outreach to stakeholders in the medical community, to the Agreement States, and other members of the public, before making a recommendation to the Commission.

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

Next slide.

MS. LOPAS: Thank you, Maryann.

The end product of our evaluation will be a paper that we will send out to our five-member Commission. That paper will either document our reasoning for recommending no changes to our current training and experience requirements or, if we do recommend that changes to our T&E regulations are warranted, we will document our reasoning in a rulemaking plan paper.

This is a simplified diagram of the information that we will consider in our development of a recommendation to the Commission on whether changes to our existing T&E requirements are warranted. This 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 will inform our recommendation to the Commission. Other important feedback will come from our coordination with our co-regulators, the Agreement States, and the NRC's Advisory Committee on the Medical Uses of Isotopes, ACMUI.

In addition to the input we receive from the public, medical stakeholders, the Agreement States, and the ACMUI, the NRC staff will also examine the issue of patient access. Our staff will attempt to determine the number of current authorized users and their geographic distribution across the United States.

Authorized user and associated geographic data is not readily available. So, the NRC staff will be spending the next few months determining of this dataset is achievable.

Staff will also review training and experience requirements in other countries, in an effort to benchmark the U.S. against the international medical regulation. And staff will also do a review of medical and radiation safety events to determine if any have a nexus to training and experience.

It's important to note that, if the staff

does end up recommending rulemaking, which we would, again, document in a rulemaking plan, 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.

If rulemaking is recommended, and subsequently approved by the Commission, that would start the NRC's extensive rulemaking process. And I'm really highlighting this process information because I think it's important that everybody understands where we are in this process.

And where we are right now is that we're in the information-gathering stage, and that information we gather and the comments we receive are going to help us determine whether a rulemaking to address training and experience requirements is even warranted.

I hope many of you have read it by now, but the NRC published a Federal Register notice on Monday, October 29th. The Federal Register notice can be accessed by that link at the top of your slide, or you can also just Google search the citation for the Federal Register notice, which is 83 FR 54380.

The Federal Register notice announced the public comment period, which ends on Tuesday, January

29th, 2019. It also announced the dates for these public webinars and meetings. And in a couple of slides I'll be talking about the additional meetings we're having after this one.

But, most importantly, The Federal Register notice asked a series of questions on which we would like medical community stakeholder input. I'm going to read straight through the questions in the next four slides, and I'm just going to go straight through them, just to provide an overall scope and context of the information that we're looking for. But, when we get to the comment period in just a couple of minutes, I am going to be kind of walking us through the topical areas to try to gather your comments kind of in an organized manner. So, hold tight. We are going to read through the comments in the next slide.

So, the first set of questions, Section A in the FRN, extensively cover the crux of what we're evaluating, whether the NRC should create tailored training and experience requirements for certain categories of radiopharmaceuticals.

So, the questions are:

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

Should the NRC develop a new tailored T&E pathway? What would be the appropriate way to categorize radiopharmaceuticals for tailored T&E 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 T&E be structured for a specific category of radiopharmaceuticals?

Section B, there are questions about the NRC's recognition of medical specialty boards. And those procedures for recognizing our medical specialty boards are on our Medical Uses Licensee Toolkit website, and the link is there on the slide.

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

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

The next topical area or set of questions covers patient access.

So, is there a shortage of the number of Aus for medical uses under 10 CFR 35.300? If so, is

that 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, the last set of questions we have, they are a set of questions asking for general input on the NRC's regulation of training and experience as a whole.

So, 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?

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

So, those are the questions that we're looking for your input on. I'll be going through those

questions when we get to the comment period in a second, but it would be great if you could have the FRNO bin and you can read through, because there's a lot of sub-questions underneath those general questions that I didn't want to laboriously read through.

So, how can you submit your comments on our evaluation and respond to all those questions? Well, in addition to speaking during today's meeting, and in any of the three future meetings that we have planned, you can submit your comments via regulations.gov. And the link on this slide will take you directly to the comment submissions form on the T&E docket, which the docket ID is NRC-2018-0230. But you can also just go to regulations.gov. Just type in regulations.gov and it comes right up. And you can enter that docket, NRC-2018-0230, into the search bar right at the top of that page, and it will bring you right to our docket page. Once you're in the comment submission form, you can either type directly into the form or you can upload a document like a Word or text file or even a PDF.

Here at the NRC I have immediate access to those comments that are submitted via regulations.gov, but I will warn everybody that there's an internal administrative process here at the NRC.

So, it takes a few weeks for those comments to become publicly viewable on regulations.gov. So, don't panic when you submit via regulations.gov and you go back to see if you can find it if you can't find it. We got it. It's just it has to go into our ADAMS system first, and then, it goes back up on the regulations.gov. So, just to clarify, your comments will be publicly available on regulations.gov and in ADAMS.

If you encounter any issues at all when you're submitting your comments via regulations.gov, please contact me. You can email me or call me. My contact information will be at the end of this presentation.

And at the end of the public comment period, we'll be compiling all the comments we received, both written and oral, and we'll be publishing them in one easily accessible comment report. Not only will that comment report list all the comments out individually, it will also summarize them. And the comment report will be available on the NRC T&E website, and I'll also ensure that it gets posted to regulations.gov. And I know that whatever recommendation paper that we develop, it will heavily reference that comment report.

I do want to point out that, because this is in a rulemaking, and the purpose of collecting our

comments is to help us inform our decision-making, we will not be responding to individual comments or even groups of binned comments. So, that's an important thing to note.

This slide just details the additional public meetings that we're going to be having on T&E in December and January, before the comment period closes out. The meetings that are going to be held on December 11th and January 10th, in addition to those meetings accessible by webinar again and teleconference, those will also be open to in-person attendance here at the NRC Headquarters in Rockville. The December 11th meeting will be held in the Commission hearing room in our 1 White Flint Building, and the Thursday, January 10th meeting will be held on the ground floor conference room in our 3 White Flint Building.

And all the details that you need to participate in those meetings, again, are on the NRC's public meetings schedule website. And if you have any questions, again, you can contact me.

This slide shows our next steps, a basic outline of our next steps, and the planned timeline of our evaluation. After the comment period ends on January 29th, the NRC will begin organizing and

evaluating the comments. The NRC staff will also be conducting that additional research that I noted earlier regarding patient access, international benchmarking, and assessing medical and radiation safety events.

The ACMUI Subcommittee on Training and Experience will provide the NRC a report on their findings and recommendations regarding the T&E requirements in the spring of 2019, and the staff will consider their input in developing their draft recommendation.

Both the Agreement States and the ACMUI will have an opportunity to provide comments on our draft Commission paper, and the NRC will consider and incorporate their comments into the final paper to the Commission, which we have to finalize in early fall 2019.

So, for more information and links to all the documents that we mentioned today, like the SECY paper from this past September or the Staff Requirements Memorandum that caused us to do this evaluation in the first place, please visit the NRC's Training and Experience Evaluation website. That's the link above. It is housed under the NRC's Medical Licensee Toolkit overall. But we will be actively maintaining this

website through the T&E effort. So, it's a good place to go.

Again, you can also go to the regulations.gov docket for T&E. So, I will also be putting public participation information on that. And what's good about regulations.gov is that it will list all the comments that we receive. So, you can look at other folks' comments.

And please reach out to me, Sarah Lopas, as the Project Manager, if you have any kind of process-type questions about the community effort. And Maryann is your point of contact for your more technical questions.

So, with that, I'm going to get us into the comment period phase of this. I do want to note that you'll press *1 on your phone to make a comment. And you can go ahead and press *1 now if you know you already have something to say. That's great. And Cedric is just going to be going down the line and unmuting lines as he receives those *1 requests.

And so, we have plenty of time for comments today. We're scheduled to go to 3:00 p.m. Eastern, but we can always go a little bit beyond that, if needed.

And I do want to remind you that our court reporter -- her name is Allegra -- she's on the phone,

too. She's transcribing everything we say today. So, when we do unmute your phone, please remember to start by introducing yourself. If you have an affiliation that you want to let us know about, you can certainly include your affiliation.

There aren't too many of us on the line. I know we've got about 24 people on the webinar, which is great, and there might be more people on the line. But I do think that we will try to go through the topical areas of the questions that we ask in the FRN, but I do understand that many of you might just have a statement that you want to just read right through. And that's okay. You don't need to try to break it up.

So, we'll just get started. With that, press *1 if you would like to make a comment.

I have brought up on the webinar Section A of the questions, and I have, of course, three questions under Section A, under tailored training and experience requirements. Those are the topics asking about:

Are the current pathways for obtaining AU status reasonable and accessible? Are they adequate for protecting public health and safety? And then, obviously, a big one, should the NRC develop new

tailored T&E pathways for a physician?

So, *1. Get something to drink; maybe get some coffee. And we can get started.

And, Cedric, just let me know whenever you have anybody on the line to get going.

THE OPERATOR: Sure. And our first question or comment comes from Amin Mirhadi.

Your line is open.

DR. MIRHADI: Thank you so much, Cedric.

Hi there. My name is Dr. Amin Mirhadi. I'm a radiation oncologist at Cedars-Sinai Medical Center in Los Angeles. I'm also the Vice Chair of the American Society of Radiation Oncology's NRC Subcommittee. And thank you for allowing me to provide this statement on behalf of ASTRO, which is the acronym for that.

ASTRO is the largest radiation oncology society in the world with more than 10,000 members who specialize in treating patients with radiation therapy. As a leading organization in radiation oncology, biology, and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science, and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

ASTRO is pleased that the NRC has invited stakeholders to provide input on training and experience requirements for radiopharmaceuticals through public meetings and written comments. We strongly oppose any reduction in the T&E requirements found in 10 CFR 35.390, training for use of unsealed byproduct material for which a written directive is required under the so-called "alternate pathway".

ASTRO believes that the requirements found in this section are appropriate. They protect the safety of patients, the public, and practitioners, and should not be diminished.

Radiopharmaceuticals are highly effective in treating cancer, with possible harmful effects to both the patient and the public if not used correctly under the supervision of the highly-trained physician.

We are pleased in this report entitled "Staff Evaluation of Training and Experiment Requirements for Administering Radiopharmaceuticals," that the NRC staff determined that the current requirement of 200 hours of classroom and laboratory hours prescribed under the alternate pathway is reasonable to acquire the fundamental knowledge that an AU would need to administer any radiopharmaceutical. However, we are concerned that paring the number of

hours of work experience required, based on categories of radiopharmaceuticals, will lead to confusion and complexity, both for licensees as well as for the NRC and Agreement States.

We are also concerned that if new radiopharmaceuticals are approved for use that do not fit clearly into one of the categories, that the NRC will have to promulgate any additional regulations to include the new agents, a process that could take time to finalize, delaying patient access to potentially lifesaving radiopharmaceuticals.

The rigorous T&E requirements contribute to the excellent safety record of radiopharmaceuticals. We believe that it is important that the person administering the radiopharmaceuticals is appropriately trained in the safe handling, exposure risk, and the management of side effects of radiation.

ASTRO looks forward to working with the NRC as they continue deliberation and review on this very important topic. In addition, I want to close by saying that ASTRO will submit more detailed written comments by the end of the comment period. And I really appreciate the opportunity to speak to you guys today.

MS. LOPAS: All right. Thank you, Dr. Mirhadi.

All right. Cedric, do we have somebody else on the line?

Again, folks, press *1 to make a comment, *1, and you can either focus on -- you could read a statement, just like Dr. Mirhadi did, or you could focus on kind of this first slide that I have up that talks about questions 1, 2, and 3.

Cedric?

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

But, again, as another reminder, if you would like to ask a question or make a comment, please press *, then 1. If you would like to withdraw that question or comment, you may press *2.

MS. LOPAS: So, *1 to make a comment, *2 to change your mind. I just learned something new. Okay.

All right. So, I can move through different slides. Again, we have three more meetings on this. My colleagues and I were determining what was the best way to get comments from folks over the phone line, and thought we would try walking through some of the questions. So, we're going to just play around with that. But we may change our comment format in future meetings, just as an effort --

THE OPERATOR: Sarah, we did have one that came through.

MS. LOPAS: All right. Let's go.

THE OPERATOR: All right. Jeffry Siegel, your line is open.

MR. SIEGEL: And thanks very much for having this meeting. I really appreciate it.

My name is Jeffry Siegel. I've been involved in reviewing -- I shouldn't even say "reviewing" -- but involved in writing and publishing about NRC requirements and regulations which have been very good.

And I figured I would want to start this off with some controversy because I totally disagree with the first speaker.

First, a brief history relevant to the T&E issue I think is in order. Prior to the NRC revision of Part 35 -- that is, pre-2002 -- only 80 hours of T&E were required for the alternate pathway to obtain AU status for therapeutic use, pursuant to 35.930 -- not for the dyslexic, 930, not 390 -- and only I-131 use was considered. At the same time, diagnostic use, pursuant to 35.920, required 700 hours.

During the revision of Part 35, NRC modified, based on a risk-informed performance-based

approach, these requirements. 35.930 was replaced by 35.390, requiring 700 hours for the alternate pathway. Eighty hours replaced the 700 hours, except for oral sodium I-131 use. Pursuant to 35.392 and .394, only 80 were, and still are, required for oral sodium iodide-131 use. Therefore, requirements have already been tailored for a specific use via 392 and 394. This may be because the NRC was persuaded by endocrinologists to maintain the 80 hours, and this was done 15 years ago. But, today, any physician desiring limited authorization to use sodium iodide can do so with only 80 hours.

Then, in 2006, a petition was submitted to the NRC requesting the 700 hours be reduced to 80. The NRC, of course, denied this petition, and it noted that I-131 was considered to be less of a radiation safety issue than the three agents in the petition; namely, Quadramet, Bexxar, and Zevalin. And the petition requested that med oncs and hematologists be allowed to do this.

NRC further believed that tailoring T&E requirements, which, of course, they had already done for sodium iodide, would increase the complexity of regulatory oversight with no benefit to anyone.

Now we skip forward to today. Using a

one-size-fits-all regulatory approach is not beneficial to oral. Oral therapeutic radiopharmaceuticals do not pose the same risk. So, it follows that their use should not be subjected to, and limited by, identical T&E requirements. This contradicts the risk-informed approach NRC is using.

If a physician is seeking limited authorization without any added flexibility for use of a relatively safe agent, 700 hours is not warranted. Requiring this number of hours, pursuant to 35.390, for limited AU status conflates a single-use requirement with the ability to administer all forms of radionuclide therapy with unlimited flexibility, which, by the way, of course, increases risks. Mandating 700 hours of training when it may not be necessary is, indeed, burdensome to those physicians desiring to attain AU status.

And as an example, Xofigo-only usage. At this point, I wanted to mention it because it is an FDA-approved commercially-available therapeutic, and physicians who want to incorporate this single agent into their practice should be encouraged to do so if they have been appropriately and sufficiently trained.

Xofigo is an alpha-emitting therapeutic, administered in only microcurie quantities, provided

as a unit dosage in a syringe, and unlike hundreds of millicuries of sodium iodide, is of no external dose concern. And since it is excreted mainly in the feces, it is not a likely source of internal contamination. Further, the dose to others is so low that patient release instructions are not even required, pursuant to 35.75. It must be pointed out that conventional nuclear medicine equipment can be used to measure and look for contamination, should it occur.

So, in closing, NRC has already tailored T&E requirements for the specific use of oral sodium iodide. So, the need for such tailoring requires no further discussion, since it already has been done. Therefore, a physician desiring to use Xofigo should be able to attain limited AU status for Xofigo-only usage if adequately trained to minimize any adverse impact on public health and safety.

Since the T&E requirements should reflect the risk involved, and in the case of Xofigo-only use this risk is much less than for oral sodium iodide, only 80 hours of T&E, perhaps even less, should be required.

Thank you very much. I realized what I just was controversial, and this should kick off public comment. Thank you very much.

MS. LOPAS: All right. Well, we appreciate all comments, controversial or not. And I do like ones that kind of get discussion going.

So, *1 if you want to respond to that comment or if you have some additional comments here on Section A.

Cedric, do we have anybody else in the line?

THE OPERATOR: Not at this time.

MS. LOPAS: Okay. All right. So, I have up on the screen, in the webinar, if you're following along on the webinar -- again, we've had some responses back to should the T&E -- well, here's the question: if we do develop tailored limited statuses, limited AU statuses, should those folks go through the same fundamental T&E required of physicians seeking full AU status? So, that was one question.

And the next slide, it kind of gets into some of the nitty-gritty of what we're looking for. We're looking for kind of, how should those fundamental requirements be structured for these specific categories of radiopharmaceuticals? And this is where we're asking for questions like, what should these requirements specifically include? Classroom and laboratory training? What topics under classroom and laboratory training? How many hours? How many hours

of work experience? And also, competency, how should competency be evaluated? Should it be evaluated through a written or practical examination or by an independent examining committee?

And let's see, what other questions do we have here? We have questions about preceptor attestation. Should it be required for fundamental T&E?

So, you can check out that slide if anybody has any comments on question 5. And then, we also have questions, which I've already received some feedback in comments. Should AU competency be periodically assessed? And if so, how should it be assessed and how often, and by whom?

So, there's a whole boatload of questions to think about.

Cedric, just let me know if anybody pops on the line.

*1 to make a comment; *2 if you change your mind.

THE OPERATOR: Okay. Will do.

MS. LOPAS: All right. Thank you.

And we can go ahead, since it is radio silence a little bit, we don't need to stick with -- if you have comments outside of those areas, those topical

areas, please feel free just to press *1 and share your thoughts. Like I said, we were just kind of exploring how to best go through the comments on this, because we do have a lot of questions in that Federal Register notice.

So, Section B was recognition of medical specialty boards by the NRC. Are there any additional boards that the NRC should be considering?

And question area C was on patient access. This is a big one. This is kind of the crux of some of the arguments that we've been hearing that our current regulations and requirements are so tough that they're impacting patient access to these valuable radiopharmaceuticals. So, if anybody has any insight on patient access, we would really be appreciative to hear some of that.

THE OPERATOR: I do have a caller in the queue.

MS. LOPAS: All right.

THE OPERATOR: I did not catch their name. I believe it was Munir.

Your line is open.

DR. GHESANI: Yes. Hi. This is Munir Ghesani from SNMMI.

I just wanted to emphasize the big-picture

point is that, if you are comparing training and experience proportionate to somebody's background, you have to keep in mind that there are certain basic fundamentals of radiation protection, radiation physics, and training in radiology sciences that cannot be simply counted in number of hours. It goes with what you are practicing day-in and day-out for years, whether you're in the training or afterwards.

So, a perfect example is understanding of radiation physics, understanding of different types of radioisotopes, and particles and non-particles of many isotopes. All of that is ingrained in the training of radiologists or radiation oncologists and nuclear medicine physicians.

So, I would really caution the group by just highlighting the point that, if somebody comes from a field where none of this is part of their regular training, and suddenly you are counting the number of hours in which they can get that lab training and you expect them to get a full understanding of the radiation, I think it's an understatement. You have to keep in mind that, for a radiology resident who spends four years in learning it or a nuclear medicine physician who spends three years after doing two years of preliminary training, all of that training

eventually allows somebody to become competent in not only administering in an uncomplicated setting, but should complications arise, being capable of handling every potential scenario of that complication.

So, while I really would like to caution that this is something that really can't add the mark in the number of hours of training. You have to keep in consideration the background of their training as well.

Thank you for your attention.

MS. LOPAS: Okay. Thank you. We appreciate that input.

Cedric, anybody else on the line?

THE OPERATOR: Not at this time.

MS. LOPAS: Okay. *1, press *1, as a reminder, to submit your comments.

If you are on the webinar and you don't feel comfortable speaking, you don't want to necessarily speak aloud, you can submit a comment using your webinar software. If you want to do that under the question function, I can read aloud your comment for you, if you prefer that. That's always an option, too.

So, I am pulling up on the webinar, I'm going back to Section A again, because the last comment

was kind of in response to should these folks seeking this limited AU status have the same fundamental training as those with the full AU status. And that last comment was basically saying, well, we shouldn't be focusing just on hours; you have to consider a physician's background. You know, do they have a background in this? And if they're really coming in with no background, there's something to consider here.

We also have Section D, which is kind of the more general questions on the NRC's T&E regulations as a whole. And I will give some background into this question.

The NRC has been looking at how we can transform how we do things at the Agency, to continue to evolve with the technologies around us. And, you know, these questions are kind of in line with that. How could the NRC transform its regulatory approach for T&E? So, we would be interested in hearing any general comments about that as well.

So, *1 if you have any comments for us.

THE OPERATOR: I'm showing no questions or comments in the queue.

MS. LOPAS: All right. Just a reminder to press *1.

And I think, just to go through, we're going

to start from the top. And if we don't get any comments --

THE OPERATOR: Excuse me. I have one that came through.

MS. LOPAS: Okay. Great. Yes, good, Cedric.

THE OPERATOR: They did not record their name, but your line is open.

MS. LOPAS: Okay. And just remember to start by introducing yourself, please.

MR. CROWLEY: Good afternoon. This is Dave Crowley from North Carolina's Radioactive Materials Program.

As an Agreement State program, I would just like to say that what we do as regulators, and along the lines of the training and experience for authorized users, it is we want to do our utmost to protect the health and safety of both the patient care side of things, but also the occupational side of the house as well.

And this comment isn't so much to answer any of your specific questions, but I do want to make a request that in this process moving forward, to better risk-inform how we proceed, that there be an evaluation of all the medical events that have taken place. And

that would be a great tool for that, and looking at some of the basis for the medical event rule itself and the reporting of those events.

Part of it is to learn whether or if it was justified, that that would give us insight as to whether training and experience was adequate or not for various medical uses. To my knowledge, I'm not aware of an across-the-board review of all medical events has taken place or not to evaluate that. But I would, I guess, recommend or suggest that an evaluation be done of all past medical events to see if there is any correlation to the training experience, either the pathways or the amount that the different authorized users had that were related to those medical events.

And that's all. Thank you.

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

And actually, I have a question for Maryann. Maryann, if you could take yourself off mute? I have a question related to Dave's comment here, so an NRC-imposed question. You can thank me later for it.

But I am wondering, Maryann, does NMED have that information? Would it have the kind of information for the doctor with how they're certified,

whether they were certified under -- would we know how they would be certified? Is it something we could find out in NMED?

MS. AYOADE: Hi, Sarah.

So, NMED doesn't always provide that detailed of information. But what I wanted to point out was that part of what we're doing is additional information gathering. For this evaluation, for this T&E, we're actually going to be looking at medical events, just as you spoke about, to see if there's any kind of correlation with what the causes are for the medical event. And then, we would look at the training and experience of the users, if it involved any kind of user error or type medical event.

MS. LOPAS: Okay. Great. Thank you, Maryann. I appreciate that.

MR. CROWLEY: I don't know if I'm still unmuted or not.

MS. LOPAS: No, you are -- yes, we can hear you.

MR. CROWLEY: Okay. Great.

Yes, as far as the NMED data, I don't believe there's a field to actually report which training pathway AUs came from or even we try to avoid personal names or identifying information in our

reports that we provide. But that is some information that the states may have. So, if you do a reference through NMED, you might see that it falls back on training being one of the underlying causes of the event, and then, you can reach back out to those states or whatever region had it take place, and maybe you'll get some more info.

Or even putting out a request to the states to provide any known trends or observations that they've made on that front. But NMED, in and of itself, probably won't just lay that info neatly, unfortunately.

MS. LOPAS: Okay. Great. Thank you, Dave. I appreciate that insight. And, Maryann, thank you.

Okay, *1 if anybody has any comments kind of related to that.

Cedric, do we have anybody waiting in line now?

THE OPERATOR: Yes.

Ralph, your line is open.

MR. LIETO: Thank you.

A point of clarification about NMED reports. They are not available to the AU or to the licensee. And I've had a lot of experience in looking

at specific NMED reports dealing with medical events, and they do not indicate any training and experience requirements as a part of the investigation, although it's probably an interesting point to add.

But, even if they did collect that information, an authorized user, a licensee, and RSO does not have access to NMED reports. This was an issue that was brought up before the ACMUI last year, I believe it was, about making these available to AUs and to licensees. And the NRC denied making that availability to those groups. So, I think that's something, even though the person before me had some good comments on, right now the NRC is on record as not making that information available.

Thank you.

MS. LOPAS: Okay. Hey, Ralph, are you comfortable with providing your last name, your full name?

MR. LIETO: Oh, I'm sorry, Ralph Lieto. I'm a medical physicist.

MS. LOPAS: Oh, sorry, can you do that one more time? Your phone is going in and out.

MR. LIETO: Ralph Lieto.

MS. LOPAS: Ralph, okay.

MR. LIETO: Got it?

MS. LOPAS: All right. Ralph Lieto. All right. Thank you, Ralph. We appreciate that.

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

THE OPERATOR: Not at this time.

MS. LOPAS: Yes, I think we're having some issues with the phone line on our end. But did you say nobody is on the line right now, Cedric?

THE OPERATOR: Yes, not at this time.

MS. LOPAS: Okay. Okay. All right. Let me check my webinar real quick.

I do have one, somebody who has submitted a question. So, I do have a question or a comment submitted that says -- and this is from Aria Razmaria -- "The wording regarding patient access on the slide, for example, geographic distribution question, are not mentioned in this detail in the FRN. Will there be an update to The Federal Register notice?"

Okay. So, let me see what we're talking about here. "The wording regarding the patient access on the slide" -- ah, okay.

No. That's a good question. So, let me go back here and close out of here.

So, I think, are you talking about how we

would be looking at patient access, what the NRC will be looking at in patient access? I'm wondering if that's what you're talking about, where we don't go into that detail in the FRN.

That information was not included in the FRN, kind of talking about how the NRC was going to try to evaluate patient access. That was just information we provided in the slide to kind of go into more detail about the NRC evaluation. So, no, we will not be updating the FRN.

But the question, we did get some feedback that we were hoping -- well, not hoping -- we did get some feedback that the NRC needed to be determining these patient access questions, finding the answers to these patient access questions. But we did want to put these questions about patient access out to the general public in the FRN, in case anybody did have some insights on that.

So, I am going to read through those questions -- unless, Cedric, is there anybody that's waiting to speak?

THE OPERATOR: No, not at this time.

MS. LOPAS: Okay. So, patient access. The questions in the FRN -- and this is kind of what the NRC's staff is going to try to look into, but we

thought we would also ask everybody in the FRN.

Question 1: 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? Explain how.

Question 2: are there certain geographic areas with an inadequate number of AUs? Identify these areas.

Question 3: do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how.

And then, question 4: do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine?

So, those are the questions that we're going to look into, but if folks on the line, and anybody out there that's planning to comment, either in written or in future meetings, has any input, we would love to hear that.

So, press *1.

And if I didn't respond to that other question adequately, you can feel free to write me another question on the webinar clarifying, and I can do my best.

Cedric, nothing?

THE OPERATOR: No questions.

MS. LOPAS: All right. Okay. And so, again, if you want to comment on something outside of patient access, that's fine. We will open the lines to any comments you have.

But I think I will go back and see if I can jog any comments on Section A. And again, Section A of the FRN, this is covering the tailored training and experience requirements. And this is really, you know, the crux of what we're trying to evaluate here, right?

The general question: are our current pathways for obtaining AU status reasonable and accessible? And we have heard some varied responses back on that.

Are the current pathways for obtaining AU status adequate for protecting public health and safety?

And should the NRC develop new tailored T&E pathways for these physicians? If so, what would be the appropriate way to categorize the radiopharmaceuticals for those tailored T&E requirements? If not, explain why the regulation should remain unchanged.

And we gave some examples of how radiopharmaceuticals could be categorized, including those with similar delivery methods, such as oral or parenteral; the same type of radiation characteristics or emissions, such as alpha, beta, gamma, low-energy photons; similar preparation methods, such as patient-ready doses, or a combination of those. Maybe there would be a category that would have a combination.

So, those are some, just to kind of jog people, those are kind of some ideas that we put in the FRN.

And *1 if you want to jump in and stop me from talking. That's how you do it. Press *1.

And I have one more question here on the webinar I'm going to open up here. Okay. That's just somebody saying goodbye and thank you.

All right. And then, question 4 of Section A: 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 for all oral and parenteral administrations under 10 CFR 35.300?

*1 if you have any comments on any of those questions.

And then, question 5 is the big one that

kind of gets into the specifics of requirements of fundamental T&E, and it's how that fundamental T&E should be structured for specific categories of radiopharmaceuticals.

So, if anybody has any comments on that, *1.

THE OPERATOR: Jeffry, your line is open.

MR. SIEGEL: Hi, Jeff Siegel again. I'm sorry for hogging this conversation, but --

MS. LOPAS: No, we're here.

MR. SIEGEL: Since you brought up again full authorization versus limited authorization, should it require the same T&E hours? I would argue, as I did in my opening, that that would not be risk-informed.

MS. LOPAS: Right.

MR. SIEGEL: Right now, most people are talking about their opinion. No studies have been done, as somebody else was mentioning before, about whether the T&E, whether it be 700 or 80, for the, I would say, non-risk-informed approach to let any physician use hundreds of millicuries of I-131 is adequate or not. And I think the NRC needs to do a little bit of homework.

But the question I would ask, is a physician

capable, or should they be allowed to use an FDA-approved commercially-available product if they think it would help their patients if they were adequately trained? So, the question is, yes or no, could a physician just pick a particular agent for his practice, like a urologist who is treating prostate cancer who says, "Ah, this is great. I would love to give it to my patients."

If they could with a reasonable T&E be able to do that, as opposed to obtaining AU status based on giving everything, which seems to me to be a non sequitur, would the NRC agree or disagree that it would be possible for a physician to medically use an FDA commercially-available product, if they were adequately trained?

And that's what, I think, the issue at hand. What would be the adequate training for a given therapeutic which is administered based on receiving, say, unit dosage, and all this interest in radiation physics and radiation dosimetry, and all this other stuff -- it's important, but moot to the single-user physician.

Thank you.

MS. LOPAS: So, I have a follow-up question for you. So, in question C, we asked, should the

radiopharmaceutical manufacturer be able to provide the preceptor attestation? So, if, for instance, like you're saying, a physician did want to pick one particular drug and become -- you know, if there was a way, a pathway to just being able to administer that drug, I would be curious to hear your ideas for how we would go about that, what that pathway would look like, and if it would involve the manufacturer.

MR. SIEGEL: Yes, well, I know if this was approved, for example, under 35.1000, as opposed to in an alternate pathway that was either 395 or 398, because I don't think you can do it as part of 390, I know that the manufacturer is allowed to give that training for these micro seals, and it was so specified, and I'm not saying it should or it shouldn't be.

All I'm saying is, a physician should be able to, if it's deemed appropriate by experts in the field who say, okay, this particular agent, no way it requires 50 years of training and experience. However, this one, the way it's provided and the way it's manufacturer supplied, because the manufacturer spent a little bit of time coming up with a distribution model that was safer than others -- so, I'm just saying it should be looked at in a way that one could, then, say -- and I agree with a lot of people who say that

only people who are board-certified or have 18 years of experience should be able to give even the simplest unit dosage.

But, remember, medical oncologists, as an example, give on a daily basis very potent, harmful drugs, that is, chemotherapy drugs. They're very skilled at doing that. So, the only difference would be in terms of what's in the syringe, and to figure out what it is to do if there's a mishap.

I think it could easily be taken care of, but that's up to you and people on the line and people who are supplying comments as to what would be the appropriate level of training, given an agent which involves much less risk and it's easier to administer than others in its class, as opposed to just saying all oral, or oral/parenteral, or whatever. Just something to think about.

MS. LOPAS: Okay. Thank you. I appreciate that.

Does anybody have any comments kind of in response to Jeff's comments or any comments on anything in general? Press *1.

Cedric, anybody on the line?

THE OPERATOR: Showing no questions.

MS. LOPAS: Okay. All right. So, *1.

THE OPERATOR: Ralph, your line is open.

MR. LIETO: Thank you.

This is Ralph Lieto again.

And some of us here were talking about one of the questions regarding the geographical issue and patient access. I think the NRC has already in their introductory comments recognized that there's the need for this information.

What would be, I think, of value to this discussion when they're gathering this information, assuming it's probably going to be by zip code or something of that nature, if they could get the distribution by the authorized used category -- in other words, is it 390, 392, 394, or 396 for this geographical distribution? And I think that would really go a long ways. Because I think some of the questions that I think -- or I should say the points that Dr. Siegel has brought up regarding the physician who wants the sort of limited use of a single modality in a therapeutic application.

Thank you.

MS. LOPAS: Okay. Thank you.

Maryann, do you have anything that you want to add with regard to how we would look at gathering that dataset?

MS. AYOADE: Hi, Sarah.

Not really. What Ralph said is something that we're considering. As we look at the authorized users for 300 uses, we'll be able to look at the different training categories that they're licensed for. So, we could get that information as well, in addition to the distribution, like he said.

MS. LOPAS: Okay. Thank you, Maryann.

Okay. *1 for any additional comments or you can submit a question or comment for me to read aloud via the webinar software. I can certainly do that for you as well, if you would like to submit your comments that way.

THE OPERATOR: Aria Razmaria, your line is open.

DR. RAZMARIA: Hi. How are you? This is Aria Razmaria speaking. I'm a Senior Nuclear Medicine Resident at UCLA Medical Center.

But I'm speaking on behalf of myself and, also, on behalf of nuclear medicine, the nuclear medical physician, on behalf of nuclear medicine training, both in nuclear medicine programs and nuclear medicine and biology programs.

And I appreciate the NRC's request for public comment. It's an important topic, and there

are kind of soft processes that lend into this, again reaching out to all different stakeholders in this regard.

One comment that we would like to make is that being able to administer radiopharmaceuticals in just the matter of a single dose being applied, and to be able to do that. It goes, also, along the line of being able to enhance and encourage research in this area. People that are dedicated to one specific field push forward and contribute to developing new pharmaceuticals, radiopharmaceuticals, for different applications. So, in this regard, it's not just a matter of application or administration, but also the science and the developmental research that goes beyond just having access to the application or administration of these radiopharmaceuticals.

Meaning that, as a body that is interested and dedicated to the science of nuclear medicine, there is a dire need in the U.S. We see that all research, almost the majority of research is coming from countries outside of the U.S. in countries that have dedicated programs for training. And there is a body of physicians that are interested in the research and, also, development of new avenues of therapy.

So, just having a single limited authorized

user license to be able to administer certain radiopharmaceuticals would not push the field forward in the U.S. and contribute to further advancement of the science of nuclear medicine.

Thank you for this opportunity to contribute to the discussion.

MS. LOPAS: Yes. Dr. Razmaria, can I ask a follow-up question related to what you just said?

DR. RAZMARIA: Absolutely.

MS. LOPAS: So, related to one of the FRN questions we have, do you think that the current regs, do they have no effect on research and development in nuclear medicine or are they adversely affecting it because they're limiting the number of people that are getting involved? Or are you saying that, if we make it easier for folks to just pick one category, that you think that wouldn't do anything to help research and development?

DR. RAZMARIA: Again, you actually are facing a situation where I believe, actually, the requirements that you are talking about, 700 hours, if you calculate that, it would be four months of training. Whereas, again, based on the American Board of Nuclear Medicine and the American Board of Radiology, there's a good understanding that that is not

sufficient, as programs have been developed sponsored by the Board of Radiology and the Board of Nuclear Medicine that perhaps included radiology and nuclear medicine. So, there is understanding that that requirement that you are talking about right now being too much of training, which is just four months, it's our understanding.

I mean, what you are facing in the U.S. is that people don't realize that to be able to advance the research and science, we have to be dedicated; we have to be understanding that just being able to read one dose and that's it, the science is weak on that. It's to be able to understand, okay, what other traces are possible, what other avenues? So, it really can be researched.

Personally, you know, I have spent the time to understand the question. What you see in the nuclear medicine, right now practiced in the U.S., the majority are by radiologists, which they are very busy. They have to cover multiple modalities. And to my understanding, radiologists, when I talk to them, they really didn't sign up to do that, but what we are facing, they are hiring from places like hospitals.

College groups, they basically don't see the need to having training in nuclear medicine, who

have done the basics for four years, nothing but just being able to understand what nuclear medicine is, professional imaging as well as PET imaging.

So, meaning, there is no time; there is no encouragement to start these projects that are dear to us, answering those specific questions that the field needs. That actually is happening, if you see across the border, in Europe, all the developments. The radiotherapists there are talking about the change in requirements, because of all that are developed in Europe, in Australia, in countries that have a strong standing in nuclear medicine, with people who have spent time not only just administering one single dose for people to be able to create revenues, but who are instructed in consultations, answering questions that are not answered in the field.

So, these are physicians that we are mentioning right now in this discussion will have in the future, how nuclear medicine that is practiced in this country. And again, there's a new generation of trainees that are interested in taking this task or taking these questions, who are dedicated and want to do that. And we need, if at all possible, to encourage that, to enhance that. Because, as mentioned, despite the U.S. being the country where nuclear medicine was

invented, we're lagging behind internationally, behind many other countries. So, the rulemaking will have a direct effect on that progress.

MS. LOPAS: Okay. All right. I appreciate that insight. Thank you.

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

*1, if anybody wants to respond in response to what this Dr. Razmaria just spoke about or anything else.

THE OPERATOR: Showing no one in queue at this time.

MS. LOPAS: Okay. Okay, folks, let's see. So, we heard a little bit about the effect that this can have on future R&D in nuclear medicine. Maybe that leads to specialty boards. We got a couple of comments in saying that maybe we don't need an alternative pathway, that maybe it should just be these specialty boards that are the only ones that can certify.

If anybody has any comments on that, press *1, or any comments in general about the NRC's medical specialty board recognition process. We're happy to hear those, too.

The current boards right now that are recognized at the NRC are the American Board of Nuclear

Medicine, the American Board of Radiology, the American Osteopathic Board of Radiology, and the Certification Board of Nuclear Endocrinology. So, that's what we have currently.

Are there other boards that we should be considering? Press *1 if you have any thoughts on that.

THE OPERATOR: I'm showing no questions or comments in queue at this time.

MS. LOPAS: Okay. Thank you.

All right. And if folks have more general, again, any more general comments on the NRC's T&E regulations in general, I know we are happy to hear those as well.

But I understand this is the first meeting. There are three additional public comment meetings. Like I said, the one in December, on December 11th and the one on January 10th, those are in-person meetings. So, if anybody is in the area and wants to travel, you can come on out and come attend one of those meetings personally. And both of those will also be accessible via webinar and teleconference again. And those will all be, again, transcribed and recorded. And then, on January 22nd, we're going to have one final webinar, and that will be about a week before the comment period ends. So, maybe comments will ramp up as we

move along.

I have one, let's see, I have one comment here that is suggesting certification of nuclear cardiology. I'm not seeing any other information related to that.

Mr. Johnson, if you want to hop on the line, feel free. *1 to hop on the line, if you want to expand on your comment on certification of nuclear cardiology. That would be helpful. Otherwise, you can submit that comment in writing as well. But I did receive that comment via the webinar here.

Okay. All right. *1.

MS. AYOADE: This is Maryann.

I'm not sure why the commenter just put down CBNC, but I'll point out that CBNC, the Certification Board for Nuclear Cardiology, who was the best for training and imaging and localization studies, which is under 10 CFR 35.200. And that's not a subpart of this section of training and experience that we're looking at.

MS. LOPAS: Okay. That's good clarification. Thank you, Maryann. That's helpful.

*1 if there's any additional comments.

Cedric, do we have anybody on the line?

THE OPERATOR: We did, but it seems like

they withdrew the question.

MS. LOPAS: All right. *1 to ask a question; *2 to change your mind. So, somebody got the *2.

I've been doing these webinars for a few years now, and I never knew *2 was an option. So, that's good to know.

Okay. All right. Well, we're going to give it a couple more minutes. But, if we continue to have no comments, we will probably end the webinar early.

So, *1.

I'm going to talk a little bit again about the comment deadline for written comments. If you want to also submit written comments, you can submit written comments via regulations.gov. It's very easy. And the docket ID is NRC-2018-0230, and you just go to regulations.gov and type that ID, that docket ID, right in the search bar, and it will pop right up. And there's a little button that says, "Comment Now" on the right-hand side, and it's very easy.

But, again, if you have any issues, I'm going to put my contact information up again. You can certainly contact myself or Maryann. If you have any issues submitting comments via regulations.gov, I can

certainly help you out with that. That's no problem.

And *1 for any final comments for folks.

(No response.)

All right. Cedric, I'm assuming it's nobody has popped on?

THE OPERATOR: Yes, no line queue at this time.

MS. LOPAS: Okay. All right. Well, I really do appreciate everybody that joined us today and took time out of the middle of their day to join us on this webinar. Like I said, we've got additional meetings, public comment meetings again, where you can get on the line and have your comments transcribed December 11th, January 10th, and January 22nd.

And I hope everybody has a great Thanksgiving.

If you need anything, contact myself or Maryann.

So, thank you all and have a great day.

(Whereupon, at 2:24 p.m., the meeting was adjourned.)