

**Official Transcript of Proceedings**  
**NUCLEAR REGULATORY COMMISSION**

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

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Tuesday, December 11, 2018

Work Order No.: NRC-0001

Pages 1-84

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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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TUESDAY,  
DECEMBER 11, 2018

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

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

## NRC STAFF PRESENT:

JOAN OLMSTEAD, NRC Facilitator

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

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

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

JENNIFER FISHER, Office of Nuclear Material  
Safety and Safeguards\*

## ALSO PRESENT:

JANICE CAMPBELL\*

RALPH LIETO, St. Joseph Mercy Health System\*

ARIA RAZMARIA\*

JOE RUBIN, United Pharmacy Partners

JEFF NORENBURG, National Association of Nuclear  
Pharmacies

JOHN WITKOWSKI, United Pharmacy Partners\*

\*Present via teleconference

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

1:04 p.m.

1  
2  
3 MS. OLMSTEAD: Good afternoon. Welcome  
4 to the Nuclear Regulatory Commission's webinar to  
5 accept comments for the staff evaluation of training  
6 and experience requirements for different categories  
7 of radiopharmaceuticals.

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

13 And Sara Lopas, a member of the Medical  
14 Radiation Safety Team, and project manager for the NRC's  
15 training and experience evaluation. And Maryann  
16 Ayode, who is a Health Physicist on the NRC's Medical  
17 Radiation Safety Team, and the technical lead on the  
18 training and experience evaluation.

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

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

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

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

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

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

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1 period.

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

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

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

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

20 Are there any questions about the  
21 logistics?

22 (No response.)

23 MS. OLMSTEAD: Okay. Next slide, please.

24 After the welcome, Sarah Lopas will go into some more  
25 detailed information for the webinar participants.

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

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

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

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

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

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

25                   The purpose of today's meeting is twofold.

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 we created for the Commission back in August 2018.

2 We also have the Federal Register Notice.

3 And then we also have the slides for today. So you  
4 can download those onto your computer if you're on the  
5 webinar.

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

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

13 And then similarly, we will refer to  
14 authorized users, i.e., those physicians who are  
15 authorized to administer radiopharmaceuticals as AUs.

16 So AUs and T&Es are what you'll hear for short a lot  
17 of times today.

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

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

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1 So, all the information from the meeting we have on  
2 November 14, you know, an identical webinar on November  
3 14, I've already posted that meeting summary and  
4 transcript, and slides from that meeting on that  
5 website. So the same thing will happen for this meeting  
6 and future meetings.

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

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

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

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

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

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

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

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

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

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

25          A physician can also be authorized if they

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

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

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

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

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

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

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1 require a written directive.

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

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

10 And the fourth section is under 10 CFR  
11 35.396 for training for the parenteral administration  
12 of any radiopharmaceutical requiring a written  
13 directive.

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

18 Also, all the Sections except 10 CFR 35.396  
19 include training and experience under the board  
20 certification and alternate pathways. However, 10 CFR  
21 35.396 is for training exclusively under the alternate  
22 pathway.

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

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1 additional hours of training and experience.

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

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

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

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

20 Specifically, some stakeholders have  
21 asserted that the seven hundred hour requirement in  
22 10 CFR 35.390 is overly burdensome for physicians who  
23 are not certified by medical specialty boards.

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

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1           thereby limits patient access to certain  
2           radiopharmaceuticals.

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

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

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

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

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

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1 T&E requirements for different categories of  
2 radiopharmaceuticals.

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

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

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

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

25 It also concluded that there are viable

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

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

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

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

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

23 This is a simplified diagram on this slide.

24 The information that we're going to consider in our  
25 development of a recommendation to the Commission on

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

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

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

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

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

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

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

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

9           And it's important to note that if staff  
10 does end up recommending a rulemaking, which we would  
11 again, document in a rulemaking plan, the Commission  
12 would then proceed to the vote on that rulemaking plan.

13          And that would determine whether or not the staff would  
14 proceed with the Part 35 rulemaking effort.

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

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

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

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1 time.

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

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

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

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

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

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

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1 their general statements.

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

8 Okay. So, the first set of questions,  
9 extensively covers the crux of what we're evaluating.

10 Whether the NRC should create a tailored training and  
11 experience requirements for certain categories of  
12 radiopharmaceuticals.

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

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

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

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

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1 of radiopharmaceuticals?

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

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

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

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

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

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

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

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1 procedures involving radiopharmaceuticals?

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

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

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

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

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

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

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1 written comments via regulations.gov.

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

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

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

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

22 We've only had six written comments  
23 submitted so far. But, I actually -- I have also posted  
24 on that T&E docket the transcript from the November  
25 14 meeting as well, so.

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

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

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

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

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

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

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1           So we have two more public meetings,  
2           January 10 that's going to be -- January 10 and January  
3           22.

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

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

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

13          So just briefly, I'll cover our next steps.

14          After the comment period ends on the 29th of January,  
15          we're going to begin organizing and evaluating all the  
16          comments that we've heard from everybody.

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

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

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

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

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

10 And the NRC will consider and incorporate their  
11 comments on our draft paper.

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

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

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

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

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

6           And then of course Maryann and myself are  
7 your points of contact. I think if you have technical  
8 questions, I would please ask that you contact Maryann.

9           And then if you have more process type questions, I  
10 can help you out with those.

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

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

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

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

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

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

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

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

14 Okay.

15 MR. RUBIN: Good afternoon. I'm happy to  
16 go first. My name is Joe Rubin. I'm appearing on  
17 behalf of United Pharmacy Partners, and alliance of  
18 83 independent commercial nuclear pharmacies and  
19 affiliate nonprofit academic medical center  
20 radiopharmacies across the country, which are focused  
21 on delivering prepared radiopharmaceuticals for  
22 diagnostic, molecular imaging, and therapeutic patient  
23 needs.

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

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1 diagnostic imaging and radiotherapy every day.

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

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

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

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

19 The same seven hundred hour requirements.

20 And NPs maybe listed on the radioactive materials  
21 license as the AU and radiation safety officer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 And we appreciate that the NRC is going

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

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

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

13 In an emergency, rural patients must travel  
14 twice as far as urban residents to the closest hospital.

15 The distribution disparity among specialists is even  
16 more acute.

17 While there are 263 specialists for every  
18 100 thousand citizens in urban areas, that number drops  
19 to 30 specialists per 100 thousand residents in rural  
20 areas.

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

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

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

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

9 The UPPI has submitted to the NRC a Freedom  
10 of Information Act request to attempt to help ascertain  
11 the number, type, and training and locations of AUs.

12 And we'd love to work with you on fulfilling that,  
13 and the process that you guys have undertaken.

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

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

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

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

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

16           Accompanying our submission, are UPPI's  
17 comments from 2016 that first raised this suggestion.

18           We will be submitting a more detailed comment later  
19 in this process.

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

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

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1 take any questions.

2 MS. LOPAS: I have one question for you.

3 Do you know -- this is Sarah Lopas. Do you know when  
4 you guys submitted that FOIA?

5 Because I'm looking at my coworker and --

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

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

9 MR. RUBIN: Yes.

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

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

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

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

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

21 MS. LOPAS: Okay.

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

25 The comment I wanted to add is that there

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

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

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

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

23 Thank you.

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

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

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

8 OPERATOR: We are showing no questions at  
9 this time.

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

12 Okay. All right, guys. I'm going to just  
13 walk us through some of these questions, and it might  
14 be radio silence and that's okay, but I'm going to try.

15 I'm going to try here, and maybe we -- we end our meeting  
16 very early, depending on if we just really get no --  
17 no input.

18 So here I just want to focus on some of  
19 the specific questions that the NRC asked in our Federal  
20 Register Notice, because we are looking at -- we would  
21 like to get some specific feedback on these questions.

22 It is going to help us develop our paper for the  
23 Commission.

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

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

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

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

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

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

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

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

22 Candy, is there anybody on the phone?

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

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

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

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

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

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

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1 pharmacies.

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

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

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

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

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

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

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

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1 that can be provided.

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

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

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

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1 a variety of different audiences.

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Pharmacy has a lot of practice

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

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

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

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

25

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

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

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

10 DR. NORENBERG: Thank you.

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

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

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

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

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

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

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

15 MS. AYOADE: Yes. So we are evaluating  
16 the training and experience requirements for  
17 radiopharmaceuticals under Subpart E, which is for the  
18 10 CFR 35.300. It is primarily therapy uses and for  
19 iodine -- iodine risks.

20 MS. CAMPBELL: So --

21 MS. AYOADE: I mean, greater than 30 --  
22 30 microcuries.

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

25 MS. AYOADE: Yes.

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

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

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

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

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

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

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

3 MS. AYOADE: That's correct.

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

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

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

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

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

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1 certification?

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

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

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

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

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

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

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

7 MS. AYOADE: Yes, that's correct.

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

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

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

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1 they are not supposed to be involved with.

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

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

19 MR. LIETO: Thank you.

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

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

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

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

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

7 DR. NOREMBERG: All right. This is Jeff  
8 Norenberg. I'm speaking as an individual. Is that  
9 better? Sorry. Jeff Norenberg, speaking as an  
10 individual.

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

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

25 And I think this has bearing on the

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

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

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

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

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

6 And I think, you know, back to my days doing  
7 therapy with investigational therapeutic  
8 radiopharmaceuticals, we have treated approximately  
9 70 patients with investigational therapeutic  
10 radiopharmaceuticals, and oftentimes, you know,  
11 plumbing is really the key to getting the drug into  
12 the patient.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 So the NRC is starting by looking at the  
13 facilities that are licensed to administer 300 drugs.

14 We're mapping those for NRC licensed facilities, and  
15 we're also looking at the AUs associated with those  
16 licensees. So we will have that information for our  
17 13 states where we are -- we are doing the licensing  
18 there.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 MS. LOPAS: So right now the NRC, we only  
6 have non-agreement state data at our disposal  
7 immediately. There is a couple complicating factors.

8 If we were to go out and ask the agreement states for  
9 all this data, it could be a pretty heavy lift, and  
10 we wouldn't need to apply for -- it's a little -- it's  
11 kind of, you know, government parlance, the Office of  
12 Management and Budget clearance information,  
13 collection clearance, and that's quite a process.

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

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

25 MR. EINBERG: That was a good summary.

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

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

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

15 I mean, I think we're going to see that  
16 this tracks with physician access in general, right?

17 I mean, you can't get brain surgery in a little teeny  
18 tiny town. You have to go to a major metropolitan city,  
19 right? I think it is going to be a little similar.

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

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

3 MR. LIETO: Are you asking me?

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

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

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

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

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

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

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

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

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

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

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

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

15 Thank you.

16 MR. EINBERG: Thank you.

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

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

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

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

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

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

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

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

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

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

3 And our comment period closes January 29th.

4 So if you are submitting those official written  
5 comments, we ask that you get them in by that date on  
6 regulations.gov. If you have any issues, again, you  
7 can just email me and I can take your comments as well  
8 and get them on the docket.

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

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

14 MS. LOPAS: Okay.

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

19 DR. RAZMARIA: Hello? Can you hear me?

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

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

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

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

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

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

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

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

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

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

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

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

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

25 Again, with respect to all of the

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

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

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

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

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

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

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

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

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

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

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

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

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

23 Thank you.

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

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

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

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

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

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

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

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

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

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

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1 for therapeutic purposes.

2 So, again, the country -- you just need  
3 to look to Europe. You just need to open the Journal  
4 of Nuclear Medicine, and you can see that, you know,  
5 the majority of studies are coming from outside of U.S.

6 And this is really kind of disheartening if you  
7 consider that nuclear medicine was in fact developed  
8 in the U.S.

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

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

19 So, again, putting all of the financial  
20 benefit to the side, looking at what the future will  
21 have, all of the areas of medicine move towards  
22 specialization in medicine. So just -- just opening  
23 up an area to kind of broad -- well, in our intent we  
24 have to always keep in mind patient access, obviously.

25 But patient access to expertise therapy, not just --

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

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

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

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

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

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

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

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1 webinar will be on January 22nd, and we will be in 2019.

2 Can you believe it?

3 Okay. Thank you very much, everybody.

4 And I will stay on the bridge line for our court

5 reporter, but thank you, and this concludes our meeting

6 on training and experience. Thanks.

7 (Whereupon, the above-entitled matter went

8 off the record at 2:44 p.m.)

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