

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: NRC-2018-0230

Location: Public Meeting at NRC Headquarters in
Rockville, MD, and Webinar

Date: January 10, 2019

Work Order No.: NRC-0054

Pages 1-81

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

+ + + + +

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

+ + + + +

THURSDAY,

JANUARY 10, 2019

+ + + + +

PUBLIC MEETING

+ + + + +

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

PRESENT:

SARAH LOPAS, NMSS/MSST/MSEB

MARYANN AYOADE, NMSS/MSST/MSEB

CHRISTIAN EINBERG, NMSS/MSST/MSEB

DONNA-BETH HOWE, NMSS/MSST/MSEB

TABLE OF CONTENTS

Welcome and Introduction.....	4
Review Agenda and Ground Rules.....	5
Presentation on the NRC's T&E Evaluation.....	7
Public Comments.....	23
Adjourn.....	78

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

P R O C E E D I N G S

(1:00 p.m.)

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

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

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

7 Then Maryann and I will do the NRC
8 presentation. And then we're going to open it up for
9 your comments. And we'll answer your questions as we
10 can. So there's plenty of time for comments. There's
11 only a few people here in the room and there are about
12 20 or so of you on the phone. So thanks for calling
13 in, we appreciate you.

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

16 MR. EINBERG: Okay, thank you, Sarah.

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

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

1 twofold:

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

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

13 The comments we receive from the medical
14 community, the agreement states, and other stakeholders
15 are critical to the NRC staff's decision making on
16 whether our existing training and experience
17 requirements should be revised. If you do not provide
18 your comments today, we encourage you to participate
19 in one of our future comment meetings in January, or
20 submit written comments using regulations.gov by
21 January 29th, 2019.

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

24 And now I'll hand the presentation back

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 to Sarah Lopas.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

22 MS. AYOADE: Great. Thank you, Sarah.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

5 So the current regulations on training and
6 experience for radiopharmaceuticals requiring a
7 written directive are under 10 CFR Part 35, Subpart
8 E. These training and experience requirements provide
9 three pathways that a physician may be authorized to
10 administer radiopharmaceuticals that require a written
11 directive.

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

16 A physician can also be authorized if they
17 satisfy the training and experience requirements via
18 an alternate pathway, which includes the completion
19 of 700 hours of training and experience, including a
20 minimum of 200 hours of classroom and laboratory
21 training in the relevant topic areas, as listed in the
22 regulations, and 500 hours of supervised work
23 experience in the relevant areas, as listed in the
24 regulations.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

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

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

6 And so this training and experience
7 evaluation is focused on the ultimate pathways. And
8 the NRC staff are looking into what tailored training
9 and experience requirements for limited administration
10 of certain categories of radiopharmaceuticals would
11 look like. And that is what we will be referring to
12 as a limited authorized user status.

13 Next slide.

14 So in Subpart E there are four sections
15 that pertain to training and experience requirements.

16 The first section is under 10 CFR 35.390 for training
17 for the use of all radiopharmaceuticals in Subpart E,
18 all of which require a written directive.

19 The second is under 10 CFR 35.392 for
20 training for oral administration of sodium iodide
21 iodine 131 requiring a written directive in quantities
22 less than or equal to 33 millicuries.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

6 So I want to point out that all these
7 sections of training and experience, including the
8 pathways for experienced authorized users already
9 listed on the license, it includes the pathways for
10 experienced authorized users that are already listed
11 on the license.

12 Also, all the sections except 10 CFR 35.396
13 include training and experience under the board
14 certification and alternate pathways. However, 10 CFR
15 35.396 is for training exclusively under the alternate
16 pathways, and it is written for the radiation
17 oncologists that are looking to become authorized
18 users. And they can do this by completing some
19 additional hours of training and experience.

20 I also want to point out that the alternate
21 training pathway under 10 CFR 35.392 and .394 is for
22 the physician to successfully complete 80 hours of
23 classroom and lab training. And that is relevant to
24 the type of uses for which they are seeking to be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

6 Next slide.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

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

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

13 Next slide.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 those requirements should be based on hours of training
2 and experience or focused more on competency.

3 Next slide.

4 In response to the Commission direction,
5 the NRC staff solicited feedback from some medical and
6 regulatory stakeholders in April and May of 2018. And
7 that evaluation, including the NRC staff's analysis
8 and feedback received of the training and experience
9 requirements in Subpart E of 10 CFR Part 35 was
10 documented in an NRC SECY paper, SECY-18-0084.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

9 So in addition to the input that we received
10 from the public and the medical stakeholders, the
11 agreement states, and the ACMUI, the staff is also going
12 to look at patient access. We've been working on
13 mapping facilities where they offer 35,300 therapies
14 in the United States. And right now we just have access
15 to NRC licensees for that data. But we do plan to go
16 out for a voluntary data request from the agreement
17 states to ask them if they can provide us that
18 information, if they have it, in kind of an easily
19 accessible form as well.

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

24 And the next thing that we're going to start

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

24 The next slide is Slide 13.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 This is the Federal Register Notice slide.

2 The Federal Register notice was published on Monday,
3 October 29th. It can be accessed at this link here.

4 You could just also do a Google search of 83 FR 54380.

5 It's also, of course, attached to your webinar too
6 as a handout. Easy enough.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

3 So Slide 14.

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

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

14 Should the fundamental T&E required of
15 physicians seeking limited AU status need to have the
16 same fundamental T&E required of physicians seeking
17 full AU status?

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

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

24 And the current boards in our current

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

2 But our questions are:

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

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

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

12 So we've been asking, we ask is there a
13 shortage in the number of AUs for medical uses under
14 10 CFR 35.300? If so, is the shortage associated with
15 the use of a specific radiopharmaceutical?

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

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

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

24 And then Section D was kind of asking

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

24 If you have any issues with submitting your

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Slide 20 are our next steps.

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

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

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

12 And then the ACMUI Subcommittee on Training
13 and Experience is going to provide their report to us
14 on March 8. So there will be a public teleconference
15 on that report probably sometime later in March. So
16 we will, we will notice that on our public meeting notice
17 and send notice of that meeting on our medical listserv.

18 So if you're not on our medical listserv, get on that.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 their input and comments on that paper.

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

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

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

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

19 And with that, that's the end of our
20 presentation. So finished up pretty quickly, 1:25.
21 I want to -- we'll start here with comments in the room.

22 Everybody has to use a microphone. So I can run this
23 mic to you if you want to use this mic, or you're welcome
24 to use the podium mic if you'd like to use the podium.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Just turn it on.

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

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

11 We're starting with a comment in the room.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

3 And we have a letter that we're preparing
4 to go out right now. It's kind of stuck in the process
5 because it requires Office of Management and Budget
6 Review and it is closed. So we're stuck in the process.

7 We probably won't get that letter out -- I mean who
8 knows, right? -- once OMB opens back up I anticipate
9 it might be three to four weeks after that that the
10 letter would go out. And then typically we give the
11 Agreement States about 45 to 60 days to respond to
12 something like that. So it will be a little while.

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

16 MODERATOR LOPAS: Yeah. Oh, absolutely.

17 MS. TOMLINSON: Okay.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 public?

2 MODERATOR LOPAS: We will be making the
3 maps public.

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

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

9 MODERATOR LOPAS: Yeah sure. No. Yeah.

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

13 MODERATOR LOPAS: Yes.

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

16 MODERATOR LOPAS: Right.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 of States. And it is literally just a pinpoint.

2 And what we are, you know, and what we are
3 doing is for -- so we have main facility locations.
4 And we -- we're going to put the number of 35.300 AUs.

5 That number is going to be next to the dot. You will
6 see at that particular location there might be five
7 35.300 AUs there.

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

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

16 MS. TOMLINSON: Okay.

17 MODERATOR LOPAS: -- dots on a map.

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

20 MODERATOR LOPAS: Yes.

21 MS. TOMLINSON: -- and it's INOVA, and you
22 know that INOVA has, whatever, 10 authorized users under
23 35.390, but one of them might work in, you know, the
24 Fairfax Hospital, one might be at Fair Oaks, and one

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

3 MODERATOR LOPAS: Right.

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

6 MODERATOR LOPAS: Right. Exactly.

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

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

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

15 MS. TOMLINSON: Okay, great. Thank you.

16 MODERATOR LOPAS: Yep.

17 MS. AYOADE: This is Maryann from the NRC.

18 Cindy, the question is to Cindy from ASTRO.

19 If for some reason based on what we shared with you
20 today you guys have, you know, any other information
21 or things that you think might be useful to use, please
22 feel free to share --

23 MS. TOMLINSON: Okay.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

6 MR. GUASTELLA: This is on, correct?

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

11 It is CORAR's position that the current
12 700 hours training and experience alternate pathway
13 for physicians who want to become authorized users to
14 safely administer patient-ready alpha, beta, and
15 beta/gamma emitting isotopes, and we kind of refer to
16 those as the non-imaging radiotherapy doses, and we
17 believe the requirements right now are excessive.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

22 All these things roll into the 700 hours
23 currently.

24 Other factors for consideration include

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

24 Thank you very much.

1 MODERATOR LOPAS: Thank you.

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

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

6 Your line is open.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 medicine residency. The NMAA student during that
2 24-month internship learns under the guidance of a,
3 you know, a nuclear medicine physician or a radiologist,
4 very similar again to a nuclear medicine residency.

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

10 So I guess that's just a very brief and
11 condensed statement about what a nuclear medicine
12 advanced associate is and our proposal. But I guess
13 some key points are, is that throughout healthcare we
14 have seen mid-level providers improve patient access,
15 efficiency, healthcare costs, and overall patient care.

16 And I believe the nuclear medicine advanced associate
17 would be no different in the field of nuclear medicine.

18 Again, we are mid-level providers, credentialed, and
19 board certified.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. AYOADE: Okay, thank you.

2 MR. DEGENHARDT: Yes. No, thank you.

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

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

9 Is there anybody on the line, Tara?

10 OPERATOR: Yes. Richard, your line is
11 open.

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

17 And to clarify, maybe give us a little
18 perspective on where the NMAA sits at the mid-level.

19 It would be akin to a nurse practitioner as opposed
20 to a nurse. So these are people that have undergone
21 not only undergraduate work but have obtained a Master's
22 Degree in graduate work and post-graduate certification
23 through a certification board.

24 In my commenting, too, through the website

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 that a physician would receive, just on a smaller scale.

2 And put that extra education and experience on top
3 of that, and that's what a nuclear medicine advanced
4 associate is.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 But I just wanted to add that comment.

2 Thank you.

3 MODERATOR LOPAS: All right. I

4 appreciate that Mr. Siska. Thank you.

5 Tara, is there another commenter on the
6 phone?

7 OPERATOR: Yes. David, your line is open.

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

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

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

24 I manage ten states currently. And there

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

21 MODERATOR LOPAS: Okay, thank you.

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

24 MODERATOR LOPAS: Okay, thank you, Tara.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 We're going to hear from Chris.

2 MR. EINBERG: Yes. This is Chris Einberg.

3 Thank you for bringing up the issue of how the NRC
4 is funded. And just want to provide a little
5 clarification there regarding that fact.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

17 MR. WITKOWSKI: John Witkowski, President
18 of UPPI.

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

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

24 UPPI sincerely appreciates the Nuclear

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

24 Since the pharmacy community has played

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 pharmacist licensing.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

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

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

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

10 This dispensing of the therapeutic doses
11 by the nuclear pharmacist has already been established
12 by the nuclear pharmacy working with the drug
13 manufacturer. Specifically, there are approximately
14 1,200 practicing nuclear pharmacist authorized users
15 through the U.S., and they are widely geographically
16 distributed.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1 UPPI envisions that the team established
2 under the proposal would consider -- would consist of
3 a nuclear pharmacist authorized user on site who would
4 cover the radiation safety aspects of the procedure,
5 while a limited trained medical oncologist authorized
6 user, one that possesses lesser hours of training than
7 700, would be present for the injection or infusion
8 of the therapy and the patient care and treatment.

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

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

6 MODERATOR LOPAS: All right, thank you
7 very much.

8 Any questions? All right, thank you.

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

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

14 MODERATOR LOPAS: Hello. Are you there?

15 DR. CZERNIN: Johannes Czernin.

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

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

20 MODERATOR LOPAS: Okay.

21 DR. CZERNIN: Can you hear me?

22 MODERATOR LOPAS: Yes.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 most grotesque proposal that I've ever heard.

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

3 MODERATOR LOPAS: Okay, thank you.

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

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

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

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

14 No? Okay.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

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

5 So additional comments that we've heard
6 is some commenters have strongly supported tailored
7 team requirements, citing that we already do this for,
8 for sodium iodide administration in 35.392 and .394.

9 And commenters have supported doing this for
10 potentially other categories and classes of drugs,
11 radiopharmaceuticals.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

15 I'm going -- I do have one comment here
16 on the webinar. Okay, I did get a request for me to
17 repeat the docket number for T&E. So the docket number,
18 I'm going to pull it up on the, on the slides as well.

19 But it is NRC-2018-0230. It's right here.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 available.

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

5 Sure.

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

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

16 Thank you.

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

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

22 OPERATOR: Vicki LaRue, your line is open.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

17 MODERATOR LOPAS: All right. Thank you,
18 Vicki.

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

21 OPERATOR: Shaemus Gleason, your line is
22 open.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 on this recent proposal.

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

10 That distribution model is distributing
11 a product that has limited injection site reactions
12 and limited adverse events associated with the therapy.

13 These patients are dosed every four weeks and are
14 immediately releasable patients.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

5 So thank you for your time.

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

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

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

13 MR. GLEASON: No problem. No problem.

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

16 DR. CZERNIN: It's Johannes Czernin again.

17 I completely understand why industry is
18 pushing for that. My comments to some other prior
19 comments that were made about kind of the needs
20 assessment are that we did the analyses and actually
21 came up, using data from Europe, that you need about
22 150 theranostics centers in the United States, number
23 one.

24 Secondly, if you talk about highly

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

14 That's it.

15 MODERATOR LOPAS: Okay. Thank you,
16 Johannes.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 22nd. That's a Tuesday. It's at 10:00 a.m. Eastern
2 time, so it's early for folks not on the East Coast.

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

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

24 We currently have at the NRC a program that

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

16 And we also have Richard Siska.

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

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

24 MODERATOR LOPAS: We'll start with Scott

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

2 OPERATOR: And we just had Richard as well
3 join.

4 MODERATOR LOPAS: All right.

5 OPERATOR: So, Scott, your line is open.

6 MR. DEGENHARDT: Yeah, thank you.

7 And I, I did hear most of that question.

8 I apologize, but what our program or what our
9 profession is, is again we started off as nuclear
10 medicine technologists, highly trained nuclear
11 medicine technologists who have advanced their
12 education or our education to a, you know, to a mid-level
13 status.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

4 Now that we have seen the emergence of
5 Lutathera here in the U.S., you know, it's a little
6 bit more of a complex administration. You know,
7 45-minute injection. And that's tying up our
8 authorized user and our physicians, you know, that
9 entirety. And, you know, they're unavailable for other
10 patient care, unavailable to dictate, you know, other
11 studies during that time as their time is dedicated
12 to that patient.

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

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

24 My name, again, Scott Degenhardt,

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

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

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

7 MODERATOR LOPAS: Okay, excellent.

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

12 Tara, is Vicki still on the line?

13 MS. LaRUE: Yes, I'm here.

14 OPERATOR: Vicki, your line is open.

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

16 MODERATOR LOPAS: We can, yes.

17 MS. LaRUE: Okay, great.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

24 So hopefully that answers the question.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MODERATOR LOPAS: Thank you, Vicki.

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

4 MR. SISKKA: Yes, I am.

5 MODERATOR LOPAS: Anything to add?

6 MR. SISKKA: I think, well, I think Vicki
7 pretty much answered the question head on.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

23 MODERATOR LOPAS: All right. Thank you,
24 Richard.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Donna-Beth, do you have any more questions?

2 Okay.

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

5 OPERATOR: Yes. Your line is open?

6 DR. CZERNIN: Just a few comments.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

12 MODERATOR LOPAS: Okay, thank you.

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

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

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

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

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

24 I just wanted to raise the topic about

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

13 And, again, the point was brought up that
14 nuclear medicine advanced associates are going to be
15 practicing under supervision of nuclear physicians or
16 nuclear radiologists. But, again, the changes that
17 are happening or being discussed are pointing out that,
18 for example, a family medicine physician could obtain
19 authorized user status, an ophthalmologist could be
20 able to obtain authorized user status by just having
21 80 hours, two weeks of training.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

11 So just bringing that to your attention.

12 This is a discussion here you're having is about
13 physicians who are going to be authorized users who
14 have the responsibility, the ultimate responsibility
15 what complications those therapies going to have.

16 Thank you.

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

19 Tara, there was another comment?

20 OPERATOR: David, your line is open.

21 MR. BURPEE: Hi. Thank you again.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 to other who might not have as much.

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

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

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

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

24 For the radium, that's an interesting

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

12 So thank you.

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

15 MR. BURPEE: It is.

16 MODERATOR LOPAS: Okay, excellent.

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

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

21 MODERATOR LOPAS: Okay.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

24 So with that, have a great afternoon,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 everybody. Thank you so much.

2 (Whereupon, the above-entitled matter went
3 off the record at 2:37 p.m.
4