

Official Transcript of Proceedings
NUCLEAR REGULATORY COMMISSION

Title: Staff Evaluation of Training and Experience
 Requirements for Radiopharmaceuticals:
 Draft Approaches for Comment

Docket Number: (n/a)

Location: teleconference

Date: Thursday, May 23, 2019

Work Order No.: NRC-0336

Pages 1-66

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

+ + + + +

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

+ + + + +

STAFF EVALUATION OF TRAINING AND EXPERIENCE

REQUIREMENTS FOR RADIOPHARMACEUTICALS:

DRAFT APPROACHES FOR COMMENT

+ + + + +

THURSDAY,

MAY 23, 2019

The public comment meeting was convened
by teleconference, at 10:00 a.m., Sarah Lopas,
Facilitator, presiding.

NRC STAFF:

SARAH LOPAS, NMSS, Facilitator

MARYANN AYOADE, NMSS

CHRIS EINBERG, NMSS

IAN IRVIN, OGC

ALSO PRESENT:

JASPREET BATRA, Johns Hopkins University

SAMUEL MAHGEREFTEH, Nuclear Medicine Residents
Organization

MICHAEL PETERS, American College of Radiology

NEAL R. GROSS

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

JOHN WITKOWSKI, United Pharmacy Partners, Inc.

C-O-N-T-E-N-T-S

Opening Remarks

 Sarah Lopas.....3

Welcome and Introduction

 Chris Einberg.....4

Webinar Logistics

 Sarah Lopas.....7

The NRC Staff's Evaluation of the T&E Requirements
for 10 CFR 35.300

 Sarah Lopas.....8

The NRC Staff's Draft Approaches Regarding T&E

 Maryann Ayode.....20

How to Submit Written Comments and Next Steps

 Sarah Lopas.....32

Public Comment

 Samuel Mahgerefteh.....38

 John Witkowski.....42

 Jaspreet Batra.....47

 Samuel Mahgerefteh.....51

 Michael Peters.....63

Adjournment.....66

NEAL R. GROSS

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

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

2 10:03 a.m.

3 OPERATOR: Welcome and thank you for
4 standing by. At this time all participants are in a
5 listen-only mode until the question and answer
6 session of today's call. At that time if you would
7 like to ask a question, please press *1.

8 Today's conference is being recorded. If
9 you have any objections, you may disconnect at this
10 time.

11 I would now like to turn the meeting over
12 to Ms. Sarah Lopas. You may begin.

13 MS. LOPAS: Hi. Good morning,
14 everybody. Welcome to the NRC's public meeting or
15 webinar to accept comments on the staff's draft
16 approaches regarding training and experience
17 requirements for different categories of
18 radiopharmaceuticals.

19 My name is Sarah Lopas and I am the
20 project manager for the training and experience
21 evaluation. I'll be facilitating today's webinar and
22 running the webinar, and I'll be giving a portion of
23 the presentation.

NEAL R. GROSS

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

1 I'm joined here by my supervisor Chris
2 Einberg who is the Chief of the Medical Safety and
3 Events Assessment Branch in the NRC's Office of
4 Nuclear Material Safety and Safeguards; Ian Irvin,
5 who's a lawyer from our office of general counsel;
6 and Maryann Ayode, who is a health physicist on the
7 NRC's Medical Radiation Safety Team and the technical
8 lead on the training and experience evaluation.
9 Thanks for joining us today.

10 So we have a short agenda. In a moment
11 I'm going to hand it over to Chris to give a welcome
12 and purpose. I'm going to run through some webinar
13 information. Then myself and Maryann will go through
14 the slide set. And I'm going to cover just a very
15 brief background on the T&E evaluation. Maryann will
16 go through the draft approaches. And then we'll open
17 it up to your comments. The rest of the time will be
18 for your comments on the record.

19 So now I'm going to hand it over to Chris
20 Einberg to talk about the purpose of today's webinar.

21 MR. EINBERG: Okay. Thank you, Sarah.

22 Yes, and good morning, everyone. Thank
23 you for taking the time to attend today's webinar.
24 Today's webinar is the second of two public comment
25 meetings that the NRC is holding on the staff's draft

NEAL R. GROSS

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

1 approaches regarding training and experience
2 requirements for administering radiopharmaceuticals
3 requiring a written directive.

4 The purpose of this webinar is to provide
5 you with an updated status evaluation on the training
6 and experience under Subpart E of 10 CFR Part 35 to
7 discuss the draft approaches regarding the training
8 and experience requirements that the staff are
9 currently considering and then to listen to and record
10 your comments on those draft approaches.

11 Before we get into the rest of the staff's
12 presentation, I wanted to provide some context as to
13 why the NRC decided to open a second public comment
14 period and hold two additional meetings.

15 Back in the late fall of 2018 and through
16 January 2019 the NRC conducted an initial public
17 comment period on the staff's plan and evaluation of
18 training and experience requirements for
19 radiopharmaceuticals requiring a written directive.
20 The staff reviewed and processed all the comments
21 received during that time, whether they are captured
22 in transcripts from the public meetings or submitted
23 as written comments using regulations.gov.

24 Based on the feedback received and the
25 sentiment from the public comments the staff formed

NEAL R. GROSS

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

1 some preliminary ideas on how the staff could address
2 the Commission's direction to evaluate whether it
3 makes sense to create tailored training and
4 experience requirements.

5 Some of the preliminary ideas, which we
6 are calling draft approaches, go beyond creating a
7 limited training and experience pathway or certain
8 pathways for certain categories of
9 radiopharmaceuticals. For instance, some of the
10 staff approaches are more performance-based and would
11 then prescribe a set number of hours of training and
12 experience.

13 We thought that some of the draft
14 approaches were different enough from what was
15 discussed during the initial public comment period
16 that it would be helpful for everyone if we had a
17 second public comment period to introduce and talk
18 about those draft approaches and get early feedback
19 from the medical regulatory community. And that's
20 why we're here today.

21 The comments we receive today and
22 throughout the rest of the comment period will help
23 shape the approaches we would include in our upcoming
24 paper for the Commission. We will include comment
25 summaries in our paper so that the Commission will be

NEAL R. GROSS

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

1 informed on stakeholders' positions and the training
2 and experience requirements.

3 So I want to thank you once again for
4 participating in today's webinar and I'll turn it
5 back over to Sarah.

6 MS. LOPAS: Thank you, Chris.

7 So just some general information. A PDF
8 of the presentation and a copy of the May 2nd *Federal*
9 *Register* notice that we're going to be referencing a
10 lot today is attached to your webinar. It's under
11 the handouts tab of your webinar. If you're not
12 logged into the webinar, you can also get those slides
13 from the meeting notice that was published for today
14 and also the NRC's Training and Experience web site.
15 So if you just Google NRC training and experience
16 evaluation, that -- the first result that comes up is
17 our web site that I maintain. And then our public
18 meeting notice, you can just Google NRC public
19 meetings and you can find today's notice that way.

20 As most of you are probably familiar, we
21 refer to training and experience often as just T&E.
22 And the same thing goes for authorized users. We say
23 AU a lot. So you'll hear T&E and AU today.

24 Today's webinar is being transcribed by
25 a court reporter so we can accurately capture your

NEAL R. GROSS

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

1 comments for the docket, and the transcript of this
2 webinar will be publicly available in about one week.
3 I'll be posting a link to the transcript on the NRC's
4 Training and Experience web site that I must
5 mentioned. And I'll also be posting it to the docket
6 site for T&E on regulations.gov.

7 So already the transcript from May 14th
8 is available in both of those locations, so if you
9 want to find the May 14th transcript. And I will be
10 producing a meeting summary in the next day or two
11 from the May 14th meeting. So look for that as well.

12 And then I wanted to also just note that
13 oral and written comments have equal weight, so if
14 you speak up today, you don't need to submit them
15 again in writing via regulations.gov. You're welcome
16 to do so, but it's not a requirement.

17 On this next slide, slide 6, I just want
18 to begin by reminding everybody that when we talk
19 about T&E, we're talking about the requirements
20 specified under Subpart E of 10 CFR Part 35. And
21 Subpart E specifically covers unsealed byproduct
22 material that requires a written directive, or that
23 may be commonly referred to as therapeutic
24 radiopharmaceuticals. So when Maryann starts to go
25 through our draft approaches, these draft approaches

NEAL R. GROSS

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

1 applies to specifically to Subpart E.

2 So the NRC's T&E regulations under
3 Subpart E at 10 CFR 35.390 provide three ways that a
4 physician can authorized user to administer
5 radiopharmaceuticals requiring a written directive.
6 They can be board-certified by one of the NRC or
7 Agreement State-recognized medical specialty boards.

8 They can complete something that we call
9 the alternate pathway, which is specified under
10 35.390(b)(1). This involves 700 hours of total T&E,
11 which breaks down to at least 200 hours of classroom
12 and laboratory training plus another 500 hours of
13 supervised work experience. This alternate pathway
14 also requires preceptor attestation.

15 And then the third way is to be
16 grandfathered by a previous NRC or Agreement State
17 license.

18 So I've highlighted that middle bullet,
19 the alternate pathway, because that's why we're here
20 today and that's what we're evaluating.

21 Since the T&E regulations were revised in
22 2002 and 2005, the NRC has received several instances
23 of feedback from the medical community stakeholders
24 that the 700-hour requirement is overly burdensome,
25 that doctors who want to treat their patients with,

NEAL R. GROSS

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

1 for example, patient-ready radiopharmaceuticals are
2 unable to do so because they can't leave their
3 practices for that length of time to complete the 700
4 hours of required T&E.

5 The stakeholders contend that because the
6 NRC's alternate pathway is discouraging non-nuclear
7 medicine and non-radiation oncology doctors from
8 becoming AUs, the T&E requirements are creating a
9 shortage of AUs in this country. Some of the
10 stakeholders also point out the disparity in patient
11 access to therapeutic radiopharmaceuticals in the
12 more rural parts of our country.

13 So over the years the Commission has
14 heard these concerns, and in 2017 they directed the
15 staff to examine the concerns. Specifically, the
16 Commission directed the staff to evaluate whether it
17 makes sense to establish tailored training and
18 experience requirements for different categories of
19 radiopharmaceuticals, how those categories should be
20 determined, such as risks posed by groups of
21 radionuclides or by delivery method, what the
22 appropriate training and experience requirements
23 would be for each category, and whether those
24 requirements should be based on hours of T&E or more
25 focused on competency.

NEAL R. GROSS

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

1 So in 2018 the staff did some initial
2 work in response to the Commission's direction and
3 the staff concluded that while it may be feasible to
4 create tailored T&E for certain categories of
5 radiopharmaceuticals, and there could be ways to make
6 this T&E more competency-based, the staff needed more
7 outreach with the medical and regulatory community
8 before making a recommendation to the Commission.

9 So this outreach, as Chris mentioned in
10 his introduction, started last fall when we published
11 our initial *Federal Register* notice. That FRN opened
12 a 90-day public comment period on the T&E evaluation
13 and asking just general questions about the current
14 T&E requirements.

15 During that first comment period the NRC
16 received 144 written comments and 35 comments were
17 spoken during the four public meetings. All the
18 public meeting transcripts, public meeting summaries
19 and written comment submissions are available on the
20 T&E docket on regulations.gov. So if you go to
21 www.regulations.gov and in that search bar you put
22 the docket, which is NRC 2018 0230, the first result
23 that will come up will be the T&E docket. Click on
24 that and you can then kind of sort through all the
25 comments and transcripts and meeting summaries.

NEAL R. GROSS

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

1 So I'm going to outline at a very high
2 level what we heard during the last public comment
3 period, but I want to stress that a more detailed
4 summary of all the comments we received during the
5 first comment period and during this comment period
6 are going to be included as an enclosure with the
7 paper that we're developing for the Commission.

8 I'll also be making publicly available in
9 ADAMS a comment binning report that will show you how
10 we extracted each individual comment and how we
11 grouped similar comments together into what we call
12 comment bins. So you'll be able to review every
13 comment that we received on the T&E evaluation in two
14 larger reports that will be publicly available. And
15 these reports will become available when the
16 Commission paper becomes publicly available.

17 So what did we hear during the first
18 comment period? Citing concerns about quality of
19 patient care and worker and public safety, there was
20 strong opposition voiced to any changes in the T&E
21 requirements. We heard this opposition form the
22 nuclear medicine community and the related medical
23 specialty boards and professional societies.

24 Going hand in hand for this support for
25 maintaining the current T&E requirements was

NEAL R. GROSS

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

1 opposition to creating tailored T&E requirements that
2 would result in a limited authorized user. And when
3 I say a limited authorized user, I mean, for example,
4 an AU that would be only permitted to use a certain
5 type or category of radiopharmaceutical.

6 Opposition to creating a limited AU today
7 was primarily rooted in concerns about protecting the
8 health and safety of patients. Basically folks
9 thought that AUs needed to have the full depth of
10 knowledge to be an AU and not have some limited amount
11 of knowledge. Commenters also warned that limited
12 AUs could be motivated by financial gain versus what
13 was best for the patient.

14 And then on the other side of the spectrum
15 citing concerns about patient care and patient access
16 to medically-necessary radiopharmaceuticals, there
17 was also support for tailored T&E requirements. And
18 we heard this from physicians such as hematologists,
19 endocrinologists, oncologists and urologists who
20 wanted to be able to treat their patients with
21 radiopharmaceutical therapies, as well as from the
22 pharmaceutical industry, related trade groups and a
23 rural health care advocacy group. These groups
24 stated that creation of a limited AU pathway for
25 certain categories or types of radiopharmaceuticals

NEAL R. GROSS

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

1 could safely expand access to therapeutic
2 radiopharmaceuticals.

3 Other commenters supported limited AU
4 -- other commenters that supported limited AU
5 pathways pointed out that the NRC's T&E requirements
6 should be more risk-based and that in the NRC's
7 evaluation of the T&E requirement staff should
8 evaluate specific categories of radiopharmaceuticals
9 such as routes of administration, radiation
10 characteristics, preparation methods and unique
11 practice setting requirements as part of its overall
12 decision making process.

13 Some commenters pointed out that the
14 precedent has already been set with regulations
15 regarding T&E for administration of oral iodine-131.
16 And that T&E carve-out already exists for this
17 radiotherapy and the carve-outs work well.

18 Groups on both sides of the issues
19 presented the NRC with detailed lists of basic
20 radiation science and health safety topics and
21 clinical training and experience requirements that
22 they thought were necessary for either a full or
23 tailored T&E. And then there was mixed support for
24 moving toward the more competency-based evaluation of
25 proposed AUs. For example, such as requiring a

NEAL R. GROSS

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

1 formal radiation safety examination to become an AU
2 and potential periodic reassessments.

3 So the NRC has been and will continue to
4 coordinate with both the Advisory Committee on the
5 Medical Uses of Isotopes, the ACMUI, and the Agreement
6 States. The next two slides will cover those
7 entities.

8 So in mid-February the ACMUI Subcommittee
9 on Training and Experience issued their draft report
10 on T&E for radiopharmaceuticals under Subpart D. A
11 public teleconference was held on February 26th, 2019
12 with the Full ACMUI and NRC staff, and during the
13 telecon the Full Committee endorsed the
14 Subcommittee's draft report and the positions and
15 recommendations in that report. The ACMUI's
16 positions and recommendations are as follows:

17 The Committee strongly supports and
18 reaffirms their 2016 submission on maintaining the
19 current and existing AU pathways; that is, the board
20 certification and the alternate pathways, which the
21 Committee believes are adequate for protecting public
22 health and safety. The Committee backed up this
23 position by stating that radionuclide therapy poses
24 the highest risk and highest impact of all nuclear
25 medicine procedures.

NEAL R. GROSS

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

1 The Committee concludes that there's no
2 objective data to confirm an AU shortage.

3 The Committee does not recommend a
4 limited- scope AU pathway for radiopharmaceuticals
5 requiring a written directive.

6 And the Committee agreed that in order to
7 ensure the safety of patients, personnel and the
8 public if the NRC chooses to pursue the creation of
9 a limited-scope AU pathway, the AU candidate must
10 acquire all of the basic knowledge topics currently
11 in 10 CFR 35.390 and the AU must satisfactorily
12 complete a formal competency assessment.

13 The Committee further recommended that
14 the individual's continued status as a limited-scope
15 AU should be dependent on successfully completing
16 formal periodic reassessments of radiation safety
17 competency.

18 Slide 10 talks about what we heard from
19 the Organization of Agreement States. The NRC has
20 been coordinating with the board and other members of
21 the Organization of Agreement States as a conduit for
22 all 38 Agreement States. In their comment submission
23 dated January 29th, 2019 the Organization of
24 Agreement States reiterated their position on the
25 adequacy of the current T&E requirements from when

NEAL R. GROSS

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

1 the NRC reached out to them before in early 2018, and
2 that position was that most Agreement States find the
3 current AU pathways to be reasonable and accessible
4 to physicians wishing to administer
5 radiopharmaceuticals.

6 There was not however a consensus opinion
7 among the Agreement States on whether there was a
8 need to create tailored T&E requirements. Some
9 states were open to exploring the idea of created
10 limited AU pathways while other states felt that
11 creating new limited pathways would just add
12 unnecessarily complexity to what are already complex
13 regulations.

14 The OAS did close out their comment
15 submission with a suggestion that the NRC consider a
16 less prescriptive approach to T&E, that perhaps
17 putting regulatory focus on whether licensees are
18 complying with 10 CFR Part 35.41, which is our
19 regulation pertaining to written directives, and also
20 focusing on the compliance of regulations regarding
21 radiation protection at 10 CFR Part 20, that that
22 approach could be a more effective way to regulate
23 medical licensees.

24 Slide 11 is recycled from old meetings on
25 this topic, but I thought it was important to include

NEAL R. GROSS

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

1 because it shows where we are in this evaluation.
2 The staff's current evaluation of T&E is not a
3 rulemaking, so I wanted to clarify that. But there
4 is a connection between this evaluation and the
5 rulemaking process, and that connection is that the
6 outcome of this evaluation could potentially be that
7 the staff recommends to the Commission that the NRC
8 should conduct a rulemaking that would amend the T&E
9 requirements.

10 I have the first box, Input for Medical
11 Stakeholders, highlighted on this slide because we're
12 still in that phase as we were back in the fall and
13 winter. And just as it did back then, the statement
14 is true now: Your input will help us refine or edit
15 the draft approaches that we've come up with and will
16 determine whether or not they should be included in
17 our paper that we're developing for the Commission.

18 Once we deliver our paper to the
19 Commission, the Commission will review and consider
20 the staff options and the staff's recommended path
21 forward and the Commission will make the ultimate
22 determination on how the staff should proceed,
23 whether that involves a rulemaking or not.

24 So that brings us back to where we are
25 today and we're here to listen to your comments on

NEAL R. GROSS

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

1 the draft approaches that were outlined in our May
2 2nd, 2019 *Federal Register* notice. The link to that
3 FRN that outlines the draft approaches is on this
4 slide, but you can also just Google the *Federal*
5 *Register* notice citation, which is 84FR18874, and
6 that will bring it right up for you.

7 We would like your feedback on the draft
8 approaches and also responses to a number of questions
9 that we have asked in the FRN. And in a moment
10 Maryann is going to walk us through those draft
11 approaches, and later on I'll also run through the
12 questions that are in the FRN, but I do want to note;
13 and this is very important, so if you're sleeping,
14 wake up, that we -- just today we published a *Federal*
15 *Register* notice that extends the comment period for
16 this effort.

17 So the comment period was originally June
18 3rd; and that's what you'll see in this *Federal*
19 *Register* notice that I have cited on this side, but
20 it has now been extended to Wednesday, July 3rd, 2019.
21 That's a 30-day extension. And we granted that
22 extension in response to several requests from
23 stakeholders asking us for more time to comment on
24 this important FRN. So just to reiterate, Wednesday,
25 July 3rd is the new comment due date. We have no

NEAL R. GROSS

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

1 more public meetings. Today is the last public
2 meeting on this topic.

3 All right. At this point I am going to
4 hand it over to Maryann Ayoadé to walk us through the
5 options, or the draft approaches.

6 Maryann?

7 MS. AYOADE: Thank you, Sarah.

8 So in the following slides you will see
9 that we have numbered and listed the draft approaches
10 using the same numerical headings as you will see in
11 the *Federal Register* notice. The same thing also
12 goes for the numbered questions that we are looking
13 to get feedback on. The questions have the same
14 number here in the slides as you will see in the
15 *Federal Register* notice. With these approaches that
16 we are presenting today, we want to emphasize that
17 all of the approaches are preliminary.

18 I also want to mention that some of these
19 approaches could add an additional pathway to the
20 existing pathways in the regulations for physicians
21 to become authorized users while some of these
22 approaches could modify the existing training and
23 experience regulations or keep the current
24 regulations as is.

25 So I will go into the approaches starting

NEAL R. GROSS

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

1 with this slide.

2 The first is the status quo approach.
3 This approach would maintain NRC's current training
4 and experience requirements, so radiopharmaceuticals
5 requiring a written directive. Here physicians would
6 still need to meet the training and experience
7 requirements under 10 CFR 35.300.

8 And so the questions that we would like
9 to get feedback on here is: If the status quo is
10 maintained, how should the NRC prepare itself for the
11 expected increase in the number and complexity of
12 future radiopharmaceuticals? The second question is:
13 Is there a challenge with NRC's current training and
14 experience requirements such as concerns that are
15 regarding patient access to radiopharmaceuticals that
16 should be addressed through a rulemaking?

17 Next slide. This slide, slide No. 14,
18 discusses tailored training and experience
19 requirement approaches, and these four tailored
20 training and experience approaches would modify the
21 existing training and experience requirements for
22 radiopharmaceuticals.

23 The first three approaches, which are:
24 the limited authorized user for alpha or beta-
25 emitting radiopharmaceuticals; the limited authorized

NEAL R. GROSS

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

1 user for unit dose patient-ready
2 radiopharmaceuticals; and the limited authorized user
3 for anyone pertaining to radiopharmaceuticals. These
4 three approaches would require a set amount of
5 training and experience that would be tailored to the
6 specific radiopharmaceuticals.

7 The fourth approach, the emerging
8 radiopharmaceuticals approach. This approach would
9 tailor the training and experience requirements for
10 each new radiopharmaceutical as they would develop,
11 similar to the approach for regulation new
12 technologies that we currently have under 10 CFR
13 35.1000.

14 So the question we would like to get
15 feedback on here is: How should the complexity of
16 the radiopharmaceutical administration protocol be
17 considered in establishing the training and
18 experience requirements or the limited approaches?

19 Next slide. This is the first of the
20 four tailored training and experience requirement
21 approaches. This approach would allow for limited
22 authorized users to administer one or more of a
23 certain type of radiopharmaceutical, and in this case
24 the physicians that are seeking authorized user
25 status would be able to administer any alpha or beta-

NEAL R. GROSS

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

1 emitting radiopharmaceutical.

2 The training and experience that would be
3 required for the user is for the user to have
4 completed at least 400 hours of training and
5 experience of which 200 hours would be in classroom
6 and laboratory training plus a minimum of 200 hours
7 of supervised work experience that would be focused
8 on alpha or beta-emitting radiopharmaceuticals. This
9 approach would also require a preceptor attestation
10 similar to what the NRC's current regulations require
11 for the alternate pathway.

12 So the question that we would like to get
13 feedback on here is: How should the NRC categorize
14 radiopharmaceuticals that have mixed emissions?

15 Next slide. Again, just like the
16 previous approach, this approach would allow for
17 limited authorized users to administer one or more
18 specific radiopharmaceuticals. For this approach the
19 physicians that are seeking authorized user status
20 would be able to administer any unit dose patient-
21 ready radiopharmaceutical. Similar to the previous
22 approach the training and experience here would be
23 for the user to have completed at least 400 hours,
24 which includes 200 hours of classroom and laboratory
25 training plus a minimum of 200 hours of supervised

NEAL R. GROSS

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

1 work experience that would be focused on unit does
2 patient-ready radiopharmaceuticals. This approach
3 would also require a preceptor attestation.

4 So the question that we would like to get
5 feedback on here is: How should the NRC define
6 patient-ready?

7 Next slide. So this is a third type of
8 limited authorized user approach. Again, similar to
9 the previous two approaches, this would allow for
10 limited authorized users to administer one or more
11 specific radiopharmaceuticals. In this case the
12 physicians that are seeking authorized user status,
13 they would be able to administer any one of the T&E
14 radiopharmaceuticals.

15 The training and experience required here
16 would be similar to the last two limited authorized
17 user approaches that require at least 400 hours of
18 training and experience of which 200 hours would be
19 in classroom and laboratory training plus a minimum
20 of 200 hours of supervised work experience, which
21 would be focused on that one radiopharmaceuticals.

22 What is different in this approach than
23 the other limited authorized user approach is that if
24 the authorized user wants to administer any new
25 additional radiopharmaceutical that comes along

NEAL R. GROSS

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

1 that's different from what they have been authorized
2 for, that authorized user would need another minimum
3 of 80 hours of tailored supervised work experience.
4 And so this approach would also require a preceptor
5 attestation.

6 Next slide. This approach, the emerging
7 radiopharmaceuticals approach. It is the fourth of
8 the limited authorized user-type of approach. It
9 would mirror that of NRC's current regulations under
10 10 CFR 35.1000, which is for other medical uses that
11 do not fall under the other sections of the
12 regulations in Part 35. It would require that the
13 NRC conduct individual reviews of each new emerging
14 radiopharmaceutical so that they can determine the
15 specific training and experience requirements for
16 each radiopharmaceutical.

17 The training and experience requirement
18 here could be tailored to consider the potential
19 users, so these would be individuals that are not
20 your traditional nuclear medicine or radiation
21 oncology physicians. So that would be, for example,
22 a hematologist, a urologist or a medical oncologist
23 that would like to administer one of the new
24 radiopharmaceuticals that are coming up in the
25 future.

NEAL R. GROSS

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

1 And this approach would in turn be creating alternate
2 training and experience pathways for each new
3 radiopharmaceutical.

4 Next slide. This slide, slide No. 19,
5 presents performance-based approaches, the first of
6 which is a competency-based evaluation approach, and
7 the second a credentialing of authorized users
8 approach. These two approaches would remove
9 prescriptive training and experience requirements
10 from the regulations and instead it would focus on
11 oversight -- it would focus oversight on the
12 performance-based assets of a licensee's medical
13 program's radiopharmaceutical administration.

14 Next slide. The first performance-based
15 approach, the competency-based evaluation. This
16 would require that proposed authorized users
17 demonstrate competency in radiation safety topics and
18 radiation safety-related job duties through a formal
19 evaluation. And so for example, an examination or a
20 preceptor attestation that would be something that
21 would be used to assess or confirm that the individual
22 is able to function independently as an authorized
23 user for the uses that are being requested.

24 So the question that we would like to get
25 feedback on under this approach is: Does a

NEAL R. GROSS

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

1 competency-based evaluation as it relates to
2 radiation safety job duties and topics ensure
3 appropriate training and experience for authorized
4 users? And if so, how?

5 Next slide. So the second performance-
6 based approach is the credentialing of authorized
7 users. In this case the NRC would no longer be
8 involved in the review and approval process for users'
9 training and experience under Part 35. Instead,
10 licensees would be -- would have to develop and use
11 their own policies and procedures to make self-
12 determinations as to whether their credential
13 submissions have the appropriate training and
14 experience to be an authorized user. Also licensees
15 would be required to maintain their own training
16 programs to ensure compliance with the requirements
17 for having procedures for administrations requiring
18 written directives in 10 CFR 35.41. And also the
19 requirement for radiation protection in 10 CFR Part
20 20.

21 So the question we would like to get
22 feedback on here is: How could physicians in smaller
23 practices be credentialed? So this is referring to
24 physicians that are not associated with hospitals or
25 other larger institutions with credentialing boards

NEAL R. GROSS

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

1 that we typically see that would review and approve
2 the physicians before they can practice at that
3 facility.

4 Next slide. This slide, slide No. 22,
5 presents team-based approaches. And so for the first
6 two approaches the radiopharmaceutical team and the
7 approach that involves teaming authorized users with
8 authorized administrators who could introduce some
9 new users. I want to point that these two approaches
10 would be more performance-based. And so this would
11 mean that the prescriptive training and experience
12 requirements would be removed from the regulations
13 and it would put more emphasis on the licensee to
14 ensure that they have a program in place to
15 accommodate authorization for any new uses that are
16 being requested.

17 The third team approach, the approach
18 that involves partnering a limited trained authorized
19 users with an authorized user pharmacist. This
20 approach on the other hand would require a more
21 prescriptive training and experience requirement for
22 authorized users because of the authorized user's
23 more prominent in administrating
24 radiopharmaceuticals.

25 So just to summarize these team-based

NEAL R. GROSS

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

1 approaches, they would either be removing the
2 prescriptive training and experience requirements for
3 authorized users and would focus the training
4 requirements on the competency of the entire team
5 involved in the procedures or it would be revising
6 the current 700-hour training and experience
7 requirement for authorized users based on pairing the
8 authorized user with another individual's expertise
9 in administering radiopharmaceuticals. And I will
10 go over these approaches in the coming slides.

11 So the question that we would like to get
12 feedback on here is: For the team-based approaches
13 how should the authorized user's radiation safety
14 responsibilities be clearly distinguished from other
15 members of the team?

16 Next slide. Under this first team-based
17 approach the radiopharmaceutical team licensees would
18 be required to have a team to administer
19 radiopharmaceuticals. At a minimum the team would
20 consist of an authorized user, a radiation safety
21 officer and a nuclear medicine technologist. The
22 team could also include some additional members like
23 an authorized medical physicist, an authorized
24 nuclear pharmacist, health physicists or other
25 physicians that manage patient care.

NEAL R. GROSS

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

1 The training and experience for the team
2 in this approach would be performance-based and
3 licensees would be required to develop policies and
4 procedures that address how their teams would meet
5 the requirements in 10 CFR 35.31, to have procedures
6 for administrations that require written directives,
7 and also to meet the requirements in 10 CFR Part 20,
8 Radiation Protection.

9 Next slide. The second team-based
10 approach is one that would team up authorized users
11 with authorized administrators. And authorized
12 administrator here would be an individual that the
13 licensee would authorize to administer
14 radiopharmaceuticals. So for example, a nuclear
15 medicine technologist or a nuclear medicine exam
16 associate, which is comparable to a physician-
17 extended position or an extension of physician
18 services by other providers.

19 With this approach licensees would need
20 both an authorized user and an authorized
21 administrator to administer radiopharmaceuticals.
22 This approach would also be more performance-based
23 and the training and experience for the authorized
24 users would focus on written directives, patient-
25 released criteria and medical event reporting. The

NEAL R. GROSS

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

1 training and experience for the authorized
2 administrators would focus on radiation safety and
3 preparation and administration protocols and this
4 would be in addition to the training that is required
5 for the authorized users, which would be on written
6 directive, patient-released criteria and medical
7 event reporting.

8 Next slide. The third team-based
9 approach. This is one that would partner up limited
10 trained authorized users with authorized nuclear
11 pharmacists. This approach would require that an
12 authorized nuclear pharmacist must be present during
13 the administrations by an authorized user. It would
14 also require more prescriptive training and
15 experience requirements for the authorized users due
16 to authorized user's more prominent role in the
17 administration of radiopharmaceuticals.

18 This approach would also require that an
19 authorized user have at least 400 hours of training
20 and experience, and this training and experience for
21 the position partnering with an authorized nuclear
22 pharmacist to be more focused on supervised work
23 experience and position cases. And it would also
24 require a preceptor attestation.

25 The training and experience for the

NEAL R. GROSS

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

1 authorized nuclear pharmacist would remain as it is
2 currently listed in NRC regulations in 10 CFR 35.55.

3 The authorized user in this approach
4 would be -- still would be responsible for
5 administrations in accordance with the written
6 directives while the authorized nuclear pharmacist
7 could be responsible for all the other radiation
8 safety-related duties during the procedure.

9 And so the question that we would like to
10 get feedback on here is: How should the radiation
11 safety responsibilities be divided between the
12 authorized user and the authorized nuclear
13 pharmacist?

14 Next slide. And so I will hand it over
15 to you to go over the rest of the questions in the
16 FRN.

17 MS. LOPAS: Okay. Thank you, Maryann.

18 So the next three slides are additional
19 questions we have in the FRN that are related to the
20 draft approaches. I'm actually going to hold off on
21 those for just a minute because -- and I'll come right
22 back to them. So you'll see why in just a minute.
23 So let me just skip through and we'll come back.

24 So what I do want to go to is slide 29,
25 which is how you can submit your written comments.

NEAL R. GROSS

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

1 So as I said earlier, the new comment due date is
2 July 3rd. And so you just go to regulations.gov and
3 you submit your comments that way. You can either
4 just type directly in the text box on regulations.gov
5 or you can upload any kind of document, a Word
6 document, a PDF. I think -- I'm not sure what you're
7 limited to, but a Word document and PDF would
8 certainly be up-loadable.

9 I have here the link to the direct comment
10 submission link, but it's very easy to navigate
11 regulations.gov, I think.

12 I will note that when you go to
13 regulations.gov right now, you will see two "comment
14 now" buttons. Both are valid. You can click either
15 one of those buttons. The reason why there is two is
16 because we just published that new FRN today that
17 extended the comment period and it's almost like
18 -- one comment period ends June 3rd. That's one
19 button. And then the second button is for the comment
20 period ending on July 3rd. So you could hit either
21 comment now button. I'm assuming that the June 3rd
22 one will go away as of June 3rd, but that will leave
23 the July 3rd comment button. So don't be confused
24 when you go to regulations.gov and see that. You
25 can't make a mistake. I'll just put it that way.

NEAL R. GROSS

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

1 Either one is fine.

2 Also note that it does take about 11
3 working days for your comments to show up on the
4 public facing side of regulations.gov. Unfortunately
5 we don't have any control over that. That's just how
6 long it -- it's an administrative process. It just
7 takes that long. However, we do receive your
8 comments immediately. I can access your comments
9 immediately. I check in regulations.gov daily to see
10 what has come in.

11 Your comments will also be in ADAMS. And
12 as I mentioned before, we're also going to -- we're
13 also going to be putting the comment summary reports
14 in our paper to the Commission.

15 And I do just want to note that because
16 this is not a rulemaking. We're not going to be
17 responding to individual comments, but like I said,
18 we'll be summarizing them. And we really do
19 thoroughly process and review them.

20 Here are the next steps for the T&E
21 evaluation. So this slide has been revised from when
22 we met last on the -- on May 14th. So the comment
23 period goes from May 2nd through July 3rd. In the
24 month of July we're going to evaluate the comments
25 that came in. We're going to finish developing the

NEAL R. GROSS

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

1 draft Commission paper.

2 Then the ACMUI and the Agreement States
3 both receive some time to provide us comments on that
4 draft Commission paper. And I think what will be
5 important to note is that in mid to late-October the
6 ACMUI T&E Subcommittee will be holding a public
7 teleconference where they will be discussing their
8 draft comments on our draft paper, or their comments
9 on our draft paper with the entire Subcommittee with
10 NRC staff. And that's a telecon that if you're
11 interested, you can call into and listen into. And
12 I believe you can make comments at the end of that
13 teleconference. Don't quote me on that, but you can
14 certainly call in and listen to that.

15 So the best way to be notified about when
16 that telecon is going to be scheduled is by joining
17 the NRC's Medical List Server and signing up for the
18 medical list server. So if you Google NRC Medical
19 List Server, the first result that comes up is how to
20 subscribe to that. And that's just a notification
21 where that's how we send out all the news related to
22 our medical regulatory activities like these meeting
23 notices, any reports that we issue, et cetera. So I
24 think it would be a good idea to sign up if you're
25 interested.

NEAL R. GROSS

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

1 Then following that ACMUI Subcommittee
2 public teleconference we'll finalize our Commission
3 paper. And we hope to -- pending no other delays, we
4 hope to deliver the paper to the Commission at the
5 very end of the year in late-2019, but we will keep
6 you posted if that changes.

7 So here you go. Here are some links for
8 more information. As I mentioned before, the T&E
9 evaluation web site. I try to keep that updated. As
10 I mentioned before, you can go to the regs.gov docket
11 and get a bunch of good information and comments.
12 And of course myself and Maryann are always here for
13 your questions and for more information if you need
14 it. Maryann is our technical point of contact
15 as a health physicist, so she's good for technical
16 questions. And I am the project manager. So if you
17 have process-type questions, you can send them my
18 way.

19 And if you have any issues submitting comments on
20 regulations.gov, if you're at all worried that your
21 comment didn't go through, you can go ahead and email
22 it to me or Maryann, or both of us, and we will make
23 sure that it gets covered, or it gets included.

24 And so now we come to the comment portion
25 of the webinar. And so what I want everybody to do

NEAL R. GROSS

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

1 is if you want to speak a comment over the phone,
2 Allison is our operator. She's going to help us out
3 with that. So all you do is press *1 on your phone.
4 So you can go ahead and do that now if you know right
5 away that you want to make a comment. Just press *1
6 and they'll -- and start a line.

7 And you can also submit shorter comments
8 and questions over -- using the webinar function, the
9 question function. I'm going to emphasize shorter
10 because it's hard to read very long questions or
11 comments on the -- via the webinar. So go ahead and
12 do that now. And press *1 to make a comment and do
13 your -- and -- or ask a question.

14 And while everybody's getting set up to
15 do that, I am going to run back through the questions
16 because I wanted to give folks time to get in line to
17 make their comment or ask their question. And I'm
18 going to run through the additional questions that
19 are in the FRN while everybody's doing that.

20 So in the FRN we have these additional
21 questions that apply to most of the draft approaches,
22 and we would really appreciate the medical
23 community's and regulatory community's input on these
24 questions.

25 So question 10: What are the advantages

NEAL R. GROSS

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

1 and disadvantages of the draft approaches?

2 Question 11: Are there significant costs
3 or benefits associated with any of the approaches?

4 Question 12: Would any of the draft
5 approaches impact patient access to
6 radiopharmaceuticals or address the stakeholder
7 concerns of overly burdensome regulatory
8 requirements?

9 Question 13: For the draft approaches
10 that consider tailored hours of T&E what are the
11 appropriate numbers of hours and what radiation
12 safety topics should comprise the limited T&E?

13 Question 14: Should the NRC consider
14 incorporating a formal radiation safety competency
15 assessment and periodic reassessment for any of the
16 draft approaches above? If so, who should establish
17 and administer these assessments?

18 Question 15: How would the draft
19 approaches impact the medical organizations that use
20 the NRC's T&E requirements as a basis for establishing
21 their training program?

22 Question 16: Are there concerns
23 regarding implementation and/or viability for any of
24 the approaches discussed?

25 Question 17: Are there any unintended

NEAL R. GROSS

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

1 consequences of the draft approaches?

2 Question 18: Which of the draft
3 approaches best position the NRC to effectively
4 regulate future radiopharmaceuticals?

5 And Question 19: Should the NRC continue
6 to play a role in the review and approval of
7 authorized users?

8 So those are our questions. Let's go
9 back to the comment -- how to make your comments. So
10 *1.

11 Allison, do we have anybody on the phone?

12 OPERATOR: Yes, we do have a question or
13 a comment from Samuel.

14 Your line is open.

15 DR. MAHGEREFTEH: Hi, everyone. Thank
16 you very much for this opportunity.

17 The Nuclear Medicine Resident
18 Organization that I'm a part of, we're taking this
19 issue very seriously. We're a branch of the ACNM,
20 the College of Nuclear Medicine. And this is an
21 issue that we -- as you know from our prior responses
22 to questions like this, we take this very seriously
23 and we think that it's potentially very dangerous to
24 decrease the amount of training that's required for
25 people to be able to give radiopharmaceuticals.

NEAL R. GROSS

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

1 One of the things that I think isn't
2 spoken about enough is that in nuclear medicine you're
3 not just kind of treating everyone in the same way.
4 In nuclear medicine every single patient that comes
5 through the door is very unique. The reasons why
6 we're treating each patient as unique, the specific
7 tracer that we're giving and the specific molecular
8 agent that we're giving are all unique. And then you
9 have to consider things about the patients like their
10 diet, their medication, their home life.

11 We never -- you should know that when
12 people train in nuclear medicine we get to know the
13 patient days, sometimes a week in advance of the
14 patient ever coming to have the radiation
15 administered. We're looking at the study. We're
16 making sure it's appropriate. We're looking at
17 previous imaging. We're calling the clinician. One
18 of the reasons is because obviously we want to make
19 sure that these patients, a lot of whom are cancer
20 patients and have a very high expectation for accurate
21 treatment and diagnostics -- we want to make sure
22 that they're getting exactly what they need. That
23 goes without saying.

24 Another thing that people don't think
25 about is these procedures that we do in nuclear

NEAL R. GROSS

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

1 medicine are extremely expensive. And if you have a
2 patient come in and there's the slightest error in
3 the way that the tracer is handled and the kind of
4 treatment the patient should be getting, which again
5 is very personalized in every case, you've lost per
6 treatment tens of thousands of dollars sometimes.
7 And that I think as molecular therapies and
8 theranostics and things become more clinically
9 relevant for us, this kind of economic hit to our
10 practice can't be tolerated. I think we're risking
11 getting into a situation where we're experimenting
12 with patients' health and the -- kind of the economics
13 of our community.

14 And I hope that as this conversation goes
15 on these issues, specifically the fact that patients
16 are really very, very unique in nuclear medicine
17 -- it's unlike anywhere else in imaging when people
18 come in for nuclear medicine diagnostics and therapy.
19 They're treated as individuals in a highly
20 personalized way.

21 MS. LOPAS: Thank you, Samuel. Do you
22 mind providing your last name for the transcript?

23 DR. MAHGEREFTEH: Sure. It's
24 Mahgerefteh. M like Mary, A-H-G-E-R-E, F like Frank,
25 T-E-H. Again, I'm speaking kind of personally, but

NEAL R. GROSS

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

1 also some of the ideas that I'm communicating here
2 are the ideas of ACNM and the Nuclear Medicine
3 Resident Organization. And you can actually
4 -- people can look at our online publications to see
5 more details of what nuclear medicine training is
6 like.

7 One thing in particular comes to mind is
8 the *Scintillator*, which is our quarterly online
9 publication. The *Scintillator*. You can read about
10 how the dedicated nuclear medicine training gets us
11 ready to really deal with each patient on a very
12 personalized way.

13 MS. LOPAS: Okay. Samuel, we appreciate
14 those comments. Thank you.

15 DR. MAHGEREFTEH: Thank you very much.

16 MS. LOPAS: Okay. Allison, do we have
17 another commenter on the line?

18 OPERATOR: Yes, our next question or
19 comment is from John Witkowski.

20 Your line is open.

21 MR. WITKOWSKI: Thank you. This is John
22 Witkowski with UPPI and I want to thank the NRC and
23 the Project Committee to allow more comment publicly
24 and to actually extend those comments for all the
25 questions and information being sought to have time

NEAL R. GROSS

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

1 to make submissions to that regard.

2 I do appreciate as you gave the
3 presentation today to talk about those that have
4 opposed to the training and education tailoring of
5 hours and to bring up some very fine points, but it's
6 also points that we can use in understanding how we
7 can provide other information to support a variation.
8 I also liked the comments from the Agreement States
9 that they have a concern that there could be
10 complexity added to the inspection and evaluation of
11 the programs and that could be put forward. And that
12 needs to be taken in consideration, too.

13 I can remember in our experience that
14 there was a time in cardiology where nuclear
15 cardiologists were able to receive limited training.
16 And that led to an evolution within nuclear cardiology
17 to a societal formation to a board certification and
18 to working with nuclear medicine and radiology.

19 I just want to take a couple moments to
20 speak about two things that are of interest with UPPI,
21 and that's one of the things that we submitted was
22 the idea of a radiopharmaceutical team and also
23 training for potential users, non-nuclear medicine,
24 non-radiology.

25 In our industry we're faced right now

NEAL R. GROSS

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

1 with the U.S. Pharmacopeia making changes to their
2 chapter on sterility, Sterile Preparation 797, and
3 devising a new Chapter 825 for Radiopharmaceutical
4 Preparation. I believe that this has come about as
5 a means that the industry is improving and moving
6 forward. There's new radiopharmaceuticals to come
7 to the marketplace and there needs to be further
8 definition of operations within the space of
9 preparation of radiopharmaceuticals. And I believe
10 there's a parallel to what we're discussing today.

11 I know from the regulations that everyone
12 can look up, and we've elicited it earlier, that there
13 is specific training for an authorized user and there
14 is specific training for an authorized nuclear
15 pharmacist. A lot of these trainings are parallel.
16 And there is also other expertise that both of the
17 parties have.

18 So with regards to a limited trained
19 authorized user perhaps teamed with an authorized
20 nuclear pharmacist, this is where the two can
21 complement each other in their experience and
22 definition of how the product could be administered
23 safely to the patient and radiation safety concerns
24 could be handled adequately with a teaming approach.

25 It is of notice that we do need to

NEAL R. GROSS

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

1 distinguish what are the radiation safety
2 responsibilities for any team that comes together.
3 Some of that is already done, but as we look at new
4 radiopharmaceuticals that come to the marketplace
5 that would involve alpha and beta therapy, whether
6 it's an injection for metastatic spread as opposed to
7 an injection of a much higher amount of radioactivity
8 for an ablation, those things need to be defined. I
9 believe that these can be done.

10 I also believe that there's been
11 submissions of what could be a potential training
12 program for limited trained authorized user, a non-
13 radiologist, non-nuclear medicine, and those things
14 can be used as a format to work out something that
15 would be a training program tailored for a specific
16 approach.

17 We think this is important because we
18 believe there needs to be an outreach to be able to
19 cover adequately the quality of care and the
20 availability of care to patients that need therapies,
21 radiotherapies, alpha and beta-type of therapies, and
22 that it can be done in an adequate and safe -- and
23 can be monitored and defined by these programs using
24 a radiopharmaceutical team or a partner relationship
25 with a limited-trained authorized user. And that's

NEAL R. GROSS

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

1 what we will address in further communications to the
2 NRC and the project management team. Thank you.

3 MS. LOPAS: Okay. Thank you, John.

4 So to make a comment over the phone, press
5 *1. And you can also submit your shorter comments or
6 questions using the webinar question function. So
7 you can do either of those.

8 Allison, do we have another comment or
9 question on the phone?

10 OPERATOR: We have no further questions
11 or comments at this time.

12 MS. LOPAS: Okay.

13 MS. AYOADE: Hey, Sarah, this --

14 MS. LOPAS: Hi, Maryann.

15 OPERATOR: One more just came in.

16 MS. LOPAS: Okay. Hang on one second.
17 We're going to let Maryann Ayoade speak, and then
18 we'll go to the next commenter.

19 Maryann?

20 MS. AYOADE: Yes, I just wanted to point
21 out for clarification, I did this at the last meeting
22 that we had because we did have a similar comment
23 about the training for the authorized nuclear
24 pharmacist being similar to what you see for the
25 training on the currently required for

NEAL R. GROSS

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

1 radiopharmaceuticals as it relates to the alternate
2 training pathway and the hours of training.

3 The authorized nuclear pharmacists, they
4 do have an alternate pathway that requires 700 hours
5 of training, but then the difference here is that the
6 supervised work experience is supervised practical
7 experience in a nuclear pharmacy. And so they would
8 be required to look at some similar things as they
9 relate to maybe radiation safety surveys and
10 calculations, but it's different than the work
11 experience that's in the 700-hour requirement for the
12 authorized users because that work experience
13 includes experience with administering doses.

14 So for the different types of
15 radiopharmaceuticals they have work experience in
16 patient case work as it relates to, for example, oral
17 administrations of iodine-131 or any parenteral
18 administration because that's what's currently
19 required for the training and experience requirements
20 for the authorized users to administer
21 radiopharmaceuticals.

22 So I just wanted to clarify that point in
23 case it comes up, and it came up in the previous
24 meeting as well.

25 MS. LOPAS: Okay. Thank you, Maryann.

NEAL R. GROSS

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

1 That is helpful. We appreciate that.

2 Okay, Allison, we are ready for that next
3 comment.

4 OPERATOR: Okay. Next we have Jaspreet
5 Batra.

6 Your like is open.

7 DR. BATRA: Hello. Hi, my name is
8 Jaspreet Batra. I'm one of the residents getting
9 trained at Johns Hopkins and I'm getting trained in
10 peer nuclear medicine and I strongly echo the thoughts
11 of Maryann as well as also Sam who just spoke before
12 me.

13 And I certainly believe that we get
14 trained in nuclear medicine over three years as peer
15 nuclear medicine physicians and it requires all the
16 essential training to administer as well as review
17 and report nuclear medicine pharmaceuticals. And I
18 strongly believe that providing an alternate pathway
19 for people to do a short-term training is stupid.
20 And here we are treating patients, not guinea pigs,
21 and we should not be subjecting patients to such a
22 low level of trained physicians or support staff to
23 administer such therapies.

24 A pharmacist cannot do -- it's not their
25 scope of practice to treat patients with

NEAL R. GROSS

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

1 radiopharmaceuticals and a physician who's not well-
2 trained in nuclear medicine will not do an accurate
3 job. And we are subjecting patients to undue risk
4 and probably also increasing the health care cost.
5 And with that I strongly condemn any dilution of such
6 recommendations. Thank you.

7 MS. LOPAS: Thank you, Jaspreet, could
8 you spell your last name for us so we can get it for
9 the transcript?

10 DR. BATRA: Yes. I'll give you my first
11 and last name.

12 MS. LOPAS: Okay.

13 DR. BATRA: First name is Jaspreet. It's
14 spelled as J as in Joseph, A as in apple, S as in
15 -- sorry, J as in Joseph, A as in apple, S as in Sam,
16 P as in Peter, R as in rose, E as in English, E as in
17 English, T as in Tango. So that's Jaspreet.

18 MS. LOPAS: Okay. Jaspreet.

19 DR. BATRA: And last name is Batra, B as
20 in boy, A as in apple, T as in Tom, R as in rose, A
21 as in apple. And I'm a second-year nuclear medicine
22 resident at Johns Hopkins Hospital.

23 MS. LOPAS: Excellent. Thank you,
24 Jaspreet.

25 DR. BATRA: Thank you.

NEAL R. GROSS

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

1 MS. LOPAS: Okay, everybody, *1 on the
2 phone. And as we've been saying start by providing
3 your name. You can also type a question or comment
4 in using the webinar, and I can read that aloud for
5 you.

6 Allison, do we have any other people on
7 the phone?

8 OPERATOR: No questions or comments at
9 this time.

10 MS. LOPAS: Okay. *1, everybody. So
11 11:01. So we're going to talk for a little while
12 longer. We're not going to end quite this early
13 because I know somebody out there wants to give us a
14 comment.

15 So, Allison, I'm going to run through
16 some of our questions again and if anybody hops on
17 the line, just feel free to interrupt me.

18 OPERATOR: Okay.

19 MS. LOPAS: And again, you can also
20 submit your question or comments by the question
21 function on the webinar, if you're logged into the
22 webinar.

23 So for question 10 we're asking about the
24 general advantages and disadvantages of the draft
25 approaches. And the NRC staff in our paper for the

NEAL R. GROSS

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

1 Commission will be outlining advantages and
2 disadvantages for each of the approaches that we put
3 forward in our paper. So we'll be doing this, but we
4 would like to hear from the medical and regulatory
5 community that will be impacted by potential changes.

6 Question 11, which is similar: What are
7 the significant costs or benefits associated with any
8 of the approaches? And again, NRC staff will be
9 coming up with a high-level cost-benefit analysis
10 looking at the approaches that we're going to put
11 forward in the paper. These will probably be costs
12 and benefits from our perspective, so we -- from a
13 regulatory perspective - we are really interested in
14 hearing the medical community's perspective on
15 potential costs and benefits associated with the
16 approaches? For instance, would benefits outweigh
17 some costs or vice versa? So that's what we're
18 looking there for question No. 11.

19 Question No. 12: How would any of these
20 approaches impact patient access to
21 radiopharmaceuticals or would they address the
22 concerns about overly burdensome regulatory
23 requirements? So that was kind of -- those two
24 concerns were kind of what got us here in this T&E
25 evaluation in the first place and we're looking to

NEAL R. GROSS

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

1 see if any of those approaches would help with that.

2 So what do you think?

3 OPERATOR: Excuse me. This is Allison.

4 We do have a comment on the phone.

5 MS. LOPAS: Hi, Allison. Excellent.

6 Let's hear it.

7 OPERATOR: All right. Samuel, your line

8 is open.

9 DR. MAHGEREFTEH: Hi, Samuel again. I'm

10 grateful for this opportunity to take advantage of

11 speaking as no one else is commenting. So I'd like

12 to ask a favor of anyone else that's going to be

13 speaking today.

14 I want to reiterate first of all

15 molecular imaging and therapy has boomed really

16 specifically because it allows personalization of

17 care. And I'd like for people who are commenting on

18 both sides, if you could, tell us how potential

19 changes to the training are going to include a kind

20 of training where the clinician will have had

21 experience in personalizing, really tailoring care to

22 each individual patient. I think that it's entirely

23 possible that a pharmacist may have a great fund of

24 knowledge and a deeper knowledge than even a nuclear

25 medicine trainee in terms of how radiopharmaceuticals

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 ought to be handled.

2 But in a clinical setting, in a situation
3 where you're dealing with an actual patient where you
4 have to consider everything from the patient's home
5 life, their diet, their exercise, who they're living
6 with and their exact diagnosis, their imaging
7 findings -- in a situation like that it's only
8 appropriate in my mind for therapy to be done by a
9 person who has had experience in tailoring the therapy
10 and the imaging to account for all of these very
11 unique factors. And again, in nuclear medicine one
12 of the things that we learn as trainee in nuclear
13 medicine is that every patient is unique.

14 So anyone who is commenting about
15 decreasing or changing the training standards, I'd
16 love if you could please comment on this on how the
17 training -- the proposed new kind of training is going
18 to account for this. How are you going to have
19 clinicians come on the field who have had hands-on
20 experience tailoring diagnostics and therapies,
21 theranostics for individual patients? Thank you.

22 MS. LOPAS: Okay. Samuel, thank you.
23 We appreciate that comment. And I want to -- and
24 maybe Maryann can jump in.

25 I'll get started and then, Maryann, as

NEAL R. GROSS

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

1 the technical lead, you can jump in.

2 But I do think there tends to be a blurred
3 line in the interpretation of what the NRC regulates
4 and the practice of medicine.

5 And, Samuel, what I'm hearing you discuss
6 is related to the practice of medicine, the experience
7 that comes with a very highly-trained nuclear
8 medicine physician knowing how to care for a patient,
9 whereas the NRC regulations are focused only on
10 radiation safety, how to safely handle these
11 materials. And that's the extent of what we try to
12 limit our T&E requirements to - radiation safety -
13 and not merge into patient care or practice of
14 medicine.

15 Maryann, do you have anything that you
16 want to follow up on with that?

17 MS. AYOADE: Not really. I think you hit
18 the nail on the head. I just maybe would point out
19 that as we're going through this evaluation and even
20 just in coming up with these approaches we were and
21 are always keeping in mind our medical policy
22 statement, which as Sarah alluded to, we are taking
23 into consideration and focusing on regulating the
24 radiation safety aspect of the patient care.

25 And so that's part of what our medical

NEAL R. GROSS

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

1 policy statement is and that's what we try to do as
2 we develop these options, and as we're moving forward
3 we're keeping that in mind. We don't want to intrude
4 into the practice of medicine unless it's necessary
5 to do so for radiation safety of the public, the
6 workers and the patient.

7 MS. LOPAS: Okay. Thank you, Maryann.

8 Samuel, I don't know if you're still on
9 the line, if you had anything you wanted to follow up
10 on.

11 DR. MAHGEREFTEH: Thank you. I
12 appreciate that. I realize what the role is for the
13 NRC. I appreciate your comment.

14 What I'm describing is something that is
15 -- all factors of a patient's therapy are interrelated
16 so that if, for example, a patient is being -- has a
17 different kind of home situation or if their therapy
18 requires a different kind of dose. All of these
19 factors have to be taken into consideration, and
20 there's an interplay. There's interplay between
21 getting the right therapy, the right amount of
22 therapy, factoring in how much radiation is going to
23 be involved, their home life. I don't think that any
24 of these factors can be taken in isolation. That's
25 what I mean when I say that these therapies are highly

NEAL R. GROSS

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

1 personalized.

2 If it was just a question of how much
3 radiation is coming out of this tube in isolation,
4 then of course the conversation would end there and
5 you could probably have a 10-minute conversation
6 about how much training is required to manage that
7 tube. But because we're talking about situations
8 where there's potential waste and mistreatment,
9 mismanagement, then all of these factors that are
10 interrelated I think have to come into consideration.
11 Thank you.

12 MS. LOPAS: Okay. Thank you.

13 Okay, everybody. *1. Maybe that jogged
14 some comments on everybody's part. *1 or you can
15 submit a comment via the webinar.

16 Allison, do we have anybody else on the
17 line?

18 OPERATOR: No further questions or
19 comments at this time.

20 MS. LOPAS: Okay. *1 if anybody wants to
21 follow up on that. I'll note related to that comment,
22 Samuel's comment, is that for some of the folks that
23 were in support of tailored T&E or limited T&E --for
24 some tailored category of radiopharmaceuticals, one
25 of the points that they brought up is they thought

NEAL R. GROSS

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

1 that the 700 hours that we currently require likely
2 includes clinical aspects, more clinical aspects,
3 patient care aspects -- under that training, and it's
4 not just limited to what we have listed in our topics
5 under 35.390(b)(1). So that's just what we heard,
6 that some of that 700 hours probably includes some
7 things that go beyond strict radiation safety and
8 what we require at the NRC. I don't know if that
9 will jog comments, too.

10 Allison, again just interrupt me if
11 anybody pops on the line.

12 I'm going to go back to these questions.
13 And again, you can submit your question or comment
14 via webinar, and I can read you it aloud if you'd
15 prefer it that way.

16 So I think we stopped at -- I can't
17 remember. We'll just go with Question 13. So for
18 the draft approaches that consider tailored hours of
19 T&E what would be the appropriate number of hours and
20 what radiation safety topics should comprise the
21 limited T&E? So for some of our limited approaches
22 we had specified at least 400 hours, and that broke
23 down to about 200 hours of classroom and laboratory
24 training, which is the same as what's required now
25 under the limited pathway, and then 200 hours of

NEAL R. GROSS

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

1 tailored focused supervised training experience.

2 So if you have ideas of a different number
3 or what should be covered under that, we would love
4 to hear that.

5 All right. Question 14 is should the NRC
6 consider inclusion of a formal radiation safety
7 competency assessment and periodic reassessments for
8 any of the draft approaches above? And if so, who
9 should establish and administer these assessments?
10 During our last public meeting on May 14th we heard
11 a number of people advocate for adding competency
12 assessments onto our existing regulations.

13 So I'm assuming that that means adding it
14 onto our alternate pathway, that our existing
15 alternate pathway should stay the same, 700 hours,
16 but we should add on an initial competency examination
17 at the end of that, plus some folks suggested an
18 annual reassessment of radiation safety competency.
19 Somebody suggested that that annual assessment should
20 be a laboratory exercise plus a graded quiz for the
21 annual assessment. So that was one idea that we
22 heard.

23 And it was noted by several members of
24 specialty boards like ABNM, American Board of Nuclear
25 Medicine, that they do -- obviously they have an

NEAL R. GROSS

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

1 examination clearly for their board, but then they do
2 periodic reassessments of competency as well. So
3 they thought that the alternate pathway should also
4 have regular reassessments as well.

5 Question 15. How would draft approaches
6 impact the medical organizations that use NRC's T&E
7 requirements as a basis for establishing their
8 training programs?

9 Maryann, I'm going to ask you to explain
10 this question a little bit, if you could.

11 (No audible response.)

12 MS. LOPAS: Maryann, you might be muted
13 still. Question 15?

14 MS. AYOADE: Hey, Sarah. Sorry. Yes, I
15 was muted. Okay. Sorry about that.

16 So the question was how would the draft
17 approaches impact the medical organizations that use
18 the NRC's training and experience requirements as a
19 basis for establishing their training programs?

20 So we know that some medical boards that
21 we see -- they also reference NRC's regulations as
22 part of their training requirements, not as the full
23 training. It's a part of their training curriculum.

24 I know we also see references to NRC's
25 regulations within the hospitals credentialing some

NEAL R. GROSS

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

1 kind of programs. So the hospitals -- like I
2 mentioned before, bigger hospitals or larger
3 institutions would have an additional credentialing
4 board that they use to review and approve their
5 physicians before they can actually let them practice
6 at that facility. And so part of their requirements
7 in addition to whatever it is that they have
8 established for that physician would be are they are
9 authorized users made with an NRC license or an
10 Agreement State license.

11 So this is what we're referring to in
12 terms of how would any of the draft changes that we're
13 examining -- how would they affect the organizations
14 that use NRC current training and experience
15 requirements? And so that's what we would like to
16 get feedback on.

17 MS. LOPAS: Okay. That was a good
18 explanation, Maryann. Thank you.

19 It kind of related to the next question.
20 And again, folks, please press *1. If you want to
21 interrupt me at any time, press *1. That's how you
22 get me to stop talking so you can talk. So *1 or
23 submit a webinar question.

24 Okay. So what Maryann was just talking
25 about, question 16, is are there concerns regarding

NEAL R. GROSS

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

1 implementation and/or -- or, excuse me, I'm going to
2 go 17. Question 17 related to what Maryann was
3 talking about a little bit.

4 Are there unintended consequences of
5 draft approaches? Are there any unintended
6 consequences? So I would almost say that what
7 Maryann was just discussing, how would these draft
8 approaches impact the other medical organizations?
9 That's kind of what we're talking about. That would
10 be an unintended consequence that we would not be
11 aware of and that's why we need your input on these
12 questions.

13 So skipping back to question 16, are
14 there concerns regarding implementation and/or
15 viability of any of the approaches discussed? And
16 these -- again, this is something where you're out
17 there in the field. Tell us if some of these
18 approaches just would not work. You just think, no,
19 that's impossible. This -- that wouldn't work
20 because of A, B or C. That's what we want to hear.

21 Question 18. Which of the draft
22 approaches best positions the NRC to effectively
23 regulate future radiopharmaceuticals? So we want to
24 make sure that we position the NRC to be ready for an
25 increased number of radiopharmaceuticals that are

NEAL R. GROSS

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

1 going to come down the line and potentially increase
2 complexity.

3 Or maybe the other side of the spectrum
4 some of these radiopharmaceuticals will evolve into
5 patient-ready doses, right? And so do patient-ready
6 doses need 700 hours of T&E in order for a physician
7 to be able to administer them? Especially let's say
8 a medical oncologist who may be familiar with the
9 toxicities of chemotherapy. Do they need 700 hours
10 to administer a patient-ready dose? So that's
11 something to think about.

12 And then question 19. Should the NRC
13 continue to play a role in the review and approval of
14 authorized users? And that the big question and it
15 relates to our performance-based options. So we
16 would like to hear from you. Should the NRC continue
17 to be involved in this?

18 Okay. So those are our questions. *1
19 to make a comment or ask a question. It's 11:17.
20 I'm going to give folks some more time to jump in and
21 ask a comment, but if I don't hear anything in the
22 next few minutes or so, we might end early because I
23 don't know if you just want to sit here and listen to
24 me talk. So *1.

25 I will point out that we did hear

NEAL R. GROSS

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

1 statistics during last week's meeting, the meeting on
2 November -- or excuse me, May 14th that cited that
3 radiopharmaceutical therapy as a part of overall
4 nuclear medicine right now is at 13 percent and that
5 it's expected that by 2030 that percentage will
6 increase to 30 percent. So that's what we're
7 thinking about here.

8 We have this opportunity -- we've been
9 asked by the Commission to look at training and
10 experience for radiopharmaceuticals requiring a
11 written directive and we feel like we have an
12 opportunity to potentially suggest changes to our
13 regulations to the Commission that would set us up
14 for that future. So that's where we're coming from
15 with question 18. We want to hear your ideas on
16 that.

17 OPERATOR: Excuse me. This is Allison.
18 We have a comment.

19 MS. LOPAS: Okay, Allison. Great.
20 Thank you.

21 OPERATOR: Not a problem. Michael
22 Peters, your line is open.

23 MR. PETERS: Hi, this is Mike Peters from
24 the American College of Radiology. First I'd just
25 like to thank NRC staff for extending the comment

NEAL R. GROSS

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

1 period. It will be very helpful to us and to other
2 stakeholders.

3 And also something came up in these
4 conversations and sort of keeps coming up, but I would
5 ask the NRC to please refrain from using the
6 terminology patient-ready in its report and other
7 communications on the AU teaming issue. This is
8 really a reference to shipping of unit dose delivery
9 systems shipped by nuclear pharmacies versus cold
10 kits or generator-based prep.

11 But to the nuclear medicine resident's
12 earlier comments, it is irrelevant to a physician's
13 use of these therapies and actual patient care. So
14 the -- if you look at the FDA-vetted labeling and
15 pre-market documentation for these products, it does
16 not include this concept with regard to physician
17 services using the product.

18 So we would ask the NRC also to not use
19 this terminology which is weighted by industry to
20 intentionally diminish the responsibilities of AUs to
21 patients, care team members, regulators and the
22 public. Thank you.

23 MS. LOPAS: Thank you, Mike. We
24 appreciate that comment. And we do hope that your
25 -- ACR's comments that you submit to us in writing

NEAL R. GROSS

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

1 will expand upon that because we specifically asked
2 a question about that. So thank you.

3 Okay. I'm going to check here. We do
4 have a question here on the webinar. The question is
5 regarding the percentage I cited earlier - is that a
6 per microcurie or per procedure statistic?

7 Lisa, I'm not 100 percent sure. I think
8 that's number of procedures. The commenter's asking
9 about the 13 to 30 percent increase in
10 radiopharmaceuticals -- it's procedures - yes - -
11 it's referring to procedures.

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

14 OPERATOR: No comments or questions at
15 this time.

16 MS. LOPAS: Okay, folks. I'm going to
17 give you a couple more minutes and to give everybody
18 one last chance to press *1. I'm just going to again
19 review the comment procedure. So July 3rd. That's
20 a Wednesday right before you leave for your 4th of
21 July vacation. Get your homework in. And your
22 homework is to submit comments to us and help answer
23 your questions that we have and so we can make an
24 informed recommendation to the Commission.

25 If you have any issues again submitting

NEAL R. GROSS

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

1 your comments, you can email them to me:
2 sarah.lopas@nrc.gov.

3 And we have another question about the
4 reference on that increase in radiotherapies. That
5 was from I want to say -- was it the Cardinal Health
6 web site? Michael Guastella, I can find that
7 reference for you and send it to you. I have your
8 email. I can send you that reference.

9 MS. AYOADE: This is Maryann Ayoad. Are
10 you referring to that 13 percent?

11 MS. LOPAS: Yes.

12 MS. AYOADE: Yes, that -- I'm not sure
13 where it was from, but I know it was Dr. Greenspan
14 that brought it up, so I don't know if that helps.

15 MS. LOPAS: Yes, we had a commenter who
16 brought that up, but I -- we had seen that percentage
17 before, Michael, so I can find that link for you and
18 send it to you.

19 Okay. And let's see. I think that's
20 going to be it. One more chance. *1. I don't like
21 ending this early, but it really is a little bit of
22 radio silence and it's boring to talk to myself. But
23 I appreciate everybody who has talked to us, because
24 we do appreciate you. And thank you for your
25 comments. And if you would like to submit written

NEAL R. GROSS

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

1 comments, you know how to do it. And you know how to
2 get in touch with Maryann and myself. I'll go ahead
3 and put our emails up again. And I think that's
4 going to be it. So thank you all for your time and
5 we look forward to getting your comments and we will
6 review them thoroughly. So thank you and have a
7 great day.

8 OPERATOR: This now concludes today's
9 conference. All lines may disconnect at this time.

10 (Whereupon, the above-entitled matter
11 went off the record at 11:23 p.m.)

NEAL R. GROSS

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