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 Requirements for Radiopharmaceuticals:
 Draft Approaches for Comment

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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STAFF EVALUATION OF TRAINING AND EXPERIENCE

REQUIREMENTS FOR RADIOPHARMACEUTICALS:

DRAFT APPROACHES FOR COMMENT

+ + + + +

TUESDAY

MAY 14, 2019

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ROCKVILLE, MARYLAND

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The Session convened at the Nuclear
Regulatory Commission, One White Flint North,
Commissioners Hearing Room, 11555 Rockville Pike, at
1:00 p.m., Sarah Lopas, Facilitator, presiding.

NRC STAFF:

SARAH LOPAS, NMSS, Facilitator

MARYANN AYOADE, NMSS

LISA DIMMICK, NMSS

CHRIS EINBERG, NMSS

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ALSO PRESENT:

BETH BLANKENSHIP, American Association of
Physicists in Medicine (AAPM) *

MUNIR GHESANI, Society of Nuclear Medicine and
Molecular Imaging (SNMMI) *

SHAEMUS GLEASON, Bayer Healthcare

ERIN GRADY, American College of Nuclear
Medicine (ACNM) *

BENNETT GREENSPAN, SNMMI *

JUSTIN PEACOCK, Brooke Army Medical Center *

JOE RUBIN, United Pharmacy Partners (UPPI) *

DAVID SCHUSTER, Emory University *

GEORGE SEGALL, ABNM *

JEFF SIEGEL *

ARIF SHEIKH, Icahn School of Medicine at Mount
Sinai *

BRUCE THOMADSEN, AAPM

*Present via telephone

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P R O C E E D I N G S

1:01 p.m.

MS. LOPAS: Good afternoon, everybody.
Thank you for coming today, for joining us here in person at the NRC in Rockville and also to those of you who are on the phone and logged into the webinar.

Welcome to the NRC's public meeting and webinar to accept comments on the staff's draft approaches regarding training and experience for radiopharmaceuticals requiring a written directive.

My name is Sarah Lopas and I'm the Project Manager for the staff's evaluation. And, I'll be facilitating today's meeting and also be giving part of the presentation.

And, our operator's name is Shirley and she's going to be helping me out with taking comments over the phone.

I'm also joined here at NRC headquarters by my supervisor, Chris Einberg. Chris is the Branch Chief of the Medical Safety and Events Assessment Branch in our Office of Nuclear Materials Safety and Safeguard.

We also have Lisa Dimmick who's the team lead for the Medical Radiation Safety Team. She's also at the table with us.

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1 And also, Maryann Ayoade, and she's a
2 Health Physicist and she's the technical lead for the
3 T&E evaluation.

4 So, we have a short agenda for today
5 because we know that the main point is public comments
6 on our draft approaches. So, Chris is going to give
7 a welcome and talk about why we're here today.

8 Then, I will be giving the presentation
9 that will involve a very short background on why we're
10 here. Next Maryann will go through the draft
11 approaches and then we'll just -- I'll talk about how
12 you can provide your comments on the record.

13 And then, we'll just go immediately into
14 public comments.

15 We may or may not take a break. We'll
16 probably just end up going straight through. But,
17 you know, we're all adults, you can get up and the
18 bathrooms are right out the door to the left when you
19 go out these doors here.

20 All right, now I'm going to hand it over
21 to Chris.

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

23 Yes, and good afternoon, everyone. Thank
24 you for taking the time to attend today's meeting,
25 whether you are here in person or participating

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1 remotely.

2 Today's meeting is the first of two
3 public comment meetings that NRC will hold on the
4 staff's draft approaches regarding training and
5 experience requirements for administering
6 radiopharmaceuticals requiring a written directive.

7 The purpose of today's meeting and the
8 meeting on May 23rd are to provide you with an update
9 on the staff's evaluation on the training and
10 experience under Subpart E of 10 CFR Part 35, to
11 discuss the draft approaches regarding the training
12 and experience requirements that the staff are
13 currently considering, and, to listen to and record
14 your comments on those draft approaches.

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

19 Back in the late fall of 2018, and through
20 January 2019, the NRC conducted an initial public
21 comment period on the staff's plan and evaluation of
22 the training and experience requirements for
23 radiopharmaceuticals requiring a written directive.

24 The staff reviewed and processed all the
25 comments received during that time, whether they were

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1 captured in transcripts from the public meetings or
2 submitted as written comments using regulations.gov.

3 Based on the feedback received, and the
4 sentiment from the public comments, the staff formed
5 some preliminary ideas about how the staff could
6 address the Commission's direction to evaluate
7 whether it makes sense to create tailored training
8 and experience requirements for certain
9 radiopharmaceuticals.

10 Some of the preliminary ideas which we
11 are calling draft approaches go beyond creating a
12 limited training and experience pathways for certain
13 pathways for certain categories of
14 radiopharmaceuticals.

15 For instance, some of the staff's draft
16 approaches are more performance based and wouldn't
17 prescribed a set number of hours of training and
18 experience.

19 We thought that some of the draft
20 approaches were different enough from what was
21 discussed during the initial public comment period
22 that it would be helpful for everyone if we had a
23 second public comment period to introduce and talk
24 about those draft approaches and get early feedback
25 from the medical and regulatory community.

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1 And, that's why we are here today. The
2 comments we receive today and throughout the rest of
3 the comment period will help shape the approaches
4 we'll include in our upcoming paper for the
5 Commission.

6 We will include comment summaries in our
7 paper so the Commission will be informed on
8 stakeholders positions and the training and
9 experience requirements.

10 So, I want to thank you again for joining
11 us today and your participation is vital to our
12 decision making process.

13 Thank you.

14 Sarah?

15 MS. LOPAS: Thanks, Chris.

16 So, just some housekeeping stuff before
17 I move into the rest of my slides.

18 So, for those of you in the room, if you
19 haven't signed in, I ask that you please sign in on
20 your way out. I think everybody got the handouts
21 that are there.

22 We have the Federal Register Notice, the
23 May 2nd Federal Register Notice, and also, the copy
24 of today's slides.

25 If you're on the webinar, if you go to

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1 the handouts tab on your webinar, I have uploaded
2 those two handouts there on the -- under that tab so
3 you can go ahead and download those if you would like
4 them.

5 I'll also note that both the slides and
6 the FRN are also attached to the meeting -- today's
7 meeting notice. So, if you know how to find the NRC
8 public meeting notice, you can click through and find
9 the slides and the handouts there.

10 And, that could be helpful for you if
11 you're logged -- if you're on the bridge line but you
12 didn't log on to the webinar for whatever reason, you
13 can find the slides on our meetings notice and click
14 along right now.

15 So, we're on slide five right now, for
16 those of you that don't have access to the webinar.

17 During today's presentation and in the
18 slides, we often refer to training and experience as
19 T&E for short; and, authorized users as AUs.

20 We have a court reporter here today and
21 he is transcribing today's -- everything that's being
22 said today so that we're capturing your comments on
23 the record.

24 So, there's no preferred way to submit
25 your comments. You can submit written comments or

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1 you could speak them here today over the phone or
2 here in person. And, comments that are submitted by
3 writing and spoken here today carry the same weight.

4 So, if you feel like you've said your
5 peace today during the -- during today's webinar, or
6 on the call, or here, you know, in person, then you
7 don't need to submit duplicate written comments.

8 You're welcome to, but just letting you
9 know.

10 And so, it's important that everybody
11 speaks clearly, introduces themselves when they get
12 up to speak their comments later on.

13 So, we will be waiting -- holding off on
14 comments until the end of the presentation. And,
15 that's when we're done our presentation, we'll open
16 up the phone lines and Shirley's going to help us
17 out.

18 And, I will be managing the webinar as
19 well. And, I see somebody has already submitted a
20 question. So, just give me a moment and I'll check
21 that out.

22 But I'll be monitoring the webinar to see
23 if anybody's sending questions or comments through
24 that as we move forward.

25 So, let me start with a little bit of

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1 background.

2 So, I wanted to remind everybody that
3 when we talk about the T&E requirements, we are
4 talking specifically about those requirements under
5 Subpart E in 10 CFR Part 35.

6 So, Subpart E specifically covers the
7 unsealed byproduct materials requiring a written
8 directive. So, when Maryann gets to our draft
9 approaches later on, just keep in mind that they are
10 talking about changes to -- potential changes to just
11 those T&E requirements under Subpart E.

12 So, currently, our regulations at 10 CFR
13 35.390, and that's under Subpart E, provide three
14 ways a physician can become an AU to administer
15 radiopharmaceuticals requiring a written directive.

16 They can be board certified by one of the
17 NRC or Agreement State recognized medical boards.

18 Or, they can complete something that we
19 call the alternate pathway which is specified under
20 10 CFR 35.390(b)(1).

21 And so, this is where it's the 700 hours
22 total of T&E that breaks down to at least 200 hours
23 of classroom and laboratory training plus another 500
24 hours of supervised work experience.

25 Plus, that alternate pathway requires

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1 some case work and a preceptor attestation as well.

2 And then, the third way is to be
3 grandfathered by a previous NRC license or Agreement
4 State license.

5 So, I've highlighted that middle bullet,
6 the alternative pathway because that's why we're here
7 today and that's what we're evaluating.

8 Since those regulations were revised,
9 those tiny regulations were revised in 2002 and then
10 amended in 2005, the NRC has received periodic
11 feedback from medical stakeholders that the 700 hour
12 requirement is overly burdensome.

13 Doctors who would like to treat their
14 patients with, for example, patient ready doses of
15 radiopharmaceuticals are unable to do so because they
16 can't take the time to get that 700 hours of T&E.

17 So, some of these same stakeholders are
18 also contend that because the alternate pathway is
19 discouraging these non-nuclear medicine and non-
20 radiation oncology physicians from becoming AUs, that
21 we're creating a shortage of AUs.

22 So, these stakeholders also point out
23 that there's a disparity in patient access to
24 therapeutic radiopharmaceuticals in more rural parts
25 of the country as well.

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1 So, that's a little bit of background.
2 And, over the years, the Commission has heard this
3 feedback and subsequently, they directed the staff,
4 in 2017, to examine some of these concerns.

5 So, this slide, slide seven, references
6 staff requirements memorandum, SRM M170817. And so,
7 that was dated August 17, 2017. And, that's where
8 the Commission evaluated the staff -- or directed the
9 staff to evaluate whether it makes sense to create
10 those tailored training and experience requirements
11 for different categories of radiopharmaceuticals, how
12 those categories should be determined, and, for
13 instance, such as by risks posed by groups of
14 radionuclides or by delivery method, what the
15 appropriate T&E requirements would be for each of
16 those categories and whether those requirements
17 should be based on hours of training and experience
18 or should they be more focused on competency?

19 And so, in 2018, the NRC staff did some
20 initial work in response to the Commission's
21 directions.

22 And the staff concluded in a SECY paper
23 from back in August 2018 that while it may be feasible
24 to create tailored T&E for certain categories of
25 radiopharmaceuticals and there could be ways to focus

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1 this T&E more on competency, that the staff needed
2 more outreach with the medical and regulatory
3 community first.

4 So, that's where we are today and that
5 outreach really started last fall when we published
6 our initial Federal Register notice.

7 The Federal Register notice opened the
8 90-day public comment period. And, we held four
9 public comment meetings during that time.

10 We received 144 written comments and
11 there were 35 comments spoken during the public
12 meetings. All the public meeting transcripts, the
13 public meeting summaries and every single comment
14 that we received are all available on
15 regulations.gov.

16 So, if you go to www.regulations.gov and
17 then, in the search bar, you enter in our T&E docket
18 which is NRC-2018-0230 and you just search that
19 docket, that webpage will pop right up and there, you
20 can see everybody's comments. You can see the
21 meeting summaries that we put together, the
22 transcripts from last fall and winter.

23 So, I'm about to outline at a high level
24 what we heard last fall and winter, but I want to
25 note that, in the Commission paper that we're putting

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1 together, we are going to be including more detailed
2 comment summaries for each public comment period.

3 Those summaries will be included as one
4 long enclosure to our paper for the Commission.

5 And, I'm also going to be making
6 available in ADAMS a full comment binning report for
7 each comment period. And, that will show how we
8 reviewed your comments, how we processed, and how we
9 extracted individual comments from overall
10 submissions and put them into what we call comment
11 bins.

12 Let's get into what we heard. So, citing
13 concerns about patient and public safety, there was
14 strong opposition voiced to any changes in the T&E
15 requirements from the nuclear medicine community and
16 the related medical specialty boards and professional
17 societies.

18 Going hand in hand with support for
19 maintaining the current T&E requirements was
20 opposition to creating tailored T&E that would
21 resulted in limited authorized users.

22 Opposition to creating limited AU
23 pathways was primarily rooted in concerns about
24 protecting the health and safety of patients and
25 concerns about quality of patient care.

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1 But other commenters also warned that
2 limited AUs could be motivated by financial gain
3 versus what would be best for their patients. And,
4 that this would be detrimental, obviously, to
5 patients, but also to the field of nuclear medicine
6 in general.

7 On the other side of this spectrum, we
8 had -- we heard cited concerns about patient access
9 and care concerns that there was support for tailored
10 T&E requirements from physicians such as
11 hematologists, endocrinologists, oncologists, and
12 urologists who would like to treat their patients
13 with radiopharmaceutical therapies as well as from
14 the pharmaceutical industry and related trade groups
15 and also a rural healthcare advocacy group.

16 These groups stated that creation of a
17 limited AU pathway for certain categories or types of
18 radiopharmaceuticals could safely expand access to
19 therapeutic radiopharmaceuticals.

20 Other commenters supporting limited AU
21 pathways pointed out that the NRC's T&E requirements
22 should be more risk based, that in its evaluation of
23 the T&E requirements, the NRC should evaluate
24 specific categories of radiopharmaceuticals, specific
25 routes of administration, radiation characteristics,

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1 preparation methods and unique practice settings
2 requirements such as a physician's previous exposure
3 or experience with toxic non-radioactive chemical
4 therapies.

5 That we should include all these in our
6 decision making process for potentially creating
7 tailored T&E.

8 Some commenters also pointed out that the
9 precedent has already been set for creating tailored
10 T&E that, for instance, we have carve outs for
11 radioactive iodine, iodine-131.

12 Groups on both sides of the issues
13 presented for the NRC detailed lists of basic
14 radiation science and health and safety topics and
15 clinical training and experience requirements that
16 they thought were necessary for either full or
17 tailored T&E.

18 And, there was mixed support from moving
19 towards a more competency focused evaluation or
20 proposes AUs -- for proposed AUs. For example, such
21 as requiring a formal radiation safety examination to
22 become an AU and potential periodic reassessments.

23 The next couple slides, I'm going to talk
24 about what we heard from our Advisory Committee on
25 the Medical Uses of Isotopes, the ACMUI, and also

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1 what we heard from the Agreement States.

2 So, it's important to note that both the
3 ACMUI and the Agreement States are both going to get
4 a chance to review our draft Commission paper this
5 summer. So, they get another opportunity to provide
6 us some input on to our evaluation process.

7 But, in mid-February, the ACMUI
8 Subcommittee on Training and Experience issued their
9 draft report on T&E under Subpart E.

10 And, a public teleconference was held on
11 February 26th with the Full Committee and, during
12 that public teleconference, the Full Committee
13 endorsed the Subcommittee's draft report in their
14 conclusions.

15 So, this slide summarizes the positions
16 and recommendations. And, they are, that the
17 Committee strongly supports and reaffirms their 2016
18 position on maintaining the current and existing AU
19 pathways, that is, board certification and the
20 alternate pathway.

21 And, the Committee believes that those
22 pathways are adequate for protecting public health
23 and safety.

24 And, the Committee backed up this
25 position by saying that, radionuclide therapy poses

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1 the highest risk and highest impact of all nuclear
2 medicine procedures.

3 The Committee concludes that there is no
4 objective data to confirm an AU shortage and the
5 Committee does not recommend a limited scope AU
6 pathway for radiopharmaceuticals requiring a written
7 directive.

8 The Committee agreed that, in order to
9 ensure the safety of patients, personnel and the
10 public, if the NRC does choose to pursue creation of
11 a limited scope AU pathway, that the AU candidate
12 must acquire the basic knowledge topics that are
13 listed under 35.390, and they must complete a formal
14 competency assessment.

15 The Committee further recommended that
16 there should be a periodic reassessment of radiation
17 safety competency for these AUs, these limited AUs.

18 The NRC has been coordinating with the
19 organization of Agreement States as the primary
20 conduit for our outreach to all 38 of the Agreement
21 States and we're going to continue to coordinate
22 closely with the Agreement States throughout the rest
23 of the staff's T&E evaluation.

24 We recognize the importance of the
25 Agreement States in our evaluation because the

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1 Agreement States regulate roughly 80 percent of the
2 materials licensees in the United States.

3 And, any changes to our regulations
4 directly impact the Agreement States as they must
5 implement compatible regulations and requirements.

6 So, in their comment submission dated
7 January 29th, 2019, the organization of Agreement
8 States reiterated their position on the adequacy of
9 the current T&E requirements and they reiterated this
10 from when we reached out to them earlier in 2018.

11 So, their position is that, most
12 Agreement States find that the current AU pathways
13 are reasonable and accessible to physicians wishing
14 to administer radiopharmaceuticals.

15 However, there was not a consensus among
16 the Agreement States on whether there was a need to
17 create tailored T&E requirements.

18 Some states were open to exploring the
19 idea of creating limited AU pathways, while other
20 states felt that creating new limited pathways could
21 just add unnecessary complexity to what are already
22 very complex regulations regarding T&E requirements
23 under Subpart E.

24 The OAS did close out their comment
25 submission with the suggestion that the NRC consider

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1 a less prescriptive approach to the training and
2 experience requirements and that, perhaps putting in
3 regulatory focus on whether licensees are complying
4 with 10 CFR 35.41 - which is our regulation pertaining
5 to written directives and also focusing on compliance
6 with their regulations regarding radiation protection
7 in 10 CFR Part 20 - this could be a more effective
8 and efficient use way to regulate medical licensees.

9 So, this slide is recycled from my
10 presentation from last fall and winter, but I thought
11 it was important just to remind folks where we are in
12 this evaluation.

13 So, just a reminder that this is not --
14 this evaluation is not a rulemaking. But the
15 connection between this evaluation and a potential
16 rulemaking is that, the outcome of this evaluation
17 could potentially result in staff recommending to the
18 Commission that the NRC should conduct a rulemaking
19 to potentially amend the T&E requirements.

20 So, we conducted our initial public
21 comment period. We reviewed and processed all those
22 comments and we received the ACMUI and Agreement
23 States positions and we developed these draft
24 approaches that Maryann is going to talk about in
25 just a minute.

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1 I have input from medical stakeholders
2 highlighted in this slide because we're still in that
3 phase, obviously. And, your input, as Chris said,
4 your input is going to help us refine and edit these
5 draft approaches and determine whether or not they
6 should be included in the paper that we're putting
7 together for the Commission.

8 And, once we deliver our paper to the
9 Commission, the Commission will review the options
10 and our recommendation. And, they will make the
11 ultimate determination of how we proceed, whether
12 that involves a rulemaking or not.

13 So, that brings us to the current T&E
14 Federal Register Notice, the one that was published
15 on May 2nd.

16 So, again, if you're on the webinar, I've
17 uploaded that for you as a handout and the handouts
18 are here in the room.

19 It was published on May 2nd and opened up
20 our public comment period which is a little more than
21 30 days. It ends on June 3rd. The FRN also announced
22 today's meeting and a meeting on May 23rd that'll
23 I'll talk about in a couple slides from now.

24 And, the most important aspect,
25 obviously, of this FRN is that it outlines our draft

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1 approaches that we're considering and it also
2 includes a series of questions that we're really
3 interested in getting input on from you all.

4 So, at this point, I'm going to hand it
5 over to Maryann to walk us through those draft
6 approaches.

7 MS. AYOADE: Okay, thank you, Sarah.

8 So, in the following slides, you'll see
9 that we have numbered and listed the draft approaches
10 with the same numerical headings as you will see in
11 the Federal Register Notice.

12 The same thing goes for the numbered
13 questions that we are looking for feedback on. So,
14 these questions, they have the same number here in
15 the slides as you will also see in the Federal
16 Register Notice.

17 With these approaches we are presenting
18 today, we want to emphasize that all of the approaches
19 are preliminary.

20 I also want to mention that some of these
21 approaches could add an additional pathway to the
22 existing pathways in the regulations for physicians
23 to authorize -- to become authorized users.

24 While some of the approaches could modify
25 the existing training and experience regulations, or

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1 they could keep the regulations as is.

2 So now, I will go into the approaches
3 starting with this slide.

4 So, the first approach is the status-quo
5 approach. This approach would maintain the current
6 training and experience requirements for
7 radiopharmaceuticals requiring a written directive.

8 And so, here, physicians would still need
9 to meet the training and experience requirements
10 under 10 CFR 35.300.

11 And so, the questions that we would like
12 to get feedback on from you all is, if the status-quo
13 is maintained, how should the NRC prepare itself for
14 the expected increase in the number and complexity of
15 the radiopharmaceuticals that we will see in the
16 future?

17 The second question is, is there a
18 challenge with the current training and experience
19 requirements such as concerns that are related to
20 patient access to radiopharmaceuticals that should be
21 addressed through a rulemaking?

22 Next slide?

23 So, slide 14 discussed tailor, train, and
24 experience approaches. And, these four tailored and
25 experience approaches would modify the existing

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1 training and experience requirements for
2 radiopharmaceuticals.

3 So, the first three approaches which are,
4 the limited authorized user for alpha or beta emitting
5 radiopharmaceuticals, the limited authorized user for
6 unit, dose, patient radiopharmaceuticals and the
7 limited authorized user for any one parenteral
8 radiopharmaceutical.

9 These three approaches would require a
10 set amount of training and experience that is tailored
11 to the specific radiopharmaceutical.

12 The fourth approach which is the emerging
13 radiopharmaceuticals approach, this would tailor the
14 training and experience for each new
15 radiopharmaceutical as they were developed.

16 And so, it would be similar to the
17 approach for regulating new technologies which is
18 currently under 35.1000.

19 And so, the question that we would like
20 to get feedback on here is, how should the complexity
21 of the radiopharmaceutical administration protocol be
22 considered in establishing the training and
23 experience requirements for the limited approaches?

24 Next slide?

25 So, this approach would allow for limited

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1 authorized users to administer one or more of a
2 certain type of radiopharmaceutical.

3 So, in this case, physicians that are
4 seeking authorized user status would be able to
5 administer any alpha or beta emitting
6 radiopharmaceutical.

7 The training and experience here would be
8 for the user to have completed at least 400 hours of
9 training and experience of which there would be 200
10 hours that should be in classroom and lab training,
11 plus a minimum of 200 hours of supervised work
12 experience that would be focused on alpha or beta
13 emitting radiopharmaceuticals.

14 This approach would also require a
15 written attestation similar to what the NRC's current
16 regulations require under the alternate pathway.

17 And so, the question that we would like
18 to get feedback on for this approach is, how should
19 the NRC categorize radiopharmaceuticals with mixed
20 emissions?

21 Next slide?

22 So, again, just like the previous
23 approach, this approach would allow for the limited
24 authorized users to administer one or more specific
25 radiopharmaceuticals.

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1 In this case, physicians that are seeking
2 authorized user status would be able to administer
3 any unit dose patient ready radiopharmaceutical.

4 And so, similar to the previous approach,
5 the training and experience required here would be
6 for the user to have completed 400 hours of training
7 and experience which includes 200 hours of classroom
8 and lab training plus a minimum of 200 hours of
9 supervised work experience and it would be focused on
10 unit dose patient ready radiopharmaceuticals.

11 This approach would also require a
12 preceptor attestation.

13 And so, the question we would like to get
14 feedback on here is, how should the NRC define patient
15 ready?

16 Next slide?

17 This is the third type of limited
18 authorized user approach. Again, similar to the
19 previous two approaches, this approach would allow
20 for limited authorized users to administer one or
21 more specific radiopharmaceuticals.

22 In this case, physicians that are seeking
23 authorized user status would be able to administer
24 any one parenteral radiopharmaceutical.

25 The training and experience required here

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1 would be similar to that of the last two limited
2 authorized user approaches and it would require 400
3 hours, at least 400 hours of training and experience
4 of which 200 hours would be in classroom and
5 laboratory training plus the minimum of 200 hours of
6 supervised work experience that would be focused on
7 that one radiopharmaceutical.

8 What is different in this approach than
9 the other limited authorized user approaches is that,
10 if the authorized user wants to administer any new
11 additional radiopharmaceutical that comes along and
12 that is different from what they had been authorized
13 for already, the authorized user would need an
14 additional minimum 80 hours of tailored supervised
15 work experience.

16 And so, this approach would also require
17 a preceptor attestation.

18 Next slide?

19 So, this approach is the emerging
20 radiopharmaceuticals approach. And, it is the fourth
21 of the limited authorized user type of approach.

22 It would mirror that of the NRC's current
23 regulations in 10 CFR 35.1000 which is for other
24 medical uses that do not fall under the other sections
25 of the regulations in Part 35.

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1 It would require that the NRC conduct
2 individual reviews of each new emerging
3 radiopharmaceutical to determine the specific
4 training and experience requirements for each
5 radiopharmaceutical.

6 The training and experience requirement
7 here could be tailored to consider the potential
8 users. So, this would be individuals that are not
9 your traditional nuclear medicine or radiation
10 oncology physicians that we see currently.

11 So, that would be, for example, a
12 hematologist, the medical oncologist or urologist
13 that wants to administer radiopharmaceuticals.

14 And, this approach would, in turn, be
15 creating an alternate training and experience pathway
16 for each new radiopharmaceutical.

17 Next slide?

18 Slide 19, this presents performance based
19 approaches, the first of which is the competency based
20 evaluation approach.

21 And, the second, the credentialing of
22 authorized users.

23 These two approaches would be removing
24 the prescriptive training and experience requirements
25 from the regulations and, instead, they would be

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1 focusing oversight on the performance based aspects
2 of the licensee's medical program for
3 radiopharmaceutical administrations.

4 Next slide?

5 So, the first performance based approach,
6 the competency based evaluation approach, this would
7 require that proposed authorized users demonstrate
8 competency in radiation safety topics and radiation
9 safety job related job duties through a formal
10 evaluation.

11 So, for example, an examination is one
12 way or a preceptor attestation, and that would be
13 something that we would use to assess and confirm
14 that that individual is able to function
15 independently as an authorized user for the medical
16 uses that are being requested.

17 So, the question that we would like to
18 get feedback on here is, does a competency based
19 evaluation as it relates to radiation safety job
20 duties and topics ensure appropriate training and
21 experience for authorized users? And, if so, how?

22 Next slide?

23 The second performance based approach is
24 the credentialing of authorized users approach. In
25 this case, the NRC would no longer be involved in the

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1 review and approval process for authorized users
2 training and experience under Part 35.

3 Instead, the licensees would have to
4 develop and use their own policies and procedures to
5 make self-determinations as to whether their
6 credentialed physicians have the appropriate training
7 and experience to be an authorized user.

8 Licensees would also be required to
9 maintain their own training programs to ensure
10 compliance with the requirements for having
11 procedures for administrations requiring the written
12 directive in 10 CFR 35.31 and also with the
13 requirements for radiation protection in Part 20.

14 So, the question we would like to get
15 feedback on here is, how could physicians in small
16 practices be credentialed?

17 So, we are looking at physicians that
18 aren't associated with hospitals or other larger
19 institutions that have credentialing boards that
20 review their physicians credentials and approve them
21 before they can practice at their facility.

22 Next slide?

23 Slide 22 presents team based approaches.
24 So, for the first two approaches, the
25 radiopharmaceutical team approach and the approach

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1 that involves teaming authorized users with
2 authorized administrators which would also introduce
3 some new users.

4 I want to point out that these two
5 approaches would be more performance based. This
6 would mean that the prescriptive training and
7 experience requirements would be removed from the
8 regulations and it would put more emphasis on the
9 licensee to make sure that they have a program in
10 place that can accommodate the authorization of uses
11 that are being requested.

12 The third team approach, the approach
13 that would partner limited authorized limited trained
14 authorized users with authorized nuclear pharmacists.

15 This approach, on the other hand, would
16 require more prescriptive training and experience for
17 authorized users because of the authorized users'
18 more prominent role in the administration of
19 Radiopharmaceuticals.

20 So, in summary here, these team based
21 approaches would either be removing prescriptive
22 training and experience requirements for authorized
23 users and would focus the training and requirements
24 on competency of the entire team involved in the
25 procedure.

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1 Or, it would revise the current 700-hour
2 training and experience requirement for authorized
3 users based on pairing the authorized user with
4 another individual with expertise in administering
5 radiopharmaceuticals.

6 And, I'll go over those in the coming
7 slide.

8 But the question, overall question here
9 for these team based approaches that we would like
10 feedback on is, how should the authorized users
11 radiation safety responsibilities be clearly
12 distinguished and defined from the other members of
13 the team?

14 Next slide?

15 Under the first team based approach, the
16 radiopharmaceutical team approach, the licensees
17 would be required to have a team that would administer
18 radiopharmaceuticals. And, at a minimum, the team
19 would consist of an authorized user, a radiation
20 safety officer, and a nuclear medicine technologist.

21 The team could also include some
22 additional members such as an authorized medical
23 physicists, an authorized nuclear pharmacist, a
24 health physicist, or other physicians that manage
25 patient care.

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1 And so, the training and experience for
2 the team in this approach would be performance based
3 and licensees would be required to develop policies
4 and procedures that address how their team would meet
5 the requirements in 10 CFR 35.41, which is for
6 procedures for administrations that require a written
7 directive.

8 And also, to meet the regulations in Part
9 20 for radiation protection.

10 Next slide?

11 The second team based approach is one
12 that would team up authorized users with authorized
13 administrators.

14 Now, these authorized administrators
15 would be individuals that the licensee would
16 authorize to administer radiopharmaceuticals.

17 So, for example, a nuclear medicine
18 technologist or a nuclear medicine advanced
19 associate, which is comparable to a physician
20 extended position or an extension of a physician
21 services by other providers.

22 With this approach, licensees would need
23 both an authorized user and an authorized
24 administrator to administer the radiopharmaceuticals.

25 This approach would be more performance

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1 based and the training and experience for authorized
2 users would focus on written directives, patient
3 release criteria, and medical event reporting.

4 The training and experience for the
5 authorized administrators would focus more on
6 radiation safety and preparation and administration
7 protocols.

8 And, this would be in addition to the
9 training that is required for the authorized users
10 which would be in written directives, the patient
11 release criteria, and medical event reporting.

12 Next slide?

13 The third team based approach is one that
14 would partner up limited trained authorized users
15 with authorized nuclear pharmacists.

16 This approach would require that an
17 authorized nuclear pharmacist must be present during
18 the administrations by an authorized user.

19 It would also require more prescriptive
20 training and experience requirements for the
21 authorized user due to their more prominent role in
22 the administrations.

23 It would require that the authorized user
24 have at least 400 hours of training and experience.

25 Now, this training and experience for the

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1 physician partnering with the authorized nuclear
2 pharmacist would be more focused on supervised work
3 experience and patient cases.

4 And, it would also require a preceptor
5 attestation.

6 The training and experience for the
7 authorized nuclear pharmacist would remain the same
8 as it is currently listed in 10 CFR 35.55.

9 The authorized user in this approach in
10 this approach would be responsible for
11 radiopharmaceutical administrations in accordance
12 with the written directive and the authorized nuclear
13 pharmacist would be responsible for all the other
14 radiation safety related duties.

15 So, the question that we would like to
16 get feedback on under this approach is, how should
17 the radiation safety responsibilities be divided
18 between the authorized user and the authorized
19 nuclear pharmacist?

20 Next slide?

21 MS. LOPAS: Okay, now that Maryann has
22 gone through the draft approaches, I'm just going to
23 run through these questions. So, these are questions
24 that were in the Section 4, the last section of the
25 Federal Register Notice.

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1 And, we put them at the end because they
2 mostly apply to all the approaches and maybe these
3 questions will help shape your feedback on these
4 approaches because these are the things that we're
5 thinking about.

6 So, question 10, what are the advantages
7 and disadvantages of each draft approach?

8 Are there significant costs or benefits
9 associated with any of the approaches? That was
10 question 11.

11 Would any of the draft approaches impact
12 patient access to Radiopharmaceuticals or address the
13 stakeholder concerns of overly burdensome regulatory
14 requirements?

15 Question 13 is, for the draft approaches
16 that considered tailored hours of T&E, what are the
17 appropriate numbers of hours of that T&E? Right now,
18 we have 400 for quite a few of them.

19 And, what radiation safety topics should
20 comprise the limited T&E?

21 Question 14 is, should the NRC consider
22 inclusion of a formal radiation safety competency
23 assessment and periodic reassessments for any of the
24 draft approaches above? And, if so, who should
25 establish and administer these assessments?

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1 Question 15 is, how would the draft
2 approaches impact the medical organizations that use
3 the NRC's T&E requirements as a basis for establishing
4 their own training programs?

5 Question 16, are there concerns regarding
6 implementation and/or viability for any of these
7 approaches discussed above?

8 Question 17, are there unintended
9 consequences of the draft approaches?

10 Question 18, which of the draft
11 approaches best positions the NRC to effectively
12 regulate the future of Radiopharmaceuticals?

13 And, question 19, should the NRC continue
14 to play a role in the review and approval of AUs?

15 So, here, just some of the basics for
16 getting us your comments.

17 So, like last time around, we're using
18 regulations.gov again to submit your written
19 comments. It's the same docket as last time. And,
20 again, and like I said, if you just go to that
21 regulations.gov and search that NRC 2018-0230 right
22 in the search bar, it's the first thing that pops up.

23 So, it's pretty easy to submit your
24 comments. But, if you have any issues submitting
25 your comments, please know that you can email myself

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1 and/or Maryann and we can get your comments that way
2 as well. That's no problem.

3 So, just keep in mind that the -- when
4 you get a confirmation from regulations.gov, you're
5 not going to see your comment pop up right away. It
6 takes about 11 working days to pull it down from
7 Regs.gov, then get into ADAMS and then back up on
8 regulations.gov, the public facing part of
9 regulations.gov.

10 So, don't panic, if you got your
11 confirmation notice on regulations.gov, the comment
12 was submitted.

13 But, again, if you're at all worried, you
14 can go ahead and email this to us as well.

15 So, all the comments are going to be in
16 ADAMS, obviously. And, I do want to point out that
17 because this is not a rulemaking, we aren't going to
18 be providing responses to your comments.

19 But, as I mentioned, it is a very
20 painstaking process that we go through to bin your
21 comments and extract individual comments. So, and
22 we are going to have what I hope are very good
23 summaries of your comments in this Commission paper
24 coming up.

25 So, we have an additional public meeting,

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1 one more on Thursday, May 23rd. It's a morning
2 webinar. It's just a webinar, so not in person,
3 10:00 a.m. to 12:00 p.m.

4 So, if you don't feel like talking today,
5 but you want to talk on that date, please dial in at
6 least the bridge line and you can register for the
7 webinar as well.

8 Everything will be the same, the slides
9 will be the same, so same meeting, just another
10 opportunity for you to get your comments on the
11 record.

12 And then, here are our next steps, just
13 so everybody has an idea of kind of how the schedule
14 got pushed back a little bit because we have this
15 second public comment period.

16 So, right now, the public comment period
17 May 2nd through June 3rd.

18 We're going to finish developing our
19 paper in June 2019 after -- or in June after we get
20 all your comments and review them.

21 Then, we expect that the ACMUI and the
22 Agreement States will have about two months in the
23 summer, maybe into September likely, to review our
24 draft Commission paper.

25 We'll get comments back from them, and

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1 we'll incorporate. And, it's also important to note
2 that the ACMUI will have a public teleconference on
3 their draft comments or on their comments on our draft
4 Commission paper.

5 So, that's a public teleconference
6 similar to what they had back in the end of February.

7 If you're interested in this topic, I
8 encourage you to call into that teleconference.

9 And, the way you can find about that
10 teleconference is making sure that you sign up for
11 the NRC's medical List Server.

12 And, the way you sign up for the Medical
13 List Server is you can just Google NRC Medical List
14 Server and the first result that comes up is the --
15 tells you how to subscribe.

16 And, that's -- we send out emails, I think
17 not too frequently, to be honest. But we send out
18 emails, so it's not going to flood your inbox, but we
19 send out emails with important announcements like
20 meeting notifications, notifications of meetings, and
21 reports, and whatnot. So, I encourage you to do
22 that.

23 So, that telecon will hopefully be in mid
24 to late September.

25 We would then finalize our paper in

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1 October and November. And we'd have a Merry
2 Christmas hopefully getting the paper out to our
3 Commission.

4 So, that's our schedule for now. And
5 then, for more information, I do try to do a good job
6 maintaining the training and experience website, so
7 check that out.

8 Of course, the, as I mentioned, the
9 regulations.gov docket, you can read everybody's
10 comments on there.

11 And then, please feel free to contact
12 myself or Maryann at any time. You know, Maryann's
13 our technical point of contact. I'm more the process
14 person, so either questions about comments or process
15 in general, you can reach out to me on those.

16 And so, with that, we're going to open up
17 to public comments.

18 So, I just want to remind everybody that
19 you're on the phone, if you're on the phone, you can
20 go ahead and press star one. And that's going to
21 indicate to Shirley, our operator, that you need your
22 line unmated.

23 So, press star one if you're on the phone
24 and you want to make a comment.

25 We have our court reporter here in the

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1 room, so please speak clearly. Please start by
2 providing your name and if you are responding to a
3 specific question in the FRN, it'd be helpful if you
4 had the question number, not the end of the world if
5 you don't, but it might be helpful.

6 And so, I think that's it. And, the
7 folks in the room, you do have to use the microphones.
8 So, you can use either one of these aisle microphones
9 and Irene also has a handheld. So, if you don't want
10 to get up, we can bring you the handheld microphone,
11 that's totally fine.

12 So, does anybody in the room want to start
13 us off with comments?

14 Yes? Do you want to -- would you want
15 to go to a podium or you want -- okay, all right.
16 And, folks on the phone, we're going to start in the
17 room and then we'll go to you.

18 And, I also want to point out that, if
19 you are a little shy and you want to submit a comment
20 via the webinar, I can read it aloud for you on the
21 webinar.

22 Okay, go ahead.

23 DR. THOMADSEN: Well, thank you very much
24 for the honor of being the first here. I will thank
25 you officially for everybody for taking the time to

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1 go to the stakeholders and get input on this important
2 topic.

3 And, my name is Brice Thomadsen. I'm the
4 current Chairman of the Board for the American
5 Association of Physicists in Medicine, the AAPM, and,
6 I will be speaking on behalf of them.

7 Just on a personal note, I was also a
8 former -- or I am a former Chair of the Advisory
9 Committee for Medical Uses of Isotopes and it's really
10 nice to be back in the halls here.

11 The AAPM did respond to the October
12 request in the Federal Register. And for the current
13 request in the Federal Register, we are still
14 preparing our answers to all of the questions.

15 And so, I do not have all comments that
16 I can give you at this moment. There are four points
17 that I can make that we have approved for bringing to
18 you from the AAPM.

19 The first is that any arbitrary reduction
20 in the training and experience will compromise the
21 safety of these treatments for patients, staff, and
22 the general public.

23 The training is more than just learning
24 how to walk through a procedure, just as learning any
25 skill requires multiple repetitions, so does

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1 radionuclide therapy.

2 Experience in a residency does not just
3 prepare somebody to mechanistically perform the
4 procedure, but to know what to do when things go wrong
5 and to have seen enough of these cases to know when
6 things are going wrong, and, when it just doesn't
7 feel right.

8 Understanding general radionuclide
9 therapy just -- not just one example gives us ability
10 to discern impending problems.

11 The second point is, there is no need to
12 make a change. When this was first proposed, as you
13 pointed out, the ACMUI did look at the distribution
14 of AUs, and there seemed to be quite enough.

15 There are portions of the country,
16 admittedly, where there is limited healthcare, not
17 just for AUs, but for medical oncologists as well.

18 Citizens living in these areas know that
19 they will have to travel for sophisticated,
20 specialized treatments. Otherwise, they would be
21 living in a city.

22 This is similar to requiring -- if
23 somebody requires brain surgery, nobody is suggesting
24 that an internists or a general family practitioner
25 with a limited ten-week course should be doing brain

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1 surgery.

2 Radiopharmaceutical treatments, not so
3 much like brain surgery, but it is a lot like rocket
4 science.

5 The third point is that the decrease in
6 the use of some radionuclide therapies is not due to
7 the lack of authorized users nor the refusal of
8 authorized users to perform these procedures.

9 There is a rapid increase in the number
10 of radiopharmaceutical treatments across the country
11 right now. Authorized users are enthusiastic about
12 doing this.

13 The decrease in the procedures that have
14 been commented on is mostly due to the fact that the
15 referrals from medical oncologists to authorized
16 users to perform these has decreased markedly.

17 And, most facilities have found better
18 ways to treat the particular diseases for these
19 particular therapies that have come to this
20 Commission.

21 The fourth and last is when considering
22 what part to put the radium dichloride treatments,
23 the ACMUI recommended three -- Part 300 in Title 10,
24 commenting that the training for all radionuclide
25 therapies is pretty much the same in order to develop

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1 the understanding of the effects, the doses, and of
2 the treatments, the hazards and the natures, which is
3 covered in the current training.

4 But a lot of the treatments do require
5 some additional training for the particulars of each
6 evolving procedure. There shouldn't be a confusion
7 between these two types of training.

8 In summary, the AAPM would maintain that
9 the current training and experience requirements have
10 worked well. There seems to be no real reason to
11 change. And, changing to abbreviated versions could
12 be hazardous to the patients, the staff, and the
13 public, and could compromise the quality of patient
14 care.

15 Thank you very much for this opportunity.

16 MS. LOPAS: All right, thank you, Dr.
17 Thomadsen.

18 Okay, so, I'm going to check with Shirley
19 to see if there's any comments on the phone before I
20 go back to our room.

21 OPERATOR: Again, just press star one to
22 ask a question.

23 We do have one question and that's from
24 George Segall. Your line is open, go ahead with your
25 question.

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1 DR. SEGALL: Thank you very much.

2 This is George Segall, and my last name
3 is spelled S-E-G-A-L-L. I'm a practicing nuclear
4 medicine physician and I'm also the Executive
5 Director of the American Board of Nuclear Medicine.

6 I would like to thank Bruce Thomadsen for
7 his comments with which I fully agree.

8 I also would like to thank the NRC staff
9 for an excellent review of the current training and
10 education requirements and the rather detailed
11 proposals that the staff had developed for
12 consideration of stakeholders.

13 The development of these possible
14 alternative pathways shows the very detailed
15 understanding of the entire situation which is very
16 confidence building.

17 The ABNM previously submitted written
18 comments during the first comment period strongly
19 supporting the current requirements for 700 hours of
20 training and experience, including 200 hours of
21 classroom and laboratory training. And, I won't
22 repeat those comments.

23 I would like to address the performance
24 based approach which is included as possibilities for
25 new training and education requirements in the second

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1 comment period.

2 One particular proposal by the NRC staff
3 under consideration is that licensees would develop
4 and use their own policies and procedures to make
5 self-determinations of whether they're credentialed
6 physicians have the appropriate training and
7 education to be an authorized user for one or more
8 radiopharmaceuticals under 10 CFR 35.300.

9 ACGME accredited nuclear medicine program
10 directors and the American Board of Nuclear Medicine
11 are aware of many reports of physician trainees
12 showing up to observe the administration of a
13 radiopharmaceutical and not fulfilling all of the
14 requirements of 35.390(b)(1) bullet points A through
15 G.

16 The reports that we have received is that
17 program directors feel pressured by their superiors
18 to attest to the training and experience that trainees
19 do not have and this training is not fulfilling the
20 NRC requirements.

21 This is of concern to us and we feel the
22 situation would be exacerbated if licensees were
23 allowed to develop and use their own policies and
24 procedures.

25 And, the ABNM further believes that a

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1 preceptor based attestation alone would not be
2 sufficient to ensure public safety.

3 The second point that I would address in
4 the competency based evaluation approach,
5 specifically, the formal assessment such as an
6 examination should be a requirement and periodic
7 reassessments should also be required.

8 This position is based on the American
9 Board of Nuclear Medicine pass rates for first time
10 takers of its certification exam. These pass rates
11 have traditionally, historically been 80 percent over
12 the past two decades and that figure is very
13 consistent.

14 What this means is, despite having the
15 training and education currently required by the NRC
16 to be an authorized user, 20 percent of physicians
17 who have had that training are not able to demonstrate
18 knowledge in a secure examination.

19 So, fulfilling simply the requirements
20 without a formal examination would also, I believe,
21 not be in the interest of public safety.

22 Furthermore, the ABNM has administered a
23 reassessment examination given every ten years
24 starting in 2002.

25 The first time pass rate on this

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1 examination is 97 percent, which is good because the
2 Board expects that most practicing physicians are,
3 indeed, competent.

4 However, on the periodic reassessment
5 examination, three percent of physicians in practice
6 are unable to sufficiently demonstrate the knowledge
7 required to practice competently and safely.

8 So, the Board feels that not only should
9 an initial formal assessment be required in addition
10 to whatever training and education is the
11 requirement, but that periodic assessment is also
12 necessary to reassure the public and to ensure the
13 safety of therapies using radioactive materials.

14 Thank you.

15 MS. LOPAS: Okay, thank you very much.

16 Do we have anybody in the room that would
17 want to speak a comment here in the room?

18 (NO AUDIBLE RESPONSE)

19 MS. LOPAS: All right, seeing nobody,
20 star one for folks on the phone.

21 Shirley, do we have any star ones?

22 OPERATOR: We do have a question that
23 comes from -- or a comment from Bennett Greenspan.
24 Your line is open, go ahead.

25 DR. GREENSPAN: Hi, thank you very much

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1 for this opportunity to speak. I'm Dr. Bennett
2 Greenspan. I'm a nuclear medicine physician and
3 radiologist and the immediate past president of
4 SNMMI. And, I'm speaking for myself.

5 According to one of the companies,
6 radiopharmaceutical therapy now comprises about 13
7 percent of nuclear medicine practice. However, it
8 is projected to increase to 30 percent by 2030.

9 Therefore, I believe it is important that
10 we get this right to provide appropriate requirements
11 necessary for highly trained, skilled, and competent
12 authorized users, the most important issue is patient
13 safety.

14 And, just below that is safety of
15 personnel and the public.

16 I recommend an extension for another 30
17 days for the comment period to July 3rd to have enough
18 time to review evidence and answer the 19 questions
19 posed by the NRC.

20 Regarding evidence, I request that the
21 NRC provide a list of citations and also include --
22 which include, but not limited -- are not limited to
23 any relation to training and work environment of the
24 Department of Authorized Users cited.

25 Seven hundred hours may have been set

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1 arbitrarily in the past, but it has worked over time.
2 A reduction of 400 hours is arbitrary and with no
3 supporting evidence.

4 The expert societies are unanimously
5 opposed to reduction in requirements. This is not
6 self-serving, but it is to protect our patients.

7 As far as competency, to me, competency
8 means that the authorized users should be board
9 certified by ABNM in nuclear medicine or by ABR in
10 diagnostic radiology, nuclear radiology, radiation
11 oncology.

12 Number two, pass duration safety exam.

13 Number three, the laboratory or
14 department in which their work should be accredited.

15 And, number four, there should be
16 periodic, probably annual, proficiency testing. And,
17 this can be accomplished by a lab exercise and a quiz
18 that is graded.

19 A team approach is, I think, a terrible
20 idea, especially if the authorized user is offsite.
21 I think there is a tremendous risk for problems.

22 However, I think the best approach of
23 these kind of therapies is a multi disciplinary one
24 with nuclear medicine, radiology, radiation oncology,
25 radiopharmaceuticals, medical physicists, probably

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1 radio chemists, and medical Oncologists, all involved
2 in a team effort to treat these patients.

3 Number -- want to answer question seven
4 briefly, how could physicians and small practices be
5 credentialed?

6 Frankly, they probably shouldn't. Small
7 practices in rural areas will not have sufficient
8 infrastructure to handle these therapies any more
9 than cabin surgery or neurosurgery as Dr. Segall
10 mentioned.

11 People who live in rural or remote areas
12 understand that they must -- that they need to travel
13 for specialty or sub-specialty expertise.

14 I think tailored requirements will be
15 difficult to establish and horrendously difficult to
16 regulate. These therapies will become more complex
17 as more agents are approved.

18 The radionuclides will be alpha and/or
19 beta emitters with different energies, path lengths,
20 and decay schemes and half lives. For instance,
21 lutetium-177 PSMA is already being used in Germany
22 and Australia and may soon be approved in the U.S.

23 Some radionuclides are both alpha and
24 beta emitters such as actinium-225 and actinium-225
25 PSMA is being discussed and actually is being used in

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1 Germany. It emits four alphas and three betas with
2 each decay.

3 So, I appreciate the opportunity to speak
4 and thank you very much.

5 MS. LOPAS: Hey, Dr. Greenspan, before
6 you get off, this is Sarah Lopas. I just wanted to
7 get some clarification.

8 You had made a statement regarding the
9 NRC should provide a list of citations, and I missed
10 what precisely you were talking about. I wonder if
11 you can expand on that a little bit?

12 DR. GREENSPAN: Okay, thank you, yes.

13 Well, I know the NRC keeps a list of
14 citations or violations of proper treatment and care.
15 And, I think it would be useful to look at that list
16 and compare it to the kinds of departments or
17 physicians who were guilty of these citations or
18 violations.

19 So, that information may be valuable in
20 determining what kind of people should or shouldn't
21 be providing radionuclide therapy.

22 And, by the way, I did want to mention
23 that I agree with the comments of Dr. Thomadsen and
24 Dr. Segall.

25 MS. LOPAS: Okay, excellent. Thank you

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1 for that clarification.

2 DR. GREENSPAN: Thank you.

3 OPERATOR: We do have another comment on
4 the phone lines, if you'd like to take it.

5 MS. LOPAS: Yes, that'd be great.

6 OPERATOR: Thanks. And, we have it from
7 David Shuster, your line is open.

8 DR. SHUSTER: Yes, I'm Dr. David Shuster.
9 Thank you for giving me the opportunity to comment.

10 I am a tenured professor at Emory
11 University and I speak for our consensus opinion at
12 Emory University, Emory Healthcare, both in nuclear
13 medicine, radiology, and radiation oncology.

14 I want to also express my support for
15 colleagues previous comments as well. They're all
16 well taken.

17 A few more points to consider is that,
18 even in the best of hands, and we have great
19 experience with these therapies at our centers, it is
20 very difficult and complex to operationalize these in
21 a safe and effective manner.

22 And, I can tell you, so that it is complex
23 enough that our own medical oncologists have not even
24 expressed any demand for us or any requests for them
25 to do this. They know that it is best and safe in

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1 our hands.

2 So, I agree that we should not relax any
3 requirements and, at the least, there should be a
4 competency test, both initial and ongoing as we
5 currently have administered by the appropriate
6 boards, either the ABNM and/or ABR, to assess both
7 initial and ongoing competence both in radiation
8 safety as well as specific to these
9 radiopharmaceutical therapies.

10 And, only in this way can I believe that
11 we will be best serving the public good.

12 I agree with the previous comment that we
13 would not do this for surgery, we would not do this
14 for, you know, anyone just being allowed to, you know,
15 do any kind of complex procedure.

16 And, if there are certain areas of the
17 country that don't have adequate resources, I believe
18 those patients do need to be referred to an
19 appropriate center who do enough of these therapies
20 that they can achieve some competency.

21 For example, we wouldn't let many rural
22 hospitals do complex heart surgery, to give an
23 example.

24 So, that is our consensus opinion at
25 Emory and we believe that the current requirements

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1 should be kept in place.

2 Thank you very much.

3 MS. LOPAS: Okay, thank you.

4 Do we have anybody in the room that would
5 like to make a comment?

6 (NO AUDIBLE RESPONSE)

7 MS. LOPAS: Okay, I'll just keep
8 checking.

9 Star one of the phone if you want to make
10 a comment on the phone.

11 Shirley, do we have any other comments on
12 the phone?

13 OPERATOR: We do have one and that's from
14 Munir Ghesani. Your line is open.

15 DR. GHESANI: Hello, hello, everyone.
16 Thank you for the opportunity to speak and thank you,
17 NRC staff and the ACMUI for putting together this
18 extensive work and collection of information that has
19 culminated into numerous rounds of phone calls and
20 opportunities to make written comments as well.

21 I'm the Chair of the SNMMI Government
22 Relation Committee and member of the Board of
23 Directors of SNMMI.

24 I am also one of the members of the
25 American Board of Nuclear Medicine, a colleague of

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1 George Segall who spoke earlier.

2 I also agree with George as well as others
3 including Bruce Thomadsen, Ben Greenspan and David
4 Shuster regarding the comments they have made so far.

5 The issue of training and experience
6 requirements are the top concern for SNMMI. We have
7 submitted public comments on this issue multiple
8 times as well as expressed our recommendations
9 through our constituents in the public meetings.

10 We have taken lengthy measures to make
11 sure that what we represent is representation of the
12 entirety of our membership which includes physicians
13 most, but not all, of whom are authorized users. That
14 also includes the technologists medical physicists,
15 radio pharmacists, and radio chemists.

16 So, a broad cross section of all that are
17 currently very heavily involved in both diagnostic as
18 well as therapeutic nuclear medicine.

19 We have actually gone on to engage our
20 patients as well as individuals and members of the
21 advocacy groups of patients to ask their opinion about
22 it.

23 And, our primary concern is it was
24 expressed earlier, is the safety of the patients as
25 well as the public. We want to emphasize the

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1 importance of ensuring access to quality care, trying
2 to expand the access to radionuclide therapy by using
3 clinicians with limited authorize user training may
4 result in its medical use at a facility that cannot
5 provide needed medical care and may not have the
6 systems to ensure radiation safety.

7 We suggest that the best practices is to
8 have the radionuclide therapy performed at the
9 facilities that have a team of medical professionals
10 including authorized users who have extensive
11 training and experience to perform the radiation
12 therapy, radionuclide therapy very safely.

13 As well as patients, there are physicians
14 who have expedited the medical care of complex
15 patients that includes the radiologists, nuclear
16 medicine physicians, and radiation oncologists with
17 appropriate training and background in being able to
18 handle these treatments and manage any potential
19 complications.

20 Additionally, based on the readily
21 available online data from the American Board of
22 Nuclear Medicine as well as other medical boards
23 including American Board of Radiology as well as broad
24 licensing by NRC graduates from other programs like
25 diagnostic radiology, nuclear medicine, and radiation

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1 oncology.

2 There are numerous eligible individuals
3 who have become authorized users. And, as it was
4 pointed out earlier by Bruce and I completely agree
5 with him, that issue of the authorized user limitation
6 has been already demonstrated that it actually is
7 nonexistent in terms of available users to administer
8 these treatments.

9 In the future, even if the number of
10 available treatments has risen above available
11 approved types of medical treatment for radionuclide
12 therapy may increase in the future.

13 So, based on the robust number of
14 authorized users, both in the workplace currently as
15 well as those who are in the training pipeline, we
16 don't think that there's a shortage of authorized
17 users.

18 So, in summary, the SNMMI does not
19 support a change in the training and experience
20 requirements. The safe use of radionuclide therapy
21 requires an integrated system of medical care
22 involving the team of medical professionals that I
23 described earlier.

24 And, changing the NRC regulations with
25 the intent of expanding access to radionuclide

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1 therapy in the absence of improving the access to all
2 types of adverse medical care can only result in
3 therapy being administered to places that have
4 adequate -- that don't have adequate medical
5 expertise in their administration.

6 So, I again thank you for the opportunity
7 to speak and would be open to hearing any comments
8 from the room as well as from those on the phone.

9 Thank you.

10 MS. LOPAS: Thank you, Dr. Ghesani.

11 Shirley, do we have any other commenters
12 on the phone?

13 OPERATOR: At this time, I'm showing no
14 further commenters.

15 MS. LOPAS: Okay. So, folks on the
16 phone, I want you to press star one. I do have a
17 comment that I am going to read on the webinar. It's
18 a lengthy one, so bear with me.

19 But, I do want to point out that if you're
20 a little shy and you don't want to speak on the phone,
21 you can type it in via the webinar, too, that works.

22 So, star one to get on the phone or go
23 ahead and type your comments in.

24 So, I'm going to read a comment from
25 Michael Baxter. So, this goes as follows:

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1 (Michael Baxter) "While we are still
2 reviewing the question, most comments today are
3 relevant to option D3." Which I believe was the
4 pairing an authorized nuclear pharmacist and an AU,
5 and question nine.

6 "On behalf of the American Pharmacists
7 Association, Academy of Pharmacy Practice and
8 Management, Nuclear Pharmacy Practice Specialist
9 Special Interest Group (SIG) consisting of over 2,200
10 members, please consider the following comments to
11 the NRC's request for comments on the T&E requirements
12 for authorized users.

13 The APHA/AAPM nuclear pharmacy practice,
14 SIG, recommends AU T&E requirements should recognize
15 the various healthcare team members involved in
16 handling and administering radiopharmaceuticals
17 safely and effectively, including nuclear
18 pharmacists, physicians, medicine technologists and
19 health physicists.

20 As you may know, 90 percent of
21 radiopharmaceuticals are dispensed by an authorized
22 nuclear pharmacist, ANP.

23 Given the varying roles and expertise,
24 the 700 hours requirements may need to be decreased.
25 However, it is difficult to quantify a level of

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1 expertise by set number of hours versus competency
2 based training.

3 The current safety record to therapeutic
4 and diagnostic radiopharmaceuticals are the result of
5 the individuals on this team who must be recognized
6 in any restructuring of AU T&E requirements.

7 Additionally, while alpha and beta
8 emitting radiopharmaceuticals are dispensed and
9 delivered to healthcare facilities as ready to
10 administer doses, new alpha and beta emitters have
11 added the important task of specialized calibration
12 of the dose calibrator to ensure the correct amount
13 of radioactivity is dispensed.

14 In conclusion, APHA/AAPM's nuclear
15 pharmacy practice, SIG, and our over 2,200 members
16 believes it's critical to recognize the important
17 role of ANPs, authorized nuclear pharmacists, and
18 their medication expertise in the healthcare team.

19 Thank you, again, for this opportunity to
20 provide information on this important issue."

21 All right, Mr. Baxter, I appreciate that
22 comment.

23 I have another comment here on the
24 webinar that I can read in just a moment, but I did
25 want to check with Shirley to see if there are any

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1 additional comments on the phone.

2 Shirley, anybody pressed star one?

3 OPERATOR: At this time, I'm showing no
4 further comments. And, at this time, I'm showing no
5 further comments.

6 MS. LOPAS: Okay, great, thank you,
7 Shirley.

8 Okay, I want to check with the room, does
9 anybody want to speak in the room?

10 (NO AUDIBLE RESPONSE)

11 MS. LOPAS: All right, I'm going to move
12 back to this next comment here via the webinar.

13 This is from Steven Walter. (Steven
14 Walter) ``My concern is related to both Part 35.200
15 and Part 35.300 uses as relating to this proposal,
16 what consideration of Part 35 Subpart N enforcement
17 was taken into account with each category?

18 Specifically, should anyone seeking
19 authorized user status submit intentionally false
20 information to the credentialing boards, how is the
21 public assured that the NRC is providing oversight?

22 As of right now, we have no way of knowing
23 when that happens. There is no avenue for those
24 events to become public. This may result in users
25 becoming an authorized user after submitting false

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1 documents in violation of Subpart N.''

2 Okay, thank you, Mr. Walter, or Dr.
3 Walter, we appreciate that comment and that's a good
4 consideration that we will take down.

5 Okay, so, you can go ahead and continue
6 to submit your comments via the webinar or press star
7 one on the phone.

8 Shirley, do we have any other star ones
9 on the phone?

10 OPERATOR: At this time, I'm showing no
11 further comments.

12 MS. LOPAS: Okay. I'm going to run
13 through some of the questions again just to jog any
14 comments because we don't want to end the meeting too
15 early.

16 We do, of course, have another meeting on
17 May 23rd, 2019 and, again, that's from 10:00 a.m.
18 until 12:00 p.m. Eastern Time.

19 It's another webinar and another
20 transcribed public meeting to provide your comments.

21 And, I do want to look at some of these
22 questions. And, these are, again, these are some of
23 these questions that we're looking to get your general
24 feedback on.

25 So, when you provide us your feedback on

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1 some of these draft approaches, we certainly hear --
2 we do hear the opposition to any changes in our T&E
3 requirements from the nuclear medicine community, and
4 we're hearing that you would like our current T&E
5 requirements maintained.

6 I've also heard a couple folks point out
7 today that they would also like to see an initial
8 competency assessment maybe for all the pathways and
9 then they would like to see ongoing competency
10 assessments.

11 So, that's a comment that we would like
12 to see -- like to hear again.

13 In addition to that general opposition,
14 it is helpful for us, though, to get specific feedback
15 on some of our options.

16 Feedback on some of our approaches and
17 even if it's feedback just on the general themes.
18 So, we have the approaches kind of split out by theme,
19 right, we have the performance based approaches, we
20 have the tailored T&E approaches, we have the team
21 approaches and then, of course, the status-quo.

22 So, even if you don't feel like splitting
23 out your comments kind of by each approach, because
24 there's a lot in them; there's ten in them, right?
25 You can just kind of make overall comments and

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1 concerns on those themes.

2 And, one thing that I'll point out is
3 that we are also interested, for instance, that
4 consideration that I just read about, you know, false
5 reporting of the AU requirements.

6 That's a consideration, right, that's
7 example of a consideration that we would like to hear
8 from you all.

9 So, to the extent that you look at any of
10 these approaches and you think, well, NRC, have you
11 thought of this? Or have you thought of that? Or
12 how would you handle that situation?

13 Those are the kind of things that would
14 be really helpful for us in helping to refine these
15 approaches to help us determine if they're, indeed,
16 feasible.

17 You know, we're interested in the
18 viability of these approaches and we're looking to
19 the medical community because you are the ones doing
20 this day in and day out. And you can give us that
21 insight.

22 So, before I keep talking away, I did
23 want to read -- I do want to read something from one
24 of our staff members, Ms. Sophie Holiday. And, she's
25 responding to the concern regarding false

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1 credentials.

2 So, we have from Ms. Holiday, and she's
3 an NRC staff member, in response to Dr. Walter's
4 question or comment, license reviewers are expected
5 to review documentation for authorized users,
6 including T&E requirements prior to granting the
7 license or amendments to add AUs.

8 "If an allegation is submitted regarding
9 false credentials, the NRC will follow up through the
10 allegation process. If it is found out that the
11 individual violated Subpart N, enforcement action can
12 and will be taken for licensees in the NRC's
13 jurisdiction."

14 And, I'm sure that the Agreement States
15 probably have a similar course of action that they
16 would handle as well.

17 And, if it's in the Agreement States'
18 jurisdiction, we refer those -- that allegation to
19 the Agreement States if we get it first, but typically
20 goes to the Agreement States for them to handle.

21 So, thank you very much, Ms. Holiday, for
22 that clarification and that answer. We appreciate
23 that.

24 Okay, all right, Shirley, did we have any
25 additional comments or questions on the phone?

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1 OPERATOR: We do have one that's come in.
2 One moment, please. And, David Schuster, your line
3 is open. Go ahead with your question.

4 DR. SHUSTER: Thank you very much.

5 I would like to comment again, if you
6 could be so patient on this last question about
7 potentially giving false credentialing or the hours
8 that one puts in.

9 I think, first of all, we appreciate the
10 efforts of the NRC in enforcement. And, we all know
11 that there are great penalties attached to putting in
12 false hours and documentation.

13 But, to kind of speak to the elephant in
14 the room, I think that it depends on how this
15 credentialing is put in place and how the hours, if
16 that -- we went down that route, would have to be
17 documented.

18 So, if this were, for example, left in
19 the hands of the various maybe companies that are
20 producing, you know, these radiopharmaceuticals, you
21 know, there may be kind of an easier pathway or maybe
22 more leniency in -- because there is a vested
23 financial interest in getting those sites online.

24 And, I have to say, we've seen that,
25 unfortunately, with some other therapies which, you

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1 know, not necessarily all radiation therapies, but I
2 won't go into specifics here.

3 But even though there are great penalties
4 attached, this is an enforcement after the fact.
5 Okay? This is potentially after a patient gets hurt.

6 You know, it would be very difficult
7 front line to say who's going to report these people
8 who are potentially, you know, skirting the various
9 rigorous documentation requirements.

10 I think, though, that if we had it in the
11 hands of the boards such as ABNM and ABR who've
12 developed very vigorous documentation requirements,
13 both for hours as well as training as well as testing.

14 Then, you may have a much more robust
15 method. Again, I do not agree that we should change
16 the requirements at all and we do currently for both
17 ABNM and ABR certified physicians have initial and
18 ongoing certification.

19 But if we did go down that path at all,
20 it should not be left in industry hands, as it's
21 sometimes currently partly is, but also it should
22 just be left in the hands of certifying boards.

23 Thank you very much.

24 MS. LOPAS: Okay, thank you, Dr. Shuster.

25 We appreciate that.

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1 I have a follow up comment from Steven
2 Walter who originally submitted that concern about
3 false credentialing or qualifications.

4 So, Steven Walter states that "the
5 public has no way to know when a violation may have
6 occurred when the authorized user goes through
7 certifying boards.

8 They do not make that process public and,
9 as far as I know, they do not report it to the NRC in
10 general."

11 I'm not sure, Lisa, Chris, do you have
12 anything that you want to follow up with that?

13 (NO AUDIBLE RESPONSE)

14 MS. LOPAS: Okay.

15 MR. EINBERG: We'll just take that
16 comment.

17 MS. LOPAS: Yes, we're just going to take
18 that comment and we'll -- we will look into that
19 further.

20 Okay, Shirley, do we have any additional
21 comments on the phone? Star one, just press star one
22 on your phone if you want to make a comment.

23 OPERATOR: We do have two comments. Our
24 first one, I believe, is from Arif Sheikh, your line
25 is open.

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1 DR. SHEIKH: Yes, hi. This is Dr. Arif
2 Sheikh. I'm a nuclear medicine physician.

3 Just a quick question with regards to
4 your -- about having a team based approach. I think
5 in this day and age, especially the use of these more
6 advanced therapies is going to require a team based
7 approach.

8 The only quick comment I want to make is
9 that I think, you know, at the center of that team
10 based approach, the person who administers the
11 therapy and makes the -- involved in the decision
12 analysis needs to be a full AU, not a limited AU.

13 Because, generally speaking, when you are
14 looking at teams of -- involving physicians in
15 treatment of, you know, various modalities such as
16 the cardiac cath, the center of that team is the full
17 fledged cardiologist, not a limited cardiologist.

18 And, you know, and so with regards to
19 these, make that case with oncology and others.

20 So, I think the person administering it
21 really needs to be a full fledged AU with the full
22 training as supported by the ABNM in order to lead
23 that team. I don't support the idea that you would
24 have a limited AU with the experience of only a single
25 radiopharmaceutical delivering it to only a single

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1 type of patient.

2 MS. LOPAS: Okay, thank you.

3 And, I want to clarify, Dr. Sheikh, that
4 so for option D-1 or approach D-1, the way we look at
5 it and we're obviously open to suggestions on how to
6 approve this approach is that the AU that would be at
7 the head of this radiopharmaceutical team would be a
8 full AU and that they would be authorized to
9 administer any radiopharmaceutical under 35.300 under
10 Subpart E.

11 However, they would need to be supported
12 by this team and the other big however is that the
13 T&E would be performance based that, you know, the
14 licensees would essentially be -- these facilities,
15 these hospitals, would be credentialing and
16 certifying that they trust in that AU to be the lead
17 of that team essentially.

18 So, now, of course, we are open to all
19 sorts of combinations of approaches and I know you
20 had just -- you just kind of mentioned that you
21 wouldn't support this team based approach if it was
22 a limited AU who only had experience in, for instance,
23 one radiopharmaceutical.

24 But do you feel differently about this
25 team approach if it's a full AU, but it's performance

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1 based T&E leading this team? Does that change your
2 mind at all about this option or this approach?

3 DR. SHEIKH: No, I think, I mean, again,
4 I still think that you do need a full AU. I mean,
5 they need to be, yes, they need -- the AU also needs
6 to be further trained. It's -- there are, you know,
7 many physicians who are not maybe a full AUs or not
8 is interested in therapies the same as others would
9 be or inclined.

10 So, there would be some performance based
11 as well, but I think, you know, there has to be some
12 basis of standard hours given in terms of training
13 and exposure prior to authorizing somebody to be able
14 to deliver these pharmaceuticals and be involved.

15 Because, frankly, a lot of --
16 radiopharmaceuticals is not just a therapy much like
17 say, other pharmaceuticals are given. There are some
18 unique characteristics about it. There's a lot of
19 knowledge about imaging coming into play that has to
20 be accounted for.

21 So, there are some very unique aspects of
22 this therapy. So, I think, you know, they really --
23 I would really support that the AU has to have
24 training well beyond being able to just deliver a
25 single radiopharmaceutical to the patient.

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1 MS. LOPAS: Okay, all right, I appreciate
2 that clarification.

3 Star one for any other comments on the
4 phone. Shirley, do we have another commenter on the
5 phone?

6 OPERATOR: We do, and that's from Joe
7 Rubin, your line is open.

8 MR. RUBIN: Thank you very much.

9 This is Joe Rubin, I'm speaking on behalf
10 of United Pharmacy Partners. UPPI is a consortium of
11 radio pharmacies and they represent about 25 percent
12 of the market, so a really significant player in this
13 space.

14 We just want to comment that we really
15 appreciate the NRC taking the time to evaluate the
16 need for alternative approaches that are obviously
17 are a significant number of exciting therapies that
18 are coming down the pike.

19 And, we believe that will dramatically
20 increase the demand for Radiopharmaceutical treatment
21 beyond just the rural versus urban debate, but in
22 general, that there will be a significant increase in
23 demand.

24 So, the ANP approach that the ACMUI
25 considered, the teaming approach was the ACMUI called

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1 it novel, well intentioned and worthy of extensive
2 consideration.

3 So, we really appreciate the NRC
4 including that in the list of possible outcomes.

5 And, I want to reiterate, the need for a
6 team has been discussed many times on this call and
7 in other comments. And, an ANP has the same basic
8 700 hours of training as an AU.

9 So, when we talk about a full AU, we
10 believe that an ANP from the context of the NRC should
11 be considered practically equivalent.

12 So, thank you very much for your time and
13 for your efforts. We really do appreciate it. And,
14 we look forward to provided a more detailed response
15 in the formal comment period.

16 MS. LOPAS: Okay, thank you, Mr. Rubin.

17 MR. RUBIN: Thank you.

18 MS. LOPAS: Okay, I want to check in with
19 the room? All right, we have a comment in the room.
20 All right

21 MR. GLEASON: Hello, and thanks for
22 taking the time today. So, my name is Shaemus
23 Gleason. I lead the Global Radiopharmaceutical
24 Strategic Operations at Bayer Healthcare.

25 I'm here today to compliment the NRC and

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1 staff on its engagement on this important issue and
2 pursuing a risk informed and nonprescriptive approach
3 to these next generation therapies.

4 The hazards associated with handling any
5 administration of alpha emitting Radiopharmaceutical
6 such as our product, Xofigo, represent a completely
7 different type and scale of radiation risk to the
8 associated missions, the quantities given and the way
9 in which the product is provided to physicians.

10 We strongly support option three or any
11 approach that encourages a risk informed approaching
12 to the licensing of physicians. And, we are working
13 on a comprehensive response to the questions listed
14 in the FRN.

15 So, thanks again for the time today.

16 MS. LOPAS: All right, great, thank you
17 for coming.

18 All right, any additional comments in the
19 room?

20 (NO AUDIBLE RESPONSE)

21 MS. LOPAS: Okay, star one on the phone
22 or if you have a relatively short comment, you can
23 submit it by the webinar because I might do it justice
24 reading it aloud.

25 So, star one or submit it via webinar.

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1 Shirley, do we have any comments on the
2 webinar -- or excuse me, on the phone?

3 OPERATOR: We do. We have one from Beth
4 Blankenship. Your line is open.

5 MS. BLANKENSHIP: Hi, my name is Beth
6 Blankenship. I'm a medical physicist. I also chair
7 the Government Relations Committee for the AAPM.
8 And, my colleague, Bruce Thomadsen is there also
9 sharing the AAPM's current belief for what should
10 happen for our traditional -- maintaining credential
11 training for our physicians.

12 I bring forward another comment and I'm
13 a medical physicist, and I'm also a radiation and safety
14 officer for multiple facilities.

15 And, two things come to mind. Again, we
16 support the traditional status quo training that we
17 have in place as the appropriate training that's
18 necessary for these radiopharmaceuticals.

19 And, one of the challenges I think I see
20 in the field and I wanted to share this is, if the
21 safety responsibilities are shared between an
22 authorized user or if the Radiation Safety
23 responsibilities that are the responsibility of the
24 authorized nuclear pharmacist, the authorized nuclear
25 pharmacist isn't typically out off site so that

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1 oversight can be a challenge because I think that's
2 important to the safety of our patients and our staff.

3 So, that is one challenge that I will
4 bring forward. I think further considerations to be
5 thought through.

6 And, why I bring that forward is, I think
7 the language that how we move forward with this, one
8 of the challenges I currently see, even though we
9 have traditionally trained physicians with multiple
10 hours that do an excellent job, there's many times in
11 outer smaller areas where an authorized user is
12 responsible for the delivery of that
13 Radiopharmaceutical.

14 However, if that physician is not
15 directly onsite to administer that
16 radiopharmaceutical, I think one of the things I would
17 like for there to be a discussion regarding is what
18 does the NRC, regardless of who is going to be allowed
19 to produce or administer this radiopharmaceutical,
20 what role do they have in this?

21 And, in by saying that they have the
22 responsibility of the program, indeed, does that mean
23 that that responsibility can be given to someone other
24 than themselves to administer a radiopharmaceutical
25 whether it's lutetium-177 procedure which is

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1 extremely complex or any other new analogues that are
2 coming along in the near future with lutetium based
3 treatments will require a team.

4 But I would like comments from -- I'm
5 looking forward to the comments from my other
6 colleagues regarding what exactly do they expect,
7 even with the 700-hour trained physician, is what I'm
8 trying to get at.

9 So, I thank you. I think it's a very
10 important topic. I think the questions will be
11 certainly answered by the government relations
12 committee at the APM point by point to explain our
13 concerns and our desire for what we think in the
14 future we should maintain.

15 But there are even additional things that
16 we -- I don't see on these slides that I think we
17 will probably make comment to, too, as it's an
18 appropriate time to bring forward things that have
19 been place that could be looked at.

20 So, thank you very much for taking my
21 call and my comment. Thank you.

22 MS. LOPAS: Yes, thank you very much, Ms.
23 Blankenship. And, exactly, please don't limit your
24 comments. We want to hear all your concerns, you are
25 not boxed in by our questions that we have in the FRN

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1 or boxed in by the approaches.

2 So, thank you, we appreciate your time.

3 Shirley, do we have any other comments on
4 the phone?

5 OPERATOR: At this time, I'm showing no
6 comments.

7 MS. LOPAS: Okay. So, star one for the
8 folks on the phone or if you want to submit a question
9 via the webinar, you can do that as well.

10 I'm just going to once again read through
11 these questions again and see if they jog any
12 additional comments.

13 So, I'll let you know that when we put
14 forward our Commission paper, we will likely have a
15 list of options for our Commission to consider and
16 we'll touch on the advantages and disadvantages of
17 each.

18 So, for question ten, the NRC is
19 certainly going to come up with advantages and
20 disadvantages but we're interested in hearing from
21 the medical community on what they think the
22 advantages and disadvantages of the approaches would
23 be.

24 Again, question 11, now the NRC will do
25 their own cost benefit analysis but, if from the

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1 medical community perspective, if you look at any of
2 these approaches and you think, oh no way, that would,
3 you know, that just doesn't make sense because these
4 costs are prohibitive or they go beyond the benefits.
5 That's what we'd want to hear there for question 11.

6 Question 12, again, we've talked a lot
7 about patient access today. We're interested in
8 hearing what approaches do you think would either
9 help with patient access or help with those concerns
10 about overly burdensome requirements.

11 And, I know not all of you have those
12 concerns, but for those of you that do, we want to
13 hear your input on that.

14 Question 13, for the draft approaches
15 that consider those tailored hours of T&E, we want to
16 hear what is the correct number of hours? What do
17 you think those hours should be?

18 I've heard a couple comments that our
19 numbers are arbitrary. So, we want to hear from you
20 what you think they would be and what do you think
21 the topics can be?

22 And, of course, we're looking into that
23 as well. We're making a determination on that as
24 well. But we take your input and we use it.

25 Question 14, should the NRC consider

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1 inclusion of formal radiation safety competency
2 assessment and periodic reassessments for any of the
3 draft approaches?

4 We have heard some support for that
5 today. So, thank you for that input.

6 And we had this question in our last FRN
7 comment period process back in the fall and winter.
8 So, we'll go back and look at that but we did have a
9 question about who would establish and administer
10 these assessments?

11 So, to the extent that you -- that some
12 of you have already answered this question, we'll go
13 back and look. But any additional thoughts would be
14 helpful.

15 How would the draft approaches impact the
16 medical organization at the NRC's T&E requirements
17 that use NRC's T&E requirements as a basis for
18 establishing their training programs?

19 So, this question is kind of related to
20 the unintended consequences question, the next slide.
21 We're trying to think how would any changes to our
22 T&E requirements ripple through the medical
23 community?

24 Question 16, are there concerns regarding
25 implementation and/or viability for any of the

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1 approaches discussed above.

2 So, again, we're just looking to hear
3 from you all out there in the field, you know, no
4 way, option whatever wouldn't work. Or you know, oh,
5 you might want to consider this, otherwise it doesn't
6 seem like that would work. That's the kind of
7 input we're thinking about for question 16.

8 Question 17, again, are the unintended
9 consequences. Now, we're trying to think of as many
10 considerations for these approaches as we can. But
11 we really need from the folks out in the field their
12 opinions on what that may be some unintended
13 consequences of our approaches.

14 Question 18, we are trying to look toward
15 the future of radiopharmaceuticals and position
16 ourselves to best regulate what's going to be coming
17 down the pike in the future for more complex and the
18 increase in expected number of these
19 radiopharmaceuticals.

20 I think somebody cited the increase of up
21 to 30 percent in nuclear medicine by 2030. And the
22 complexity of some of these administrations that are
23 coming down the pike.

24 So, which draft approach, or is there one
25 that you can think of that we don't have -- that we

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1 didn't think of -- that would best set us up to
2 regulate the future radiopharmaceuticals?

3 And then, finally, question 19 which I
4 think is the big one, should the NRC continue to play
5 a role in the review and approval of AUs?

6 Some of our performance based options led
7 us to put this question in there and you'd probably
8 answer it naturally in your critique of our
9 performance based approaches.

10 But so those are our questions that we're
11 hoping to get feedback on. I want to check in on the
12 phone again with Shirley to see if we have any final
13 comments via the phone?

14 OPERATOR: We do have one from Karen
15 Grady. Your line is open.

16 DR. GRADY: Thank you so much, it's Erin
17 Grady, E-R-I-N, sorry about that if it was hard to
18 understand.

19 Anyhow, I am president of the American
20 College of Nuclear Medicine. And, the ACNM is a
21 professional organization that directly represents
22 the interests of the nuclear medicine physicians
23 before legislative or regulatory bodies and other
24 medical organizations, media, and the public.

25 The college comprises physicians and

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1 scientists dedicated to enhancing the practice of
2 nuclear medicine through study, education, and
3 important improvement of clinical practice.

4 The goal of ACNM is to ensure
5 legislative, legal, regulatory, and economic
6 framework to encourage the safe practice of nuclear
7 medicine in the United States.

8 And, it's my pleasure to join you and
9 it's also I would like to express my gratitude for
10 you guys having this public forum where people can
11 speak their opinions. It's very important.

12 So, I do want to say that the American
13 College of Nuclear Medicine is going to be submitting
14 formal comments in conjunction with the Society of
15 Nuclear Medical and Molecular Imaging.

16 And, we are working toward a pretty
17 comprehensive letter for you. I want to echo some
18 other comments that I heard earlier today calling for
19 lengthening of the time limit for comments.

20 I think Dr. Greenspan has indicated about
21 a month extra would be very helpful if possible.

22 I want to go on the record for the ACNM
23 as also being in favor of the status quo for the
24 training and experience of requirements.

25 We feel that the both alpha and beta

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1 radiopharmaceuticals pose unique concerns and safety
2 issues for patients. And, these should not be taken
3 lightly.

4 We feel that it's very important to
5 protect the patients and public and not decrease the
6 requirements.

7 In addition to this, I wanted to ask just
8 a couple of other questions for the group providing
9 the meeting today.

10 I was wondering if it would be possible
11 to get the slides that were presented at the beginning
12 of the meeting? I wasn't able to be here for the
13 entire length of the meeting.

14 MS. LOPAS: Yes, the slides are available
15 in a couple places. I don't know if you're logged
16 into the webinar. If you're logged into the webinar,
17 they're on the handouts tab of the webinar.

18 If you're not on the webinar, if you go
19 to the NRC's public meeting page, so if you just
20 Google NRC public meeting schedule, that'll bring you
21 to the first result that pops up is the NRC public
22 meeting schedule website.

23 And, if you click on that and you look at
24 today's date, you should find the listing for this
25 meeting, the training and experience meeting.

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1 And, if you just kind of click through
2 that, that meeting notice, I did post our slides
3 there. They're an attachment that you can download.
4 The FRN is posted as well.

5 So, that's how you can find the slides.
6 They're also on the NRC's training and experience
7 evaluation website, too. So, you could just Google
8 NRC training and experience evaluation and if you
9 kind of scroll through there, you can find the slides
10 pretty easily as well.

11 DR. GRADY: Thank you very much.

12 OPERATOR: We do have another comment if
13 you'd like to take it?

14 MR. EINBERG: Yes, before we move on,
15 this is Chris Einberg. I wanted to acknowledge and
16 thank you for your request for the extension. We've
17 also received the request for extension from ACRS,
18 ASTRO, and SNMMI in addition to AAPM and we're
19 evaluating those requests at this time and we'll take
20 it under consideration.

21 MS. LOPAS: Okay, Shirley, yes, we will
22 take another comment.

23 OPERATOR: Thank you. And, that comes
24 from Jeff Siegel, your line is open.

25 (NO RESPONSE)

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1 OPERATOR: Please check your mute
2 feature, your line is open.

3 (NO RESPONSE)

4 OPERATOR: Jeff Siegel, your line is
5 open, go ahead with your comment.

6 (NO RESPONSE)

7 OPERATOR: We'll move on to the next one
8 and that comes from Joe Rubin. Your line is open.

9 MR. RUBIN: Hey, just a quick follow up
10 question with regards to the potential for a delay.
11 The NRC is, I guess, in the process of evaluating the
12 distribution of authorized users. Could you give us
13 an update of that status? Is that completed? Is
14 that -- where does that stand? And, how is that
15 going to be incorporated into your evaluation?

16 MS. LOPAS: Yes, hi, Mr. Rubin, this is
17 Sarah Lopas.

18 So, we are getting close to finishing
19 that up so we have gone ahead and we've mapped all
20 the NRC licensees who are authorized to use 35.300
21 materials.

22 We did put out the request to the
23 Agreement States to provide us that same data and we
24 heard back from -- I can't remember if it's like nine
25 or ten Agreement States -- it was a voluntary request

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1 to the Agreement States. So, we do have a handful
2 of Agreement States that stepped up to the plate and
3 gave us that data as well.

4 And, we're almost done mapping that and
5 those maps are going to be in an enclosure to our
6 Commission paper. So, that's when those maps will
7 become publically available.

8 Does that help?

9 MR. RUBIN: Yes, thank you very much.

10 OPERATOR: We also have another comment
11 if you'd like to take it?

12 MS. LOPAS: Yes, yes, we'll take all
13 comments.

14 OPERATOR: Okay, thank you. That comes
15 from Justin Peacock, your line is open.

16 DR. PEACOCK: Hi, this is Justin Peacock.
17 I am currently a fourth year resident in radiology at
18 Brooke Army Medical Center.

19 I'm also on the ACNM and the ASTRO board
20 as well as the SNMMI trainee committee. And, our
21 tasks are obviously involved with regards to nuclear
22 medicine training, both residents and fellows and
23 ensuring that we have good training and that we have
24 successful careers in nuclear medicine.

25 My comments are with regards to -- and I

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1 want to first of all state that we are very grateful
2 for the NRC for allowing us the opportunity really to
3 have this great opportunity to weigh in on policy and
4 changes potentially to training. And, we're really
5 grateful for the multiple opportunities you've given
6 us to kind of voice our opinion on this matter.

7 I want to state that I agree
8 wholeheartedly with Dr. Grady, Dr. Shuster,
9 Dr. Segall and others from the nuclear medicine
10 committee.

11 One thing that I wanted to bring up was,
12 you know, there's several of these questions that I
13 think are resolved really through the current
14 processes of certificate on within the nuclear
15 medicine radiology and radiation oncology worlds.

16 You know, so, with regards to question,
17 for example, question one, you know, how do we ensure
18 that, let me go back to it, sorry, how do we ensure
19 that, you know, if the status quo is maintained, how
20 do we expect to respond to the increase in number and
21 complexity of future radiopharmaceuticals?

22 Well, I think, you know, the best way to
23 do that is really through the ABNM, through the ABR
24 and through other credentialing boards ensuring that
25 not only the training is performance but also that

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1 competency is assessed and reassessed over time
2 through testing of radiologist, nuclear medicine
3 physicians and radiation oncologists.

4 With regards to question seven, you know,
5 in a lot of small practices, a lot of these
6 radiopharmaceuticals aren't even able to be utilized
7 because you require that whole team environment as
8 well as the hospital network to support it.

9 And, I think, you know, within the text
10 above that question, asserting that licensees could
11 develop and use their own policies and procedures to
12 make self-determination as to whether credential
13 physicians have the appropriate T&E.

14 I think that leads down dangerous road.
15 You know, I think we've had together with the NRC, I
16 think nuclear medicine, radiology, and radiation
17 oncology of has had a very successful history of
18 maintaining safety with regards to
19 radiopharmaceutical administration.

20 And, I think if we deviate from that by
21 allowing licensees to develop their own policies with
22 regards to how to credential physicians or AU status
23 members, I think we run the risk really of having
24 differential standards which would lead to
25 potentially poorer patient outcomes, poor patient

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1 care and potentially poorer outcomes with regards to
2 those within the field that are treating these
3 patients.

4 And then, I could go on, but you know,
5 there's multiple questions from, you know, 15 through
6 19 really that I think address that, that really,
7 this partnership between NRC and nuclear medicine,
8 radiology, and radiation oncology has worked well for
9 so many years now that to deviate from that and to
10 allow people to have their own preceptors or their
11 own credentials really would lead to, I think,
12 substandard care or differences in standards of care
13 that don't meet the needs of patients in terms of
14 good patient outcome and patient safety as well as
15 healthcare worker safety.

16 And, with that, I'll conclude. But, I
17 think you know, really, a lot of these questions can
18 be really addressed by the fact that we currently
19 have a great system going and I think the current
20 credentialing mechanisms through ABNM and ABR really
21 meet the standards for ensuring that, in the future,
22 new therapies, new radiopharmaceuticals, new
23 diagnostic procedures will be conducted in a safe and
24 efficient manner.

25 Thank you.

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1 MS. LOPAS: All right, thank you, Dr.
2 Peacock. We appreciated that comment.

3 Shirley, do we have other folks on the
4 phone? Star one if you want to ask a question or
5 make a comment on the phone, star one.

6 OPERATOR: At this time, I'm showing no
7 comments.

8 MS. LOPAS: Okay. I'm going to read a
9 question from the webinar.

10 "Form 313A, AUT, will expire 6/30/2019.
11 Can you explain if there are any impacts on licensees
12 prior to the teleconference in September 2019? So,
13 I think he's referring to the ACMUI teleconference,
14 their comments on our draft paper, or the final paper
15 by the end of 2019 on the license applications for
16 new AUs or renewals?"

17 We are getting a response from Dr. Donna-
18 Beth Howe because she is our NRC expert on handling
19 the forms.

20 DR. HOWE: The current NRC -- this is Dr.
21 Donna-Beth Howe -- the current NRC form 313s for the
22 new rule that took effect in January are not available
23 at this point.

24 We are still looking for an OMB clearance
25 for them. We expect to have those forms published

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1 maybe the end of the summer.

2 In the meantime, we have instructions on
3 our website for how to provide the information that
4 is needed to meet the current requirements.

5 Having said that, for the NRC Form 313
6 which is any license application, it expires June 6,
7 but there is an application into the Office of Budget
8 and Management to extend that date and because we
9 have an application into them, that date will be
10 extended until the Office of Budget and Management
11 has actually reviewed and approved the new -- the 313
12 and will -- so the form will continue to be used.

13 If you are an Agreement State, you can
14 use the old 313 A series for training and experience.
15 You will need to go into the NUREG-1556 Volume 9
16 Revision 2 to find copies of those documents.

17 So, that -- the 313, 313A's will continue
18 to be used. The new ones won't be available until
19 probably the end of the summer.

20 MS. LOPAS: Okay. And that was Dan Hill
21 from Carinal Health who asked that question. So,
22 Dan, I hope that answered your question.

23 Shirley, do we have any comments on the
24 phone?

25 OPERATOR: At this time, I'm showing no

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1 comment.

2 MS. LOPAS: Okay. All right, I want to
3 give folks one last chance to get their comments in,
4 so press star one or submit it via the webinar.

5 While you're waiting -- while I'm waiting
6 to get any last minute comments, I just want to point
7 out that we have received some several requests to
8 extend our comment period by 30 days.

9 We have not made a decision on that, but
10 when and if we do, we will make sure that everybody
11 knows and it's thoroughly publicized.

12 But in the meantime, you know, move
13 forward as if it's June 3rd and you're going to submit
14 your comments via regulations.gov under that docket
15 ID. If you have any issues at all, contact me or
16 Maryann, we'll help you out.

17 And the transcript for this public
18 meeting will become available in about a week or so.
19 We'll get it up on our website, the training and
20 experience website. I will also put it on
21 regulations.gov and I will be putting together a
22 meeting summary as well that's going to be available
23 a couple weeks after that.

24 So, Shirley, I want to check in to see if
25 there's any other comments on the phone.

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1 OPERATOR: We do have one and that is
2 from Jeff Siegel, your line is open.

3 DR. SIEGEL: Hi, I'm sorry about last
4 time, my phone just died, so I had to dial back in.

5 So, in case I missed it, I'm sorry about
6 that.

7 My name is Jeff Siegel, I have a quick
8 comment and point to make. I haven't heard anybody
9 talk about this, whether or not it was necessary for
10 NRC to do a formal risk evaluation?

11 My assumption is that everybody or most
12 people think that all agents are created equal and
13 they all represent the same risk.

14 My understanding is that NRC cannot
15 intrude into the practice of medicine unless it's a
16 safety issue. So, I'm assuming that all agents are
17 assumed to be equally risky and I hope that's not an
18 outgrowth of the LNT and ALARA philosophy.

19 So, I'd just like to know if NRC ever
20 intends to do a formal risk assessment and maybe that
21 way it could tailor agents because, as everybody
22 knows, 390 already has a tailor, that is either you're
23 a full fledged, certified, exam taking, board
24 certified, nuke med physician or you have a 700 hours.

25 And, what about 392 and 394 which already

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1 requires 80 hours? I don't hear anybody saying that
2 ought to be taken off the books.

3 So, I'd just like to hear if NRC believes
4 they should do a risk evaluation or if they don't
5 need to since every agent is highly risky.

6 Thank you.

7 MS. AYOADE: Hi, Jeff, this is Maryann
8 Ayoade. Thank you for your comment.

9 You know, as part of this evaluation
10 we're doing now, we're taking a look at our training
11 and experience requirements under 35.300. But, we
12 will take into consideration you question, you know,
13 to further look into it in terms of a risk assessment.

14 I mean, yes, in terms of a risk
15 assessment.

16 DR. SIEGEL: Well, that's great. Could
17 you still hear me?

18 MS. AYOADE: Yes.

19 DR. SIEGEL: Because NRC, and I love NRC,
20 don't get me wrong, NRC's requirements we know are
21 risk based. So, if indeed they are, that's great.

22 But to have an overly burdensome
23 regulation that isn't risk based, which would prevent
24 somebody from administering a medically approved
25 agent, I don't think is the right way to go.

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1 But I know people believe that all
2 therapeutics must pass the threshold of radiation
3 risk and therefore there's no way to have a spectrum
4 of T&E.

5 I don't agree with that, but I haven't
6 heard anybody say anything about that yet. But,
7 thank you, Maryann, for that comment.

8 MS. AYOADE: Well, thank you and I just
9 want to add, you know, again, as part of even the
10 NRC's Medical Policy Statement, our goal as we do
11 this evaluation is to make sure that we're keeping in
12 mind that we're not interfering with the practice of
13 medicine and so I just wanted to add that to my
14 comment.

15 DR. SIEGEL: Well, right, unless it's a
16 safety issue, correct.

17 MS. AYOADE: Yes.

18 DR. SIEGEL: And, that's why I love the
19 NRC. That's true.

20 MS. AYOADE: Great.

21 DR. SIEGEL: Thank you.

22 MS. AYOADE: Thank you.

23 MS. LOPAS: Okay, Shirley, do we have any
24 other commenters on the phone?

25 OPERATOR: At this time, I'm showing no

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1 further comments.

2 MS. LOPAS: Okay, I want to check back
3 in the room, anybody have any final statements here
4 in the room?

5 (NO AUDIBLE RESPONSE)

6 MS. LOPAS: Okay, nobody's moving.

7 All right. I'm going to go back to the
8 staff and let the staff make some comments.

9 MS. AYOADE: Yes, there was a comment
10 earlier related to the training of the nuclear --
11 authorized nuclear pharmacists being similar to that
12 of the 700 hours requirement for the authorized user.

13 I just wanted to clarify that currently
14 in the regulations, the authorized nuclear pharmacist
15 can either come under the board certification pathway
16 or an alternate pathway for 700 hours.

17 And, that's 700 hours is not exactly
18 similar to what we require for the authorized users
19 for Radiopharmaceuticals. The 700 hours does include
20 the classroom and laboratory but, as it relates to
21 the work experience, the supervisory work experience,
22 it doesn't include that or it doesn't require that
23 they have that experience in patient case work and
24 all of the different categories that we currently
25 have for the radiopharmaceuticals.

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1 And so, I just wanted to clarify that it
2 is different than what the 700 hours that we require
3 as for radiopharmaceuticals.

4 MS. LOPAS: Thanks, Maryann, I appreciate
5 that clarification as that relates to option D-3
6 regarding teaming an AU with an authorized nuclear
7 pharmacist.

8 Okay, with that being said, I'm going to
9 check in on the phone again. Star one on the phone,
10 anybody? Shirley, anybody else on the phone?

11 OPERATOR: At this time, I'm showing no
12 further comments.

13 MS. LOPAS: Okay, well, if you come up
14 with another comment, that's great because you can
15 submit it to us via writing, via regulations.gov or
16 you can join us again on Thursday morning, May 23rd,
17 10:00 a.m. to 12:00 p.m. and we can get together again
18 and do this all over again and hear your comments
19 again. That will again be a transcribed meeting.

20 Chris and/or Lisa, do you guys have
21 anything to say?

22 MR. BINBERG: I just want to thank
23 everybody for your active participation and the
24 excellent comments that we've received. We certainly
25 evaluating those comments and they will be used as

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1 part of the decision making process.

2 We've heard you as far as the request for
3 extending the comment period by 30 days. We'll --
4 as soon as we make a decision as Sarah pointed out,
5 we'll, you know, make sure that everybody knows that.
6 We'll communicate that extensively.

7 If we've made that decision or when we
8 make that decision, and so, thanks again for coming.

9 MS. IOPAS: Okay, thank you, everybody,
10 this ends the meeting.

11 (Whereupon, the above-entitled matter
12 went off the record at 3:02 p.m.)

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