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 on the NRC's Evaluation of Training and
 Experience Requirements for Different
 Categories of Radiopharmaceuticals

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING

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

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TUESDAY,

JANUARY 22, 2019

+ + + + +

The meeting was held via webinar at 10:00
a.m. Eastern Time.

PRESENTERS FROM THE NRC:

MARYANN AYOADE, NMSS, MSST, MSEB

SARAH LOPAS, NMSS, MSST, MSEB

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

2 (10:02 a.m.)

3 MS. LOPAS: Hi, everybody, good morning.
4 Welcome to the Nuclear Regulatory Commission's
5 webinar to accept comments on the Staff's evaluation
6 of training and experience requirements for different
7 categories of radiopharmaceuticals.

8 This is our last of four public
9 meetings/webinars that we've had on this topic. And
10 I want to remind everybody that our comment period
11 ends a week from today on Tuesday, January 29th.

12 My name is Sarah Lopas and I'm a member
13 of the NRC's Medical Radiation Safety Team, which is
14 part of the Medical Safety and Events Assessment
15 Branch in the NRC's Office of Nuclear Materials Safety
16 and Safeguard.

17 I'm the project manager for the NRC's
18 training experience evaluation and I'll be
19 facilitating today's webinar and giving part of the
20 presentation.

21 And here to help me out is Maryann Ayoade,
22 who is a health physicist in the NRC's Medical
23 Radiation Safety Team. And she is the technical lead
24 on the training and experience evaluation. So
25 Maryann will be giving part of the presentation as

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1 well.

2 We have a short agenda for today's
3 webinar. I'll just be going over some basic
4 information about the webinar and then Maryann and I
5 will go through 15 slides that will cover background
6 information on the NRCs evaluation on training
7 experience evaluations, we're going to discuss the
8 Federal Register notice that was published on October
9 29 and then we're going to cover how you can provide
10 your written comments by that January 29th deadline,
11 if you would like to provide written comments.

12 Then we're going to open up the phone
13 lines to take your comments and any kind of process-
14 type questions you have. And you can also submit
15 questions or comments via the webinar software. I'll
16 keep an eye on that.

17 The purpose of today's webinar is
18 twofold. It's to provide you background information
19 on the staff's planned evaluation of developing
20 tailored training and experience requirements for
21 administering different categories of
22 radiopharmaceuticals, for which a written directive
23 is required.

24 And that's in accordance with your
25 regulations in 10 CFR Part 35. And those are

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1 regulations for medical use of byproduct material.

2 And specifically, under Subpart E, of
3 Part 35, which covers unsealed byproduct material
4 written directive required.

5 And most importantly, the reason why
6 we're here is to listen to and record your comments
7 on the evaluation. So, the comments that we received
8 from the medical community, the agreement states and
9 other stakeholders, are critical to our decision
10 making on whether our existing training and
11 experience requirements should be revised.

12 And so, if you don't provide comments
13 today, orally over the phone, just please make sure
14 you get them in. You get your written comments in
15 by regulations.gov by January 29th. That due date.

16 And I'll be going over how you can do
17 that a couple more slides from now.

18 So, for general webinar information
19 today, I want to note that if you aren't logged into
20 the webinar that's okay, there's a couple ways to get
21 our slides. You can either go to our public meeting
22 schedule web page and that provides-if you find
23 today's meeting, which should be one of the top
24 meetings listed-there's a link to our slides.

25 If you go to the NRC's T&E website, if

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1 you just Google "NRC training and experience
2 evaluation," that will bring up our T&E website.
3 And there's a link to today's slides if you scroll
4 down the page and look for today's meeting as well.

5 So, there is a couple of ways to get to
6 our slides if you're just listening in without the
7 webinar.

8 Today we're going to be discussing our
9 evaluation of training experience requirements for
10 certain categories of radiopharmaceuticals. We're
11 likely going to refer to them as, training experience,
12 as T&E for short. And also, we tend to refer to
13 authorized users, which are those physicians who are
14 authorized to administer radiopharmaceuticals, as
15 AUs.

16 So those are some terms that you'll hear
17 today.

18 And today's webinar is being transcribed
19 by a court reporter. And a full transcript of this
20 webinar will be publicly available in about a week
21 and a half or so. Or maybe we might try to get it
22 turned around a little bit quicker before the comment
23 deadline. I'll try to do that for you all.

24 And it's going to be available in the
25 NRC's agencywide Documents Access and Management

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1 System, that's ADAMS. And I'll be posting a link to
2 this transcript on the NRC's training and experience
3 website. It will also go up on regulations.gov too.

4 And you can find all of the transcripts
5 that we have for our past three public meetings on
6 that T&E website as well. And also on
7 regulations.gov.

8 On regulations.gov, under our docket
9 (NRC-2018-0230), there is a category called
10 supporting documents. And that's where I've listed
11 the meeting summaries and transcripts, if you're
12 interested in what people have said during past
13 meetings.

14 And I do want to say that all the comments
15 that are spoken here today will make it on our docket
16 since they are being transcribed. And that oral and
17 written comments have equal weight. So if you don't,
18 if you've spoken your mind today and you don't feel
19 like typing it in or sending it by regulations.gov
20 afterwards, that's perfectly fine because we will get
21 it today.

22 So, right now everybody is in listen only
23 mode. And as Cedric mentioned, when Maryann and I
24 finish the presentation, that's when I'll be opening
25 the phone lines. And all you have to do is press

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1 star-1.

2 And I'll remind everybody that you do
3 need to make sure that you introduce yourself and
4 clearly state your name. And if it's a tricky name,
5 maybe spell it out for our court reporter. That's
6 vitally important so we know who is saying what.

7 So now I'm going to hand the presentation
8 over to Maryann so she can talk about our T&E
9 regulations and give you some background.

10 MS. AYOADE: Great, thank you, Sarah.
11 Good morning, everyone.

12 Today I will be presenting information on
13 an overview of the regulations on training and
14 experience for radiopharmaceuticals requirement and
15 directive, some background on the related stakeholder
16 concerns received for this evaluation and the NRC's
17 efforts on the evaluation thus far.

18 So, the current regulations on training
19 and experience for radiopharmaceuticals requiring a
20 written directive, are under 10 CFR Part 35, Subpart
21 E. These training and experience requirements
22 provide three pathways that a physician may be
23 authorized to administer radiopharmaceuticals that
24 require written directives.

25 A physician can be authorized to

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1 administer these radiopharmaceuticals if they are
2 certified by a medical specialty board. This
3 certification process is recognized by the NRC or an
4 agreement state.

5 A physician can also be authorized if
6 they've satisfied the training requirements via an
7 ultimate pathway, which includes the completion of
8 700 hours of training and experience, including a
9 minimum of 200 hours in classroom and laboratory
10 training in relevant topic areas as listed in the
11 regulation. And 500 hours of supervised work
12 experience in the relevant areas as listed in the
13 regulations.

14 A physician can also be authorized if
15 they have been previously identified as an authorized
16 user on an NRC or agreement state license or permit.

17 So, this training and experience
18 evaluation is focused on the alternate pathways. And
19 the NRC staff are looking into what tailored training
20 and experience requirements, for limited
21 administration of certain categories of
22 radiopharmaceuticals would look like. And that is
23 what we will be referring to as an admitted authorized
24 user status.

25 Next slide. In Subpart E, there are four

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1 sections that pertain to training and experience
2 requirements.

3 The first section is under 10 CFR 35.390,
4 for training for the use of all radiopharmaceuticals
5 in Subpart E. All of which require a written
6 directive.

7 The second is under 10 CFR 35.392, the
8 training for oral administration of sodium iodide, I-
9 131. Requiring a writing directive in quantities
10 less than or equal to 33 millicuries.

11 The third is under 10 CFR 35.394, for
12 training for oral administration of sodium iodide, I-
13 131. Requiring the writing directive in quantities
14 greater than 33 millicuries.

15 And the fourth section is in 10 CFR
16 35.396, for training for the parenteral
17 administration of any radiopharmaceuticals requiring
18 the written directive.

19 I want to point out that all of these
20 sections of training and experience, include the
21 pathways for an experienced authorized user that is
22 already listed on a license. Also, all the sections,
23 except for 10 CFR 35.396, include training and
24 experience under the board certification and ultimate
25 pathways.

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1 However, 10 CFR 35.396 is for training
2 exclusively under the ultimate pathways. And it is
3 really for the radiation oncologist that are looking
4 to become authorized users. And they can do this by
5 completing some additional hours of training and
6 experience.

7 I also want to point out that ultimate
8 training pathways, under 10 CFR 35.392 and 394, is
9 for the physicians to successfully complete 80 hours
10 of classroom and lab training that is relevant to the
11 type of use for which they are seeking to be
12 authorized.

13 Whereas, ultimate training pathways,
14 under 10 CFR 35.390, is for the physician to
15 successfully complete 700 hours of training and
16 experience, which includes 300 hours of classroom and
17 laboratory training.

18 Next slide. So, this slide provides
19 background information on stakeholder concerns that
20 have been received related to these training and
21 experience requirements.

22 Since the revision to the training and
23 experience requirements in 2002, and again in 2005,
24 stakeholders have raised concerns about the effects
25 of some of the requirements on patient access to

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1 certain therapy related pharmaceuticals.

2 Specifically, some of the stakeholders
3 have asserted that the 700 hour requirements in 10
4 CFR 35.390, is overly burdensome for physicians that
5 are not certified by a medical specialty board and
6 that the extensive requirements have resulted in a
7 shortage of authorized users. Which thereby limits
8 patients access to radiopharmaceuticals.

9 As a result, in 2015 and in 2016, in
10 separate efforts to NRC Staff and the NRC's Advisory
11 Committee on the medical uses of isotopes, also known
12 as the ACMUI, independently reviewed the training and
13 experience requirements for the medical uses
14 authorizes under Subpart E.

15 Specifically, the NRC Staff has reviewed
16 the regulatory basis and comments received on past
17 rulemaking related to the medical use of byproduct
18 materials and did not identify any new information
19 that will call into question the basis of the existing
20 requirements.

21 As a result, the NRC Staff did not
22 disclose any changes to the regulations at the time.
23 And the NRC Staff is continuing to work with the ACMUI
24 in this ongoing training and experience evaluation
25 effort.

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1 Next slide. As part of the Staff
2 requirements memorandum dated August 17, 2017, and
3 that is publicly available in ADAMS via the hyperlink
4 that is referenced on this slide, the Commission
5 directed the NRC Staff to evaluate whether it makes
6 sense to establish tailored training and experience
7 requirements for different categories of
8 radiopharmaceuticals. It also evaluates how this
9 category should be determined.

10 So, such as the risk posed by
11 radionuclides or by delivery method. It also
12 evaluates what the training and experience
13 requirements would be for each category and to
14 evaluate whether those requirements should be based
15 on hours of training and experience or focus more on
16 competency.

17 Next slide. In response to the
18 Commission direction, the NRC Staff obtained feedback
19 from some medical and regulatory stakeholders in
20 April and May of 2018.

21 That evaluation, including the NRC Staff
22 analysis and the feedback that was received of the
23 training and experience requirements in Subpart E of
24 10 CFR Part 35, was documented in an NRC SECY paper,
25 which is the SECY-18-0084.

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1 The results of that evaluation concluded
2 that it may be feasible to establish tailored training
3 and experience requirements, for different categories
4 of radiopharmaceuticals and to create a means of
5 authorizing the administration of certain categories
6 of radiopharmaceuticals, which is the limited
7 authorized user status.

8 It also concluded that there are viable
9 options for creating a competency-based approach to
10 demonstrate accessible training and experience for a
11 limited authorized user status. But, however, the
12 Staff does need to conduct more extensive outreach to
13 stakeholders in the medical community, to the
14 agreement states and to other members of the public,
15 before making a recommendation to the Commission.

16 And that is what brings us to our current
17 evaluation to date. I will now hand it back over to
18 Sarah, who will discuss our current evaluation
19 efforts and how you can participate. Next slide.

20 MS. LOPAS: Thank you, Maryann. So, the
21 end product of the NRC Staff's evaluation will be a
22 paper that we're going to send to our five-member
23 Commission.

24 And that paper is going to document the
25 results of our evaluation. Which would either be

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1 maybe recommending no changes or recommending some
2 options for potential changes.

3 And, if we do recommend some options, we
4 will also have to accompany that paper with a
5 rulemaking plan.

6 On this slide, we're on Slide 11 now,
7 this is a simplified diagram of the information that
8 we're going to consider in our development of a
9 recommendation to the Commission. The diagram
10 illustrates why this comment period is so important
11 to this effort because, in large part, the feedback
12 that we receive on the questions that we've asked in
13 our Federal Register notice, are going to inform our
14 recommendation to the Commission.

15 And other important feedback will come
16 from our coordination with our co-regulators, the
17 Agreement States, and the NRC Advisory's Committee on
18 the Medical Uses of Isotopes, ACMUI as Maryann had
19 mentioned earlier.

20 In addition to the inputs we receive
21 from--

22 (Technical interference)

23 MS. LOPAS: -- the Agreements States and
24 the ACMUI, the NRC Staff is also examining the issue
25 of patient access. So, we are currently attempting

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1 to map NRC licensees that are licensed to use 10 CFR
2 Part 35.300 materials.

3 These are licensee facilities that could
4 potentially offer these therapeutic
5 radiopharmaceuticals. So, we're going to be mapping
6 those. And there will be a series of maps of the
7 individual states for the data that we have.

8 The NRC only has access currently to non-
9 agreement states - - our licensees. And those are
10 about 13 states at the moment.

11 We are planning to issue a voluntary
12 request for information to the Agreement States for
13 their information on --

14 (Technical interference)

15 MS. LOPAS: -- for these therapies as
16 well. So that would hopefully give us a little bit
17 more complete of a picture of the --

18 (Technical interference)

19 MS. LOPAS: -- United States, depending
20 on how many Agreement States are able to respond back
21 to us and help us out with this data.

22 I will note that we are stuck a little
23 bit right now with that request. That voluntary
24 request to the Agreement States. It does need to be
25 reviewed and approved by the Office of Management and

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1 Budget.

2 And the Office of Management and Budget
3 is closed due to the partial Government shutdown.
4 So, at the moment, we're kind of stuck. But I would
5 hope that that letter would go out to the Agreement
6 States --

7 (Technical interference)

8 MS. LOPAS: -- maybe two to four weeks
9 after the partial shutdown ends and --

10 (Technical interference)

11 MS. LOPAS: -- everything goes back up.

12 The other things that the staff is going
13 to look at are -- we're reviewing our training and
14 experience requirements in other countries in an
15 effort to benchmark what other, what the
16 international community is doing with regard to
17 training and experience.

18 And then we also are reviewing -- doing
19 an extensive review of recent medical events in our
20 NMED database. The Nuclear Materials Events
21 Database. NMED is our database that covers events
22 with nuclear materials -- to see if any medical
23 events have a nexus to training and experience.

24 So, we have to dig a little deeper into
25 those events to see if we can get to a root cause of

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1 training and experience. So, those are the two
2 additional things that we're looking at. Three
3 additional things we're looking at.

4 In addition to evaluating your comments
5 --

6 (Technical interference)

7 MS. LOPAS: -- and what we hear from the
8 ACMUI and the Agreement States.

9 So, it's important to --

10 (Technical interference)

11 MS. LOPAS: -- is to our regulations,
12 that we would need to document, again, document that
13 in a rule making plan. And then our Commission would
14 the proceed to vote on that rulemaking plan.

15 And that would determine whether or not
16 we would move forward with another Part 35 rulemaking
17 effort. And if rulemaking is recommended and the
18 Commission approves it, that would then start our
19 extensive rulemaking process that many people are
20 familiar with.

21 And I am highlighting where we are in
22 this process so everybody understands where we are.
23 And where we are is that we're still in the
24 information gathering phase. We --

25 (Technical interference)

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1 MS. LOPAS: -- kept in mind, you know,
2 we're really at the beginning of this. And until we
3 really get all, until the public comment period ends
4 and we get everybody's comments in and we get a chance
5 to really digest them and we hear from the agreement
6 states --

7 (Technical interference)

8 MS. LOPAS: -- a path forward yet. So,
9 I just wanted to highlight that.

10 Next slide, Slide 12, covers our Federal
11 Register notice. So, that was published back on
12 Monday, October 29th. The Federal Register notice
13 can be accessed by this link.

14 And I also want to point out that there
15 are some handouts attached to the webinar. So, if
16 you click on the little handouts button on your
17 webinar, you'll see, I believe, a copy of these slides
18 that you can download if you want.

19 I have the SECY paper that Maryann
20 referenced from last August --

21 (Technical interference)

22 MS. LOPAS: -- And I also have a copy of
23 the Federal Register notice. So you can download all
24 of those documents from the --

25 (Technical interference)

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1 MS. LOPAS: -- webinar. So, the Federal
2 Register announced the comment period. It ends on,
3 a week from today on Tuesday, January 29th.

4 And most importantly, the Federal
5 Register notice asks a series of questions on which
6 the NRC would like specific input on from the medical
7 community.

8 So, I'm going to read through those
9 questions in the next four slides just to give
10 everybody some context of kind of the information
11 that we're looking for.

12 But then, we will be opening it up to
13 public comments after I'm done here in a couple of
14 minutes. So, we can certainly walk through the
15 questions later on or however we want to do it, so,
16 don't worry, I'm just going to read through the
17 comments now, or the questions now, to put some
18 context into what we're looking to get.

19 So, Slide 13, here we are. Questions in
20 the FRN.

21 So, Part A was asking about tailored
22 training and experience. And these aren't all of our
23 questions so that's why I do encourage you to read
24 through the whole FRN, there's a lot of subparts to
25 these questions --

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1 (Technical interference)

2 MS. LOPAS: -- You can review the FRN
3 that I've attached to the webinar and read through
4 them maybe during the comment portion of today's
5 meeting.

6 Question 1. Are the current pathways for
7 obtaining AU status reasonable and accessible, are
8 they adequate for protecting public health and
9 safety?

10 Question 2. Should the NRC develop a new
11 tailored T&E pathway? What would be the appropriate
12 way to categorize radiopharmaceuticals for tailored
13 T&E requirements?

14 Question 3. Should the fundamental T&E
15 required of physicians seeking limited AU status need
16 to have the same fundamental T&E required of
17 physicians seeking full AU status?

18 Question 4. How should the requirements
19 for this fundamental T&E be structured for a specific
20 category of radiopharmaceuticals?

21 Slide 14 goes over the NRCs recognition
22 of medical specialty force. And if you Google NRC
23 medical licensee toolkit, these procedures for
24 recognizing the medical specialty boards are on that
25 medical licensee toolkit website. But, what boards,

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1 other than those already recognized from the NRC,
2 could be considered for recognition for medical uses
3 under 10 CFR 35.300. And those other boards are,
4 American, or the boards that we currently recognize
5 are, American Board on Nuclear Medicine, American
6 Board of Radiology, American Osteopathic Board of
7 Radiology, Certification Board of Nuclear
8 Endocrinology.

9 And two, are the current NRC medical
10 specialty board recognition criteria sufficient? If
11 not, what additional criteria should the NRC use?

12 Slide 15 goes over the patient access --
13 (Technical interference)

14 MS. LOPAS: -- perspective of folks that
15 may or may not be impacted by our regulations on
16 patient access.

17 So, is there a shortage in the number of
18 AUs for medical uses under 10 CFR 35.300? If so, is
19 the shortage associated with the use of a specific
20 radiopharmaceutical?

21 Are there certain geographic areas with
22 an inadequate number of AUs?

23 Do current NRC regulations on AU T&E
24 requirements unnecessarily limit patient access to
25 procedures involving radiopharmaceuticals?

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

4 And we have gotten some feedback or
5 questions about, why is the NRC asking --

6 (Technical interference)

7 MS. LOPAS: -- this? And I would answer
8 that and say that, you know, we are interested in the
9 perspective of folks that are out there doing this -
10 what are the impacts that people are noticing with
11 regard to patient access?

12 You know, we have heard from some
13 physicians that, No, there is no patient access issue,
14 there are plenty of AUs out there. And then we've
15 heard from some other industry folks saying, yes,
16 we're having hard time finding AUs.

17 So, that's the kind of feedback that we'd
18 like to hear. And that's why we thought it was
19 important to include in the FRN.

20 And then Slide 16 are questions, just
21 general questions about the NRC's training and
22 experience regulations as a whole. These are kind
23 of in an effort to, for us to kind of maybe look
24 transformatively at our medical regulations with
25 regard to training and experience.

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1 So, Question 1. Should the NRC regulate
2 the T&E of physicians for medical uses?

3 Are there requirements in the NRC's T&E
4 regulatory framework for physicians that are
5 non-safety related?

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

11 So, those are all the questions. And
12 like I said, there's multiple sub-questions
13 underneath each one of these questions, so I really
14 encourage you to check out the Federal Register
15 notice.

16 So, this slide just gives you the
17 important details about submitting your written
18 comments. So, like I mentioned, January 29th, one
19 week from today at 11:59 p.m., the regs.gov portal
20 will stop accepting comments.

21 So, how do you submit comments to
22 regulations.gov? Well, you simply just go to
23 www.regulations.gov and there's a search bar will
24 popup right at the top and you just type in, NRC-
25 2018-0230.

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1 And that will just bring you right to the
2 T&E page, docket page. And it's very self-
3 explanatory on submitting comments.

4 This is also, that second bullet there on
5 the side is just the direct link to submit comments,
6 so that will get you there as well.

7 I do want to note that, let's see, last
8 Friday regulations.gov, I think, went down for about
9 half a day. You could not access anything on
10 regulations.gov.

11 And it was related to the Government
12 shutdown affecting a portion of the Environment
13 Protection Agency, which actually manages
14 regulations.gov. But it is back up and running.

15 It did come back up and running about, I
16 don't know, half way through the day on Friday. And
17 I've been told, I've been assured that it should
18 remain up and running through the rest of the comment
19 period, through January 29th.

20 Now, if you have any issues at all with
21 submitting your comments by regulations.gov, if you
22 go to log on and you can't get to it, it's shutdown
23 for some reason, you can email your comments to me or
24 Maryann. That is no problem, that's perfectly
25 acceptable.

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1 And that's going to be the work around if
2 for some reason regulations.gov shutdowns anytime
3 between now and January 29th. But I've been checking
4 regulations.gov a few times a day, every day because
5 I'm nervous about about it, and it's so far so good.
6 Except for that one Friday. Or, I think it was
7 Thursday that it actually went down.

8 So, my contact information and Maryann's
9 contact information will be in the slide, the next
10 slide, so you'll see that. But I just want to make
11 sure that everybody knows that emailing your comments
12 to me is a perfectly fine option if regulations.gov
13 isn't working.

14 I do want to note that when you submit
15 your comment on regulations.gov, you're not going to
16 see it posted right away. It takes a few weeks.

17 But I will, I promise you that we are
18 getting it so don't worry. It sends you a little
19 confirmation that your comment has been received.
20 And we receive them.

21 It just takes a, we have an internal
22 administration, an admin type process where we have
23 to pull it down off the regulations.gov, put it into
24 our ADAMS system, so your comments will also be in
25 ADAMS, and then we re-post it back on regulations.gov.

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1 So that's why it takes a little bit longer.

2 At the end of the comment period, so we're
3 going to be compiling all the comments, organizing
4 them, reviewing them and we'll be summarizing them.
5 And we'll be putting together a nice summary report
6 that will be attached to the paper that we send to
7 the Commission. And the summary report will
8 summarize everything we've heard from everybody.

9 And I do want to note that because this
10 is not a rulemaking, so we aren't going to responding
11 individually to comments, the comments are simply to
12 inform us. So we aren't going to be responding back
13 to your comments.

14 Okay, next slide is Slide 18. These are
15 just next steps, so this is just a basic outline.

16 So the comment period ends on January
17 29th. And then in February and March we're going to
18 be evaluating your comments, reviewing that
19 additional information that I talked about.

20 You know, conducting the patient access,
21 doing the patient access maps, looking at
22 international benchmarking and accepting medical and
23 radiation safety events. We'll be looking forward
24 to getting a draft report from the ACMUI subcommittee
25 on T&E, so hopefully we'll get that in mid-February

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1 or so.

2 I will encourage folks to check out the
3 T&E website. And if you aren't signed up for the
4 NRC's medical Listserv please do that as well. We
5 will be having a public teleconference with the ACMUI
6 to discuss their draft subcommittee report on T&E.

7 So that may really be of interest for
8 many of you that has been on these webinars. So,
9 keep an eye out for that. It will be on our website.

10 It will be on the NRC's public meeting
11 website. It will be noted there. And also, a note
12 will go out via our medical Listserv about when that's
13 going to be happening and how you can participate in
14 that.

15 And then, once we do our draft paper, the
16 ACMUI and the agreement states will both get to review
17 that draft paper and send us back their comments.
18 There will be another ACMUI teleconference on their
19 comments on our draft sometime in the summer.

20 So, again, you would just keep an eye out
21 on the medical Listserv and the websites to see when
22 that is going to happen.

23 And then we will finalize our paper and
24 hopefully deliver it to the Commission sometime in
25 the fall. The Fall of 2019. So that's our general

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1 schedule.

2 So, for more information, next slide,
3 Slide 19. I really encourage you to visit the T&E
4 website there. Like I said, the regulations.gov
5 page, that docket page, that shows everybody's
6 comments that they've submitted to date.

7 So if you're interested in reading
8 through some comments that people have sent in so
9 far. I also have been posting the meeting summaries
10 and transcripts there.

11 And then of course, if you have any
12 questions, you can contact me at sarah.lopas@nrc.gov.
13 As the PM I kind of can talk you through the more
14 process type questions.

15 But I encourage you to reach out to
16 Maryann Ayode. She is the technical lead on the
17 project, so regulation type questions or have some
18 technical questions, she is who you should go to.

19 And that's it for our presentation. So,
20 before we open up the phones, I just want to remind
21 everybody that, again, we're being transcribed by the
22 court reporter so we can accurate comments for our
23 T&E docket, so please being by introducing yourself.
24 Maybe spell your name if you think it's a tricky name.
25 And speak clear.

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1 You can press star-1 at any point, so
2 just go ahead and press star-1 if you already want to
3 jump in. And then you are also free to submit your
4 questions and comments via the chat function or the
5 question function on the webinar. I'll keep an eye
6 on that. And I can certainly read those aloud for
7 you.

8 So, star-1 on the phone. And I'll just
9 go to Cedric, if you can just let us know if anybody
10 pops on the line?

11 THE OPERATOR: Sure. And also, if you'd
12 like to ask a question, please remember to un-mute
13 your phone and record your name clearly when prompted.

14 MS. LOPAS: Star-1 for any questions or
15 comments.

16 THE OPERATOR: I'm currently showing no
17 questions in queue.

18 MS. LOPAS: All right, everybody, this
19 is your last, this is your last time to shine in
20 public, so, if you want to get on the line and tell
21 us how you feel, this is it. Otherwise make sure you
22 do submit your comments by regulations.gov. Your
23 written comments that is, by January 29th.

24 So, just press star-1. Or if you're a
25 little shy, you can type it into the webinar, and

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1 I'll read it aloud.

2 THE OPERATOR: And our first question
3 comes from Ben Greenspan. Your line is open.

4 DR. GREENSPAN: Thank you very much. My
5 name is Dr. Ben Greenspan and I'm representing myself.

6 The bottom line of my comments is that I
7 think the NRC should not make a separate category for
8 authorized users for people who haven't gone through
9 approved board certification process and should not
10 reduce the requirements.

11 I think that physicians need to master
12 not only the previously submitted curriculum
13 submitted by the SNMMI, and I know there's also
14 curriculum by the ACMUI, and the number of other
15 features that I think I'll send in writing. I don't
16 want to read all this here.

17 But I think it's important for authorized
18 users to have the full range of competency no matter
19 which agents they are using. And there's going to
20 be a whole range of agents in the future with all
21 sort of different types of features and
22 characteristics and risk factors and so on.

23 And it's also important to understand the
24 radiation safety aspects and logistics of how we
25 receive these radiopharmaceuticals and how they

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1 dispose of waste and all that.

2 I also wanted to say I do not know of any
3 evidence that there is an insufficient number of
4 authorized users. Nuclear medicine physicians are
5 authorized users, many nuclear radiologists are
6 authorized users and many radiation oncologists are
7 authorized users.

8 And I don't think, as a patient access
9 problem, I think the major issue here is that many
10 medical oncologists are not referring patients for
11 these procedures. And now they want to give them
12 themselves without any training, and I think that's
13 really unacceptable.

14 Another thing, another point I wanted to
15 make is, that I think competency is a better way to
16 provide documentation of expertise rather than the
17 number of hours. And there are a number of ways to
18 do that.

19 One is certification by the appropriate
20 boards, with maintenance of certification. Another
21 is accreditation of the programs that these people
22 are involved with, the departments of nuclear
23 medicine and radiation oncology or whatever.

24 And certification can be accomplished by
25 board exams, such as from the ABNM or the ABR.

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1 Accreditation can be accomplished, and that can be
2 setup very easily.

3 And then you could also actually setup
4 proficiency testing, which would really be a good way
5 to assess the department and the qualifications and
6 expertise of the physicians.

7 And with that I think I'll quit, and I'll
8 send in some comments in writing. Thank you.

9 MS. LOPAS: All right, thank you, Dr.
10 Greenspan, I appreciate you calling in.

11 DR. GREENSPAN: Thank you.

12 MS. LOPAS: Okay. Cedric, do you have
13 anybody else on the line?

14 THE OPERATOR: Yes. The next question
15 comes from Ralph Lieto. Your line is open.

16 MS. LOPAS: Ralph.

17 MR. LIETO: Yes, thank you. My name is
18 Ralph Lieto, I'm representing myself. My question
19 for NRC Staff, in light of this big shutdown and your
20 proposed timeline that was in the slides, is this
21 timeline taking into account the delays due to the
22 shutdown or is the timeline is likely going to be
23 shifted back a little bit?

24 Because it seems like, in light of this
25 shutdown and then your attempts to get additional

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1 information, it looks like it's overly optimistic.

2 MS. LOPAS: That's a good question,
3 Ralph. This is Sarah Lopas.

4 So, this timeline doesn't account for the
5 shutdown impacting us at all. At the moment, I don't
6 see the partial shutdown affecting us. You know, the
7 NRC is fully funded.

8 Like I said, the only thing that kind of
9 is, that were being affected right now by the shutdown
10 is the Office of Management and Budget needs to review
11 our letter to the Agreement States for that voluntary
12 information requests going out to them.

13 I don't anticipate that delay impacting
14 our overall schedule to be honest. So, we will of
15 course keep you posted.

16 The other thing that I think is minutia,
17 that I don't think really applies to much, but the
18 Office of the Federal Register is shutdown at the
19 moment. It is affecting our, the only thing I can
20 think of is it is affecting our ability, we have to
21 register, we have to notice to the Federal Register
22 when we're going to have an ACMUI public meeting, and
23 I might check with, I have a lawyer here in the room.

24 We must notice in the Federal Register
25 notice before we can have that meeting? I'm asking

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1 somebody in our room.

2 MR. IRVIN: So, this is Ian Irvin with
3 the Office of General Counsel. I got to admit, that's
4 with another attorney --

5 MS. LOPAS: Okay. Yes.

6 MR. IRVIN: -- counsel, with what most
7 be noticed in the Federal Register.

8 MS. LOPAS: Yes.

9 MR. IRVIN: But we have received some new
10 guidance --

11 MS. LOPAS: Okay.

12 MR. IRVIN: -- about what we can publish
13 in the Federal Register.

14 MS. LOPAS: Okay.

15 MR. IRVIN: And we're still reviewing it.
16 We just received that.

17 MS. LOPAS: Yes. So, Ralph, I'll be
18 honest, I have to, if for some reason we were -- we
19 have to notice that ACMUI, A-C-M-U-I, public meeting,
20 public teleconference, ideally 15 days ahead of the
21 meeting.

22 You can, under extenuating circumstances,
23 do it like ten days or so ahead and note it's because
24 of shutdown or whatever.

25 MR. LIETO: Okay.

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1 MS. LOPAS: If for some reason that backs
2 up that meeting, that public teleconference, that
3 might back us up a little bit. So, I can just say
4 stay tuned. If there's a delay it would be a very
5 minor delay. So, does that help?

6 MR. LIETO: Yes. I'm just really
7 concerned in the data that's going to be obtained
8 from just NRC states alone. Not that that data is
9 problematic, but I think it's not going to provide a
10 typical cross section of the AUs that are out there
11 because of the potential states that are non-
12 agreement.

13 So, I think it would be tremendously
14 valuable for the NRC to obtain as much Agreement State
15 information that they're willing to provide.

16 MS. LOPAS: Yes, I would agree with that.
17 Yes. Okay, do you have any other additional
18 questions or comments, Ralph?

19 MR. LIETO: Not at this time. I'm going
20 to be providing written comments also. But I echo
21 many of the comments that Dr. Greenspan provided in
22 that I think the current T&E is an acceptable
23 methodology for assuring that the AUs are, have
24 appropriate training and experience.

25 I will make one anecdotal comment, and I

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1 think that you have mentioned in your introductory
2 about the investigation, deeper investigation of
3 medical events in the NMED database. And I have a
4 lot of, shall I say, take it with a large grain of
5 salt that that's going to be of any value.

6 I think if you look at the ACMUI comments
7 from their own reviews annually of the NMED events
8 involving medical events. That the data there is
9 inconsistent across the states. Including the NRC
10 investigations.

11 And I was involved with these for about
12 eight years with the ACMUI. And this was a big
13 complaint that the information and investigation of
14 these events are sometimes very superficial. And
15 it's not standardized across the Agreement States
16 themselves, even relative to the NRC.

17 And I have never seen a medical event
18 reported, in the years that I have reviewed it, where
19 training experience was identified as a major cause
20 of a major contributing cause.

21 So, I am a little concerned that the NRC
22 is going to, "delve deeper" to find out if there are
23 medical events that have training and experience,
24 when that isn't even not reported in the events to
25 date. I would think that that would be a major thing

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1 if an investigator found that in one of the states.

2 And even sort of anecdotally again, some
3 of the most highly publicized medical events over the
4 last 20 years that the NRC has been involved with,
5 training and experience was never identified as a
6 major cause.

7 So, with that I'll let other people
8 comment. Thank you for your time.

9 MS. LOPAS: Yes, thank you. Okay, star-
10 1 to make a comment or ask a question or you can also
11 type a short comment or short question in your webinar
12 using your webinar software.

13 Cedric, do we have anybody else on the
14 line that would like to have their line open?

15 THE OPERATOR: Yes. The next question
16 come from Jeffrey Siegel. Your line is open.

17 MR. SIEGEL: Good morning. Thank you
18 for having this -- sorry?

19 MS. LOPAS: Good morning. Sorry.

20 MR. SIEGEL: Good morning. Thank you
21 for having this webinar and inviting comments.

22 Just a brief history before I begin with
23 my comments. I've submitted written comments on the
24 website, and I'm waiting for them to appear. It's
25 been two weeks. But I understand it takes a while.

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1 Historically there was great reason for
2 there to be lots of T&E for physicians because most
3 agents were not supplied as a unit dosage, they had
4 to be manipulated. And hundreds of millicuries and
5 a wide variety of agents were given. And this was a
6 new field.

7 And, the T&E requirements, from
8 historical aspects, are not necessarily germane to
9 today's supplied agents.

10 Also, as I understand it, T&E
11 regulations, for medical use, are only for, if
12 justified by radiation risk to patients. They have
13 nothing to do with the practice of medicine.

14 So what I'd like to say is that, first of
15 all, the FRN is talking about radiopharmaceuticals
16 categories, I think that's wrong. I think it should
17 be for specific radiopharmaceuticals. Because,
18 within a given category, not all agents pose the same
19 risk.

20 So, now for my comments. Currently
21 physicians are not free to attend limited used
22 authorization for any given radiopharmaceuticals,
23 regardless of its safety profile, as they must contain
24 full AU status pursuant to 35.390.

25 This of course is not true for limited

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1 use authorization which is available for sodium
2 iodide. Since a physician would undoubtedly choose
3 the ultimately pathway pursuant to 392 or 394, since
4 much fewer T&E AUs are required.

5 The pathways for obtaining AU status
6 pursuant to 390 are therefore not reasonable since
7 physician desiring limited AU status for another
8 radiopharmaceutical, even if it possesses radiation
9 safety risk than oral sodium iodide, are required to
10 have the same T&E as physicians seeking full AU
11 status.

12 Tailoring, therefore, should be based on
13 use of this specific agent, not an entire category.
14 As I said, since not all radiopharmaceuticals, in any
15 given category, pose the same radiation risk.

16 And when we're talking about categories,
17 how many are there? 390 has four dosage categories.
18 The first two are all sodium iodide. Not categories
19 at all, just specific agents.

20 The last two are for parenteral
21 administration of any beta emitter or photon emitting
22 radionuclide with a photon energy less than 150 keV
23 or parenteral administration or other
24 radiopharmaceutical.

25 Therefore, this authorization for a given

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1 category only pertains to those two categories. And
2 that's all that's currently codified.

3 So there are three choices. Specific
4 radiopharmaceuticals in these last two categories
5 should either be placed into their own requirements,
6 such as a new codified 10 CFR 35.395, if their
7 radiation safety profiles justify it or reduce T&E
8 that is appropriate and sufficient to protect
9 workers, the general public, patients, et cetera or,
10 two, they should be regulated under 35.1000 or,
11 lastly, they should remain lumped together as is.

12 Unless the first two choices are
13 implemented, the ability to attain limited AU status
14 is justified, would be entirely ruled out. NRC
15 already believes limited AU status is justified, at
16 least for oral sodium iodide.

17 NRC therefore needs to objectively, not
18 suggestively, assess the associated risks for a given
19 radiopharmaceuticals. Such an assessment should
20 include, how is it supplied, its ease of
21 administration, the intended administered activity,
22 half-life and purity, radio contaminate levels, root
23 of elimination from the body, waste disposal,
24 potential dose to others, potential for internal
25 contamination and patient release issues.

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1 Unless this assessment is not done, it
2 cannot be entirely regulated appropriately and the
3 hours necessary for ensuring safety cannot be done.

4 Reducing T&E requirements for specific
5 agents will undoubtedly increase the complexity of
6 regulatory oversight. But when justified, should be
7 of minor concern as it would be a more risk informed
8 approach and is great benefits to patients and their
9 treating physicians.

10 Restricting patients access to and
11 ability to use an FDA approved and commercially
12 available agent by imposing unwarranted and unduly
13 burden to community regulations that may not be
14 reflective of the radiation risks involved, is
15 detrimental to them and their patients.

16 Conflicts with NRC guidelines of minimizing
17 intrusion into medical judgement, as the medical use
18 policy statements say, only when justified by
19 radiation risks will such requirements be imposed,
20 and such an approach is most assuredly not risk
21 informed.

22 I thank you for listening to my comments.
23 Thank you.

24 MS. LOPAS: All right, thank you, Mr.
25 Siegel. All right, Cedric, do we have another

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1 commenter on the line? Star-1 to get your line un-
2 muted.

3 THE OPERATOR: Sure. Next question and
4 comment comes from Michele Panichi. Thank you, your
5 line is open.

6 MS. PANICHI: Good morning. How are you
7 guys doing?

8 MS. LOPAS: Good morning. Great.

9 MS. PANICHI: So, I'm going to have to
10 respectfully disagree with Dr. Siegel. I know Jeff
11 very well. He's very respected and I respect his
12 opinion.

13 However, I believe that we should not
14 change our training T&E requirements. These are
15 relatively dangerous radiopharmaceuticals that we're
16 talking about. They have long half-life's, they're
17 alpha and beta emitters.

18 And there's a reason why a written
19 directive is required. We don't consider this, you
20 know, a diagnostic 140 keV, six hour half-life kind
21 of isotope.

22 Industry is pushing primarily to sell
23 their products. That being said, they want industry
24 people to proctor physicians for this. Big mistake.

25 As soon as you allow somebody other than

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1 a current authorized user in that category to oversee,
2 you're opening up a large can of worms.

3 In the previous webinar there was a
4 pharmacist who said that pharmacists require an
5 authorized nuclear needs 4,000 hours. Well, that's
6 not quite an accurate statement.

7 If you read the training requirements for
8 that, the 4,000 hours is to get a board certification
9 exam acknowledged by the NRC.

10 And the idea is that a nuclear pharmacist
11 can oversee radiation safety for an authorized user
12 is also not feasible. If you want to talk about a
13 shortage of physicians, there's a huge shortage of
14 nuclear pharmacists.

15 I dare say, there is a whole lot less
16 fewer nuclear pharmacists than there are authorized
17 users.

18 I don't believe there is a shortage of
19 authorized users out there. I believe that every
20 radiologist, and that radiation oncologist, now they
21 have the opportunity to become authorized users.

22 I believe the people, the physicians who
23 are pushing this, the MDECs and sometimes the
24 urologists, they're more self-serving than we would
25 like to see in a physician group. They need, want

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1 to keep their patients in their practice. It has
2 nothing to do with the availability of an authorized
3 user.

4 And that's about it. I will be also
5 submitting my comments in writing. And that's about
6 it. Thank you.

7 MS. LOPAS: All right, thank you. Okay,
8 star-1 to have Cedric un-mute your line for you.
9 star-1. Cedric, do we have somebody up next?

10 THE OPERATOR: Yes. We have a follow-up
11 with Jeffrey Siegel. Your line is open.

12 MR. SIEGEL: Hi, since my name was
13 mentioned I must respectfully disagree with Michelle,
14 of course. Because, objectivity is what's required.

15 We can't just say, all agents are equally
16 hazardous because they are not. And if we're going
17 to follow that all radiation is risky, ALARA and LNT,
18 which I believe is not true at all, then that would
19 be true.

20 But I think we owe it to the patients and
21 the physicians and the community and everybody, to
22 have an objective assessment of each agent. And the
23 level of risk it involves. Thanks.

24 MS. LOPAS: Okay, thank you, Dr. Siegel.
25 Okay, star-1 to get in on the conversation. Cedric,

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1 do we have anybody else in line?

2 THE OPERATOR: None currently.

3 MS. LOPAS: Okay. All right, everybody
4 star-1. We will hang on for a few minutes, but I
5 want to, let's see.

6 I'm going to go, I pulled up on the
7 webinar some of the questions, the more detailed
8 questions under A. Tailored training and experience
9 requirements.

10 You know, Dr. Siegel had mentioned that
11 he didn't think it was appropriate to categorize state
12 radiopharmaceuticals that may be, such as by their
13 type of radiation admission or characteristics
14 because not all, may be drugs within those admission
15 categories, are the same.

16 So, some other options that were
17 suggested in the FRN was to characterize
18 radiopharmaceuticals by similar delivery methods.
19 Whether it's oral, parenteral.

20 Of course, the radiation characteristics
21 or emission, alpha, beta, gamma, low-energy photon.
22 Or similar preparation methods, such as patient ready
23 doses or a combination of that.

24 So that's something that we're looking to
25 get comments on. And, Cedric, you can just interrupt

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1 me.

2 THE OPERATOR: Sure. We do have David
3 Burpee that's on.

4 MS. LOPAS: Okay.

5 THE OPERATOR: Your line is open.

6 MR. Burpee: Good morning, everyone,
7 thank you for this opportunity and for all the good
8 comments.

9 As far as enough authorized users, I
10 think the key word is really treating authorized users
11 that have the ability to.

12 I witness, as I manage ten states for
13 license and compliance for Xofigo, numerous scenarios
14 where patients cannot be treated at even very large
15 institutions, typically due to infighting between
16 authorized users who could be treating.

17 There's a very large place in north
18 Chicago with 400 beds for four years, fought between
19 authorized users as to who could have the privileges
20 at that institution, and therefore they didn't treat
21 at all. That story is fairly ubiquitous. And it
22 goes in many directions.

23 For example, another large group needed
24 to have preceptorships and they solicited another
25 group to do that and at the end of the day the other

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1 group decided they were competition and wouldn't sign
2 the attestation forms, and so no one was able to treat
3 at those institutions.

4 The rural situation is acute in that
5 there are not enough out there to help cover all these
6 places. And therefore in general, all these
7 scenarios require the men to travel. Men were sick
8 and don't want to travel typically.

9 So, we do need to look at how we can have
10 more options for being an authorized user.

11 I think something dawned on me recently
12 that I think is germane to this in that, if you look
13 at alpha emitters, there has never been any formal
14 trading for authorized users with alpha emitters.
15 They are very unique.

16 And Dr. Siegel's comments are right on
17 the money, that there are certainly incredibly
18 differently qualities to those products compared to
19 all beta emitters and every other types of therapy
20 that has been out there.

21 So, thanks for those considerations and
22 for this time.

23 MS. LOPAS: Sure.

24 THE OPERATOR: Thank you. We have an
25 additional comment with Ben Greenspan. Your line is

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1 open.

2 DR. GREENSPAN: Thank you. This is Ben
3 Greenspan. I am a nuclear medicine physician and
4 radiologist and I wanted to make some comments
5 regarding some of the comments we just had.

6 First of all, I think, while there may be
7 different lists of various, of these therapeutic
8 radiopharmaceuticals, they're still potentially
9 dangerous. And I also think that many of them will
10 be given in combination. So we may give alpha
11 emitters and beta emitters with patients to various
12 cancers.

13 And therefore, the alpha's user who is
14 treating these patients really needs to know the full
15 range of the basic science and clinical expertise to
16 handle all this.

17 In terms of various physicians, I have
18 great respect for the clinical abilities of medical
19 oncologist, and urologists, but I don't think they
20 should be treating these patients by themselves.

21 I don't think they have the requisite
22 background in radiation sciences and, if they
23 actually wanted to get it all and spend whatever time
24 it took to come up to the same level as a nuclear
25 medicine physicians and radiation oncologist, then

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1 that's fine. But I doubt any of them would.

2 As far as authorized users and patient
3 access, I'm not aware of too many places having these
4 kinds of logistical issues with infighting. I guess
5 some of them do but I don't think that's a huge issue.

6 In terms of rural areas, I don't think,
7 I think patients realize they have to travel if
8 they're in a rural area. For just about everything
9 beyond simple things.

10 So, if they want coronary bypass surgery,
11 they're not going to get it by the surgeon who does
12 one a year, they're going to go to a major medical
13 center and get one by an expert. And the same should
14 be true for treating with radiopharmaceuticals.

15 They have potential risks if they're
16 misused or there are problems. And these should be
17 provided by experts who know what they're doing, and
18 I think patients realize that. Thank you very much.

19 MS. LOPAS: Okay, thank you, Dr.
20 Greenspan. Press star-1, again, if you want to get
21 in on the conversation.

22 I do have one question from the webinar
23 that I'm going to read aloud. So there was a question
24 about whether or not the NRC has been conducting any
25 outreach to the referring visits physician

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1 communities, such as medical oncology, et cetera, for
2 input on this.

3 And we did send out, back when the FRN
4 first went out, we did send out the FRN and ask them
5 to provide questions to about 100 different
6 stakeholder groups. And so, a lot of the stakeholder
7 groups included, let's see, kind of professional
8 societies for urologists, for cardiologists, for
9 medical oncology.

10 So, we did do some attempt at outreach in
11 that matter. I don't know if any of those are support
12 to be on our medical Listserv, but we did reach out
13 to the professional societies. And hopefully that
14 those groups put the word out to their membership
15 that this is something that we are looking at.

16 We also, and I can't remember off hand
17 right now, but we did publish short little
18 advertisement type articles, less than one page or
19 so, kind of in a number of journals. Not medical
20 journals per say but kind of like newsletter monthly,
21 sort of either online or printed newsletters, for a
22 number of organizations just alerting them to these
23 public meetings and our effort and our FRN questions.

24 We did do a fair amount of outreach to
25 what we think would be those communities, those

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1 referring physician communities. So, thank you for
2 that question, that's a good one.

3 Because we, exactly, we'd like to hear
4 from those folks as well. This is what they want to
5 be getting into.

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

8 THE OPERATOR: None currently in the
9 queue.

10 MS. LOPAS: Okay. All right, star-1 or,
11 again, submit a question or comment via the webinar,
12 we're happy to go that route.

13 Maryann and I attended recently, just
14 this past weekend, on Thursday through Saturday,
15 Maryann and I attended the Society for Nuclear
16 Medicine and Molecular Imaging, their mid-winter
17 meeting, which was in Palm Springs, which was very
18 nice. But we got a lot of good feedback from the
19 folks attending that meeting.

20 And I know some of you are on the line
21 that we saw there, so thank you for calling in and
22 we're definitely looking forward to your written
23 comments as well.

24 star-1. And, Cedric, just let me know
25 is anybody pops on the line.

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1 THE OPERATOR: Okay.

2 MS. LOPAS: So, Question 5 here on the
3 tailored training and experience requirements.

4 Question 5 gets into, if we were to create
5 tailored T&E categories, what should those specific
6 requirements include for the classroom and lab
7 training?

8 How many hours, what should be covered
9 under that classroom and lab training, what topics?

10 The work experience, we asked exactly, we
11 heard some comments about whether or not the
12 pharmaceutical manufacturers should be able to
13 provide the preceptor attestation. That's one of our
14 questions we'd like feedback on.

15 And the competency, we have been hearing
16 some feedback on competency that we, the NRC, should
17 look into whether or not we could move our regs to
18 evaluate competency rather than just straight hours
19 of T&E. So, those are some of our questions in our
20 Federal Register notice.

21 Also, some questions on who should
22 establish and administer these curriculums on an
23 examination. And also, how often should AU
24 competency be periodically assessed?

25 We have been getting some questions on

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1 recent myths of training and so that's important to
2 think about too. Should it be a number of cases
3 every year or so that the physician AUs are required
4 to maintain their competency or are required to
5 maintain that AU certification?

6 So these are all good things to think
7 about.

8 THE OPERATOR: Excuse me, Sarah, we do
9 have a question. Miguel de la Guardia, your line is
10 open.

11 MR. DE LA GUARDIA: Hi, this is Miguel
12 de la Guardia and I am the RSO at Cook Children's
13 Medical Center in Fort Worth. And we are one of the
14 major trading centers for neuroblastoma using iodine-
15 131 MIBG.

16 First, I want to echo Jeffrey Siegel's
17 comments. I think they're spot on.

18 But next I also want to concur with the
19 comments of the lack of authorized users. There are
20 plenty of authorized users for diagnostics but for
21 therapy is very difficult.

22 Right now we only have two authorized
23 users here that can actually administer diamygadia
24 (phonetic). And sometimes it's very difficult to
25 schedule these treatments based on their

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1 availability.

2 And as far as rural areas, we are very
3 keenly aware of that because we get patients from all
4 over the place. If you go west of Fort Worth, where
5 we are, there is nothing as far as being able to treat
6 these patients until you get to Arizona or California.
7 So, there is a critical shortage out there of
8 physicians that can do therapies.

9 Now, I do know that nuclear medicine, we
10 would like hold on to as much as we can, but prior
11 experience shows that when other groups get involved,
12 such as the endocrinologist or cardiology, which
13 actually launched nuclear cardiology made, basically
14 saved nuclear medicine in many respects, I think that
15 having a pathway for other physicians to be able to
16 do these treatments will be very helpful.

17 Especially now that most of the therapies
18 can be obtained from a nuclear pharmacy as a unit
19 dose and you don't have to manipulate the product
20 onsite.

21 So I want to thank you for the opportunity
22 to commenting and for sponsoring this webinar. Thank
23 you.

24 MS. LOPAS: Yes, thank you.

25 THE OPERATOR: Still no further questions

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1 or comments.

2 MS. LOPAS: Okay, thank you. Okay, and
3 I will maybe, just to kind of spur some conversation,
4 the last public meeting we had was on January 10th.
5 And during that meeting we got some unique ideas
6 submitted by a comment.

7 One was to allow to open up the AU status
8 to non-physicians. So, including maybe authorized
9 nuclear pharmacists. Also maybe including some
10 advance trained technologist.

11 We specifically got comments from nuclear
12 medicine advance associates who undergo, you know,
13 who have been technologist for many, many years and
14 then they go on to continue their training with two
15 years of a master's program and then they do a nuclear
16 medicine kind of internship or they kind of, they
17 kind of call it analogous to a residency. They
18 offered up, they thought that potentially they could
19 be considered for AU status.

20 So, we, at the NRC, even though our
21 questions in FRN are kind of very specific, we are
22 open to hearing any ideas on how, if we do think, you
23 know, if you do think that's there's a patient access
24 issue on how we can improve that situation.

25 So, that would include providing us

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1 comments on whether you think it would be a good idea
2 to allow certain categories of folks practicing in
3 this medicine field to become AUs. Right now, in the
4 Part 35 regulations an authorized user is only
5 defined, can only be a physician, a dentist or a
6 podiatrist.

7 So obviously the majority of our AUs are
8 physicians. And so, we did get some comments that
9 maybe we should consider expanding that definition of
10 authorized user.

11 So, star-1 to provide any additional oral
12 comments.

13 THE OPERATOR: We do have an additional
14 comment with Michelle Panichi. Your line is open.

15 MS. PANICHI: Oh my goodness.

16 (Laughter)

17 MS. PANICHI: This is a tough one. So,
18 let us not forget these are prescription medications.
19 So, they have to be prescribed by a physician.

20 As much as I would like to say, as a
21 nuclear med tech, that I am equally qualified as a
22 nuclear medicine physician, I am not.

23 I also have the honor of being the RSO at
24 nuclear pharmacies, and I can confidentially tell you
25 that the majority of nuclear pharmacists that I have

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1 met should not be prescribing these medications.
2 Remember, this is not just administering.

3 I have no problem with a nuclear med tech
4 administering a radiotherapy, with an authorized user
5 in place. A lot of times it is simply passing a
6 pill, injecting a patient.

7 But that's not what requires the AU
8 status, it's the prescribing of these medications.
9 And they are prescription drugs.

10 So, an NMAA or a nuclear med tech, even
11 a nuclear pharmacist, they're not in the practice of
12 prescribing pharmaceuticals. Thanks.

13 MS. LOPAS: Yes, thank you.

14 THE OPERATOR: Another addition question
15 or comment comes from Ralph Lieto. Your line is
16 open.

17 MR. LIETO: Thank you. I also would like
18 to echo Michelle's comments that I think that these
19 suggestions of non-physicians becoming authorized
20 users basically would turn the NRCs whole regulatory
21 framework upside down.

22 If you allowed this for therapeutic
23 radiopharmaceuticals, you are opening up a literal
24 Pandora's Box where you could have other specialists,
25 you could have an RSO making a case that they oversee

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1 all this and probably supervises as much as the AU
2 does, the operations of radiation safety in these
3 aspects, making a case for them to be the "AU."

4 Which I think is absolutely abhorrent as
5 a medical physicist and radiation safety officer. I
6 think that, like I said, this is just a very, very
7 bad thought process for suggesting this.

8 And if the NRC would be considering this,
9 you basically would undermine the whole intent of
10 having a physician involved with not only the
11 therapeutic aspect of it, but also the diagnostic
12 imaging aspect of it.

13 As Michelle pointed out, the AU is not
14 just involved with overseeing the administration, but
15 supervising all aspects of receipt, patient
16 assessment, administration and follow-up. And they
17 are the best persons for this.

18 And I think my objections as a
19 technologist and a nuclear pharmacist would be, a pun
20 intended, just a set of nuclear land mines for the
21 NRC.

22 I do have another comment that, regarding
23 your previous slide. I think it was on Item 5 where
24 you, the NRC uses the word competency.

25 I think this has some different

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1 connotations to different groups. The ACMUI, over
2 the years, has addressed this several times in the
3 definition, or excuse me, the description of the
4 preceptor attestation.

5 And I think NRC should stay away from
6 that term because competency is more than just an
7 assessment of the understanding and having a
8 requisite knowledge to perform the supervisory
9 aspects of the radiopharmaceuticals that the
10 applicant is applying for.

11 It's maybe just a, maybe a pet peeve of
12 whatever, but I think competency, as used in this
13 slide, is not what you're really trying to evaluate.
14 I think what you want to know is, did the training
15 and experience that the individuals get can reassess
16 that that training and experience contains the
17 requisites body of knowledge that they need to
18 function independently in supervising these types of
19 radiopharmaceuticals. Thank you for the comment.

20 MS. LOPAS: Okay, thank you.

21 THE OPERATOR: We have a follow-up with
22 Miguel. Your line is open.

23 MR. DE LA GUARDIA: Thank you for taking
24 my follow-up. I'm not sure if I was clear on my
25 comments.

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1 I am a nuclear medicine technologist, but
2 I am not in favor of nuclear medicine technologists
3 prescribing. That is not part of our scope of
4 practice.

5 Also, similarly, I think in almost every
6 state here in the United States, pharmacist are not
7 allowed to prescribe most medications. So, that
8 would require a change completely in pharmacy
9 practice.

10 I know in some other countries,
11 pharmacist can prescribe, but commonly that's not
12 true here in the United States. So, when I was
13 talking about authorized user, I'm talking about
14 physician authorized users. Thank you.

15 MS. LOPAS: Yes, thank you, Miguel. And
16 I didn't mean to imply that you were suggesting that,
17 I was just stating that in our previous meeting on
18 January 10th, we had received some comments along
19 those lines about potentially, the NRC should
20 potentially consider opening up AU status to some
21 non-physicians. So, understood. Understood.

22 THE OPERATOR: Thank you. And the next
23 question, comment comes from Scott Degenhardt. Your
24 line is open.

25 MR. DEGENHARDT: Yes, thank you. Yes,

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1 my name is Scott Degenhardt. I am actually a nuclear
2 medicine advance associate speaking on behalf of
3 myself here.

4 I just want to clarify what a nuclear
5 medicine advance associate is. While one time, at
6 one time we were technologists, we're actually mid-
7 level providers in the field of nuclear medicine.

8 Again, yes, we were technologists at one
9 point, but we have gone through a two to three year
10 additional schooling at the master's level where we
11 have didactic course work, but we also undergo a 24
12 month internship under the supervision of a
13 physician, most under a radiologist or a nuclear
14 physician.

15 Where we, at the end of the program, are
16 actually, we meet all training requirements for what
17 is currently asked of, of an authorized user. So,
18 we wouldn't, you know, if the NRC would consider the
19 nuclear medicine advance associate for authorized
20 user status, we wouldn't be compromising training and
21 education, the current training and education
22 requirements.

23 But I guess I just wanted to clarify that
24 we are not technologist, we're actually mid-level
25 providers in the field of nuclear medicine. Almost

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1 every other field in the healthcare industry has mid-
2 level providers that do prescribe drugs, under the
3 supervision of a physician. And that's the model
4 that we were proposing there.

5 The nuclear medicine advance associate
6 would be working under the supervision of an
7 authorized user, again, just as that physician
8 extender alongside them.

9 I guess, any other questions I'm happy to
10 answer but I just wanted to clarify that. Thank you.

11 MS. LOPAS: Yes, thank you, Scott. Thank
12 you for that clarification.

13 THE OPERATOR: Our next question or
14 comment comes from Ben Greenspan. Your line is open.

15 DR. GREENSPAN: Thank you. This is Ben
16 Greenspan again, I'm a nuclear medicine physician and
17 radiologist and I wanted to make some comments.

18 First of all, I agree with Ralph Lieto's
19 comments. Regarding Scott's comments just now, I
20 agree pretty much.

21 I mean, these NMAAs, the Nuclear Medicine
22 Advanced Associates, are technologists who have had
23 an extra two plus years of training and are certainly
24 expert in radiation safety. And in other aspects of
25 dealing with radiopharmaceuticals.

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1 But they're not physicians. And if they
2 were given AU status, they still have to, I would
3 think they'd still have to work under an authorized
4 user, under a physician. And I don't see how that
5 adds anything.

6 I think they could certainly help with
7 the process of treating a patient, and they could
8 certainly give the radiopharmaceuticals, most of
9 which would be given parenteral, but they still have
10 to work under an authorized user, i.e. under a
11 physician. And I think that would be most
12 appropriate.

13 On the other hand, I really do think
14 that's a very good program and I'd like to see it
15 expand and have more technologists, nuclear medicine
16 technologists, go into those programs. I think it
17 helps the field.

18 Mid-level providers, as these people are
19 seen throughout medicine now and they are physician
20 extenders, and I think they would help nuclear
21 medicine practice. Including in radionuclide
22 therapy. Thank you.

23 MS. LOPAS: All right, thank you.

24 THE OPERATOR: Thank you. And our next
25 question, comment comes from Rachel Semon. Your line

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1 is open.

2 MS. SEMON: Thank you. Can you hear me
3 okay?

4 MS. LOPAS: Yes, we can.

5 MS. SEMON: Okay, great. I appreciate
6 the opportunity to comment. I'm really not going to
7 comment one way or the other as to which direction
8 this should go, in terms of T&E, but I did want to,
9 for the record, provide some feedback regarding
10 pharmacy and the practice of pharmacy and that there
11 certainly is precedent outside of the nuclear
12 medicine, or the nuclear medicine world, where
13 pharmacist do have provider status.

14 It is quite often you will see this
15 actually in medical oncology. There is board
16 certifications based on specialty. So, I am a board
17 certified nuclear pharmacist.

18 I could say today I would not be
19 comfortable being in a AU, a full AU, overseeing
20 patient management. It's certainly something to
21 consider moving forward. Perhaps in conjunction
22 within the nuclear medicine department.

23 And we talk about potential shortage of
24 AUs. And what I know that I have seen historically,
25 is that the current RVU model tends to provide some

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1 barrier to a nuclear medicine physician being torn
2 between the requirements of reading images, the
3 diagnostic portion versus having to spend 30 minutes
4 to an hour with a patient for therapy.

5 And so, perhaps there is something here
6 that could help facilitate patient access and ease
7 the requirements of time spent, et cetera, in the
8 future.

9 But just for the record, I wanted to say
10 that provider status is not, there is a precedent for
11 provider status outside of nuclear medicine,
12 particularly in medical oncology. And there are
13 pharmacists who have limited prescribing rights as
14 well.

15 Typically, it is under the supervision of
16 a physician. So I think there is some room here.
17 Maybe not immediately, but not to be close minded
18 with that. That's it, thank you so much.

19 MS. LOPAS: Great, thank you. And,
20 Cedric, do we have anybody else? star-1 if you want
21 to get in on the conversation, get your comments
22 transcribed to go on the record.

23 THE OPERATOR: None currently in the
24 queue, but, again, press star-1.

25 MS. LOPAS: So, this is Sarah again. And

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1 so, I will say that, related to that comment that we
2 just heard, we have had some comments submitted that
3 the NRC should be open to the idea of, maybe not
4 necessarily making an authorized nuclear pharmacist
5 an AU, but maybe some sort of requirement or new
6 regulatory requirement for an alternate, an alternate
7 pathway of having a limited authorized user physician
8 teamed with a authorized nuclear pharmacist.

9 That authorized nuclear pharmacist
10 undergo extensive training and, per our requirements,
11 also require 700 hours of T&E, become an authorized
12 nuclear pharmacist.

13 So, if you teamed an authorized nuclear
14 pharmacist with perhaps a limited trained authorized
15 user physician, that you would still be meeting the
16 spirit of those 700 hours of training and experience.
17 Because you'd have those two individuals working
18 together.

19 So that was one comment that we received
20 on the January 10th meeting. That's a little bit
21 different from just suggesting that authorized
22 nuclear pharmacists should be considered for AU
23 status.

24 Okay, we're going to -- anybody else on
25 the line, Cedric?

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1 THE OPERATOR: Yes. Ralph Lieto, your
2 line is open.

3 MS. LOPAS: Okay, Ralph.

4 MR. LIETO: Yes, Sarah. I'm glad you
5 brought that subject up. I had heard about this but
6 I was wondering if this was something the NRC was
7 seriously going to consider or not.

8 Again, I think this is something that
9 would basically set the licensee up for a lot of
10 potential problems. Because, it's my understanding
11 of this proposal that you would have a centralized
12 nuclear pharmacist teamed with a limited AU that would
13 be onsite, something to that nature.

14 And to me this is matched with two chiefs
15 with no Indians.

16 I think that these types of situations
17 you need, with therapeutic radiopharmaceuticals, a
18 person that's signing the written directive needs to
19 be in AU. And that AU has to be responsible for the
20 proper management of that radiopharmaceutical, to
21 that patient.

22 This dual AU, that would be fine as long
23 as everything goes great, but what happens if
24 something goes wrong, okay, and there's a medical
25 event or there's a problem with the patient or the

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1 assay at the site.

2 You can't have this dual AU
3 geographically separated and expect that it's not
4 just going to create further problems. And
5 especially from the aspect of supervision, which is
6 something that the NRC takes quite seriously. And
7 not just in the diagnostic side but even more so on
8 the therapeutic side.

9 And I think this dual AU is, again, just
10 fraught with all kinds of potential problems that's
11 going to place the licensee, who's going to be the
12 management, in a lot more potential problems of trying
13 to resolve this.

14 Because the nuclear pharmacist is going
15 to be offsite at, and operating under a different
16 license than the administration. Just so many things
17 that add up to, that this is just a very, very poor
18 idea.

19 MS. LOPAS: Okay. Yes, and I think to
20 clarify, now, I haven't received the written comments
21 on this, on this particular idea yet. They have not
22 been submitted yet.

23 But just from hearing from public
24 meetings, I think the idea that they're proposing is
25 that the authorized nuclear pharmacist would travel

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1 to the limited AU position site for a day of
2 treatments, right. So they would be paired together
3 physically, during an administration.

4 So, that's just a clarification from what
5 I recall from the January 10th meeting. But yes, if
6 you have any follow-up on that, Ralph, go right ahead.

7 MR. LIETO: I would just say that, if you
8 have an AU that's onsite to administer it, then you
9 wouldn't need the nuclear pharmacist to be present.

10 MS. LOPAS: Right.

11 MR. LIETO: I think it just, again, I
12 think it kind of goes back that, what are you trying
13 to sell here. And it is not anything that is going
14 to improve the radiation safety management
15 supervision at the site where the, where all the work
16 is going to be done.

17 MS. LOPAS: Okay, thank you, Ralph. Does
18 anybody else have a comment? star-1 or feel free to
19 type one via the webinar software, I can read it
20 aloud.

21 Okay, I'm just going to give it another
22 minute or so. I do appreciate everybody calling in
23 today and taking the time.

24 And I know that many of you have called
25 in for a number of these meetings. So, I really

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1 appreciate you guys taking the time to do and it means
2 a lot to the NRC. And we do really, we're going to
3 really examine everybody's input.

4 Whether you've spoken on one of these
5 meetings or, and/or when you send it in, send in the
6 written, your written comments.

7 And I just want to remind folks, you have
8 until January 29th, end of that day, to get your
9 comments in. That's a week from today. It's a
10 Tuesday.

11 Try to use regulations.gov if you can.
12 And if you're encountering any difficulties or at all
13 concerned, I'm happy to take your comments via email.
14 And, again, my email is in the slides here. It's
15 sarah.lopas@nrc.gov. So either myself or Maryann
16 will take your comments via email, that's fine too.

17 And, I don't know, Cedric, can I check in
18 on the phone one last time?

19 THE OPERATOR: No questions or comments.

20 MS. LOPAS: Okay. I think that's it.
21 And Dr. Siegel, I will say, I think you had noted
22 that you're waiting for your comments to get up on
23 regs.gov.

24 They are in ADAMS and I did see them come
25 through in my email, I think on Friday. So they

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1 should be on regulations.gov shortly.

2 But there is a number of kind of
3 rulemakings and other efforts going on at the agency
4 and we only have a few administrative staff that kind
5 of handle the processing of all the comments that we
6 receive from the public on all of our projects. So,
7 I apologize for the delay, I know that's difficult.
8 But I'm going to reach out to our folks and see if
9 they can expedite some of the processing on regs.gov.

10 So, Maryann, do you have any follow-ups?

11 MS. AYOADE: Yes, Sarah, I was waiting
12 for everybody to provide their comments. Just to add
13 to and clarify Ralph Lieto's comment on competency.
14 Thank you for bringing that up.

15 I just wanted to, as you have recognized
16 the sensitivity with the word competency and the
17 misunderstanding that it could come about from that.
18 And so, with the new rule, I just wanted to point out
19 that with attestation statement, it replaced the text
20 that used to formally say, attestation demonstrate
21 that the individual has achieved a level of competency
22 to function independently.

23 That has been replaced with, the
24 individual has demonstrated the ability to function
25 independently to procure the radiation safety related

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1 duties. So thank you for bringing that up.

2 Now, when this evaluation started, it was
3 still with the former regulations. The new rule
4 become effective last Monday, January 14th, at the
5 NRC licensees.

6 And so, just a, I just wanted to bring it
7 to your awareness that you recognized that. And
8 thank you for bringing that up.

9 MS. LOPAS: Okay, thanks, Maryann. And
10 on the NRC's medical toolkit licensee, or medical
11 licensee toolkit website, Maryann, I think there is
12 a page that's dedicated to the Part 35 rule changes
13 that just went into effect, is that right?

14 MS. AYOADE: That's correct. And if you
15 even just go to, if you Google the 10 CFR 35
16 regulations, they are now updated with the new rule.
17 So, if you can't find it in our medical use toolkit,
18 if you just Google 10 CFR 35 to get into the new rule,
19 it's updated with the new rule.

20 MS. LOPAS: Right. And I think the
21 slides from some public meetings that we had on the
22 Part 35, the new rule changes, those are also on the
23 medical licensee toolkit website I believe.

24 So those are available for people to pull
25 up the PDF of slides if they just want to see an

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1 overview. Although it's about a 96 slide overview,
2 but it's an overview.

3 Okay. Cedric, do we have any other final
4 comments on the line?

5 THE OPERATOR: No questions in queue.

6 MS. LOPAS: Okay. All right, Maryann,
7 is there anything else?

8 MS. AYOADE: No, that's it.

9 MS. LOPAS: Okay. All right, everybody,
10 January 29th, deadline to get your comments in. But
11 Maryann and I are here for your questions and comments
12 before, and after that date obviously. Please keep
13 checking out our website that I have the slide up on
14 right now for any updates.

15 And if you are signed up to receive our
16 medical Listserv emails that's great. If not, do
17 that. I suggest doing that because that's a good way
18 to stay informed of all the NRC's medical regulations
19 and news and all that good stuff.

20 All right, thank you so much for your
21 time today and that will be the end of our meeting.

22 THE OPERATOR: Thank you, and that
23 concludes today's conference. You may all disconnect
24 at this time. Speakers, you may standby for post-
25 conference.

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1 (Whereupon, the above-entitled matter
2 went off the record at 11:35 a.m.)

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