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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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THURSDAY,

MARCH 1, 2018

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The meeting was convened via teleconference at 2:00 p.m., Philip O. Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

DARLENE F. METTER, M.D., Diagnostic Radiologist

MICHAEL O'HARA, Ph.D., FDA Representative

CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine Physician

MICHAEL A. SHEETZ, Radiation Safety Officer

JOHN J. SUH, M.D., Radiation Oncologist

LAURA M. WEIL, Patients' Rights Advocate

PAT B. ZANZONICO, Ph.D., Vice Chairman

NON-VOTING MEMBERS PRESENT:

RICHARD GREEN

MEGAN SHOBER

ZOUBIR OUHIB

NRC STAFF PRESENT:

CHRISTIAN EINBERG, Acting Deputy Director, NMSS/MSST

DOUGLAS BOLLOCK, ACMUI Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Alternate Designated Official and ACMUI Coordinator

MARYANN AYOADE, NMSS/MSST/MSEB

JENNIFER BISHOP, R-III/DNMS

SAID DAIBES, Ph.D., NMSS/MSST/MSEB

ROBIN ELLIOTT, R-I/DNMS

SARA FORSTER, R-III/DNMS

LATISCHA HANSON, R-IV/DNMS

VINCENT HOLAHAN, Ph.D., NMSS/MSST

ESTHER HOUSEMAN, OGC/GCLR/RMR

DONNA-BETH HOWE, Ph.D., NMSS/MSST/MSEB

JAN NGUYEN, RI/DNMS

PATTY PELKE, R-III/DNMS

GRETCHEN RIVERA-CAPELLA, NMSS/MSST/MSEB

RAEANN SHANE, NMSS

NRC STAFF PRESENT (cont.):

ZAHID SULAIMAN, R-III/DNMS

KATHERINE TAPP, Ph.D., NMSS/MSTR/MSEB

LESTER TRIPP, R-I/DNMS

TARA WEIDNER, R-I/DNMS

JENNY WEIL, OCA

IRENE WU, NMSS/MSST/MSEB

MEMBERS OF THE PUBLIC:

BETTE BLANKENSHIP, American Association of Physicists in Medicine (AAPM)

MARY BURKHART, Illinois Emergency Management Agency (IEMA)

DAVID BURPEE, Bayer Health Care

WHITNEY COX, IEMA

ROBERT DANSEREAU, New York State Department of Health

BRIAN ERASMUS, British Technology Group (BTG)

SHERRIE FLAHERTY, Minnesota Radioactive Materials Unit

KAREN FLANIGAN, New Jersey Radioactive Materials Program

SANDRA GABRIEL, *unaffiliated*

MUNIR GHESANI, NYU Langone Health

BENNETT GREENSPAN, Society of Nuclear Medicine and Molecular Imaging (SNMMI)

MICHAEL GUASTELLA, Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR)

CAITLIN KUBLER, SNMMI

RALPH LIETO, St. Joseph Mercy Health System

CAROL MARCUS, University of California at Los Angeles (UCLA)

RICHARD MARTIN, American Association of Physicists in Medicine (AAPM)

MICHAEL PETERS, American College of Radiology (ACR)

JOSEPHINE PICCONE, *unaffiliated*

WAYNE POWELL, SNMMI

A. ROBERT SCHLEIPMAN, Partners Healthcare

EUGENIO SILVERSTRINI, Northwell Health

BOBBY SMITH, Mississippi State Department of Health

GLENN SULLIVAN, Cardinal Health

CINDY TOMLINSON, American Society of Radiation Oncology (ASTRO)

TONY WANG, New York Presbyterian/Columbia University Medical Center

JAMES YU, Yale School of Medicine

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

P R O C E E D I N G S

2:06 p.m.

CHAIRMAN ALDERSON: (presiding) Good afternoon, and welcome to today's ACMUI public teleconference.

I'm Phil Alderson. I'm the current Chair of the ACMUI.

Today we'll be discussing the topic of the Interim Report on Training and Experience Requirements.

I'll now turn this meeting to Mr. Bollock from the NRC for opening remarks.

MR. BOLLOCK: Thank you, Dr. Alderson.

As the Designated Federal Officer for this meeting, I'm pleased to welcome you to this public meeting of the Advisory Committee on the Medical Use of Isotopes.

My name is Doug Bollock. I am the Branch Chief of the Medical Safety and Events Assessment Branch, and I've been designated as the Federal Officer for the Advisory Committee, in accordance with 10 CFR Part 7.11.

Present today as the Alternate Designated Federal Officer is Sophie Holiday, our ACMUI Coordinator.

This is an announced meeting of the Committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

This meeting is being transcribed by the NRC, and it may also be transcribed and recorded by others.

The meeting was announced in the January 23rd, 2018 Federal Register, Volume 83, page 3191.

The function of the Committee is to advise the staff on issues and questions that arise on the medical use of byproduct materials. The Committee provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the Commission. The NRC solicits the views of the Committee and values their opinions.

I request that, whenever possible, we try to reach a consensus on the various issues that we will discuss today, but I also recognize there may be minority or dissenting opinions. If you have such opinions, please allow them to be read into the record.

At this point, I would like to perform roll call of the ACMUI membership participating today.

Dr. Phil Alderson?

CHAIRMAN ALDERSON: Here.

MR. BOLLOCK: Dr. Pat Zanzonico?

(No response.)

Okay. Dr. Vasken Dilsizian?

MEMBER DILSIZIAN: Here.

MR. BOLLOCK: Dr. Ronald Ennis?

(No response.)

Okay. Moving on, Dr. Darlene Metter?

MEMBER METTER: Here.

MR. BOLLOCK: Thank you.

Dr. Michael O'Hara?

MEMBER O'HARA: Here.

MR. BOLLOCK: Thank you.

Dr. Christopher Palestro?

MEMBER PALESTRO: Here.

MR. BOLLOCK: Thank you.

Mr. Michael Sheetz?

MEMBER SHEETZ: Here.

MR. BOLLOCK: Thank you.

Dr. John Suh?

MEMBER SUH: Here.

MR. BOLLOCK: Thank you.

And Ms. Laura Weil?

MEMBER WEIL: Here.

MR. BOLLOCK: Thank you.

Dr. Zanzonico, did you join us on the conference line?

MS. HOLIDAY: I think he might have dialed in with a different passcode.

MR. BOLLOCK: Okay. So, we'll try to get Dr. Zanzonico in, but we believe he is able to listen to us at least at this point.

OPERATOR: Excuse me. This is the operator. If he is on the line, he can press *0 and I can open his line for him.

MS. HOLIDAY: Thank you.

MR. BOLLOCK: Okay. Also on the phone, do we have Mr. Zoubir Ouhib?

MR. OUHIB: Here.

MR. BOLLOCK: Thank you.

Mr. Richard Green?

MR. GREEN: Here.

MR. BOLLOCK: And Ms. Megan Shober?

MS. SHOBER: Here.

MR. BOLLOCK: Thank you.

Mr. Zoubir Ouhib has been selected as the ACMUI Therapy Medical Physicist. Mr. Richard Green has been selected as the ACMUI Nuclear Pharmacist, and Ms. Megan Shober has been selected as the ACMUI

Agreement State Representative. Messrs. Ouhib and Green and Ms. Shober are pending security clearance, but may participate in the meeting. However, they do not have voting rights at this time.

I now ask NRC staff members who are present to identify themselves. I'll start with the individuals in the room here.

DR. HOLAHAN: Vincent Holahan.

MS. WU: Irene Wu.

DR. DAIBES: Said Daibes.

MS. HOLIDAY: Sophie Holiday.

MS. HOUSEMAN: Esther Houseman.

DR. HOWE: Donna-Beth Howe.

MR. EINBERG: Chris Einberg.

MS. HOLIDAY: Dr. Katie Tapp is also on the phone.

MR. BOLLOCK: All right. Okay. Now I'll go to the NRC Headquarters employees on the phone. Are there any other employees on the phone?

MS. HOLIDAY: Maryann Ayoade is also on the phone.

MR. BOLLOCK: Okay. Thank you.

Members of the public who notified Ms. Holiday that they would be participating in our phone conference will be captured in the transcript. Those

of you who did not provide prior notification, please contact Ms. Holiday at sophie.holiday@nrc.gov. That's S-O-P-H-I-E dot H-O-L-I-D-A-Y @nrc.gov. Or her telephone number is 301-415-7865.

We have a bridgeline available, and that phone number is 888-790-6447. The passcode to access the bridgeline is 2790867 followed by the pound key.

It is also using the GoToWebinar application to view the presentation handouts real time. You can access this by going to www.gotowebinar.com and searching for the meeting ID 506-651-115.

The purpose of this meeting is to discuss the Draft Report for the standing ACMUI Training Experience Subcommittee. Individuals who would like to ask a question or make a comment regarding a specific issue the Committee has discussed should request permission to be recognized by the ACMUI Chairperson, Dr. Philip Alderson. Dr. Alderson, at his option, may entertain comments or questions from members of the public who are participating with us today.

Comments and questions are usually addressed by the Committee near the end of the presentation after the Committee has fully discussed

the topic. We ask that one person speak at a time, as this meeting is also closed captioned.

I would also like to add that the handouts and agenda for this meeting are available at the NRC's public website.

At this time, I ask that everyone on the call who is not speaking to place their phones on mute. If you do not have the capability to mute your phone, please press *6 to utilize the conference line mute and unmute functions. I would ask everyone to exercise extreme care to ensure that the background noise is kept at a minimum, as any stray background sounds can be very disruptive on a conference call this large.

At this point, I would like to turn the meeting back over to Dr. Alderson.

VICE CHAIRMAN ZANZONICO: Doug, this is Pat Zanzonico. Can you confirm that you can now hear me?

MR. BOLLOCK: Hi, Dr. Zanzonico. Yes, we can hear you. Thank you.

VICE CHAIRMAN ZANZONICO: Thank you.

CHAIRMAN ALDERSON: Thank you. Good to have you with us, Dr. Zanzonico.

This is Dr. Alderson. And as was said

before, we are discussing today the Interim Report of the Committee's Subcommittee on Training and Experience Requirements. The members of that Subcommittee are Dr. Darlene Metter, Dr. John Suh, Ms. Laura Weil, and Dr. Christopher Palestro, who is the Chair of the Subcommittee.

I will now turn the meeting over to Dr. Palestro.

MEMBER PALESTRO: Thank you, Dr. Alderson.

And as Dr. Alderson indicated, this is our Subcommittee's Draft Interim Report. I would like to extend my thanks to Drs. Darlene Metter and John Suh and to Ms. Laura Weil for their invaluable contributions and efforts to put this report together.

I begin with the charge of this Committee. And the specific charge of this Subcommittee is to periodically review the training and experience requirements that are currently in effect for all modalities, which includes both unsealed byproduct materials, 10 CFR 35.100, 200, 300, and 1000, as well sealed byproduct materials, 35.400, 500, 600, and 1000, and to make recommendations for changes as needed.

The guiding principle of our Subcommittee is that we recognize that any recommendations for or against changes in training and experience should ensure that the requirements and provisions in Part 35 which, quote, "provide for the radiation safety of workers, the general public, patients, and human research subjects," closed quotes, are satisfied, while simultaneously ensuring that patient access to these procedures is not unnecessarily compromised.

And I think it would behoove us to review some of the background, as it gets a bit complicated. In June 2015, as a result of concerns expressed by various stakeholders, a Subcommittee was formed to determine if the 700-hour training requirement placed a hardship on patient access to alpha- and beta-emitting therapeutic radiopharmaceuticals and, if necessary, to make recommendations for potential changes and establish recommendations for the total number of hours of training and experience for use of unsealed byproduct material for which a written directive is required. 10 CFR 35.390.

Based on its investigation, the Subcommittee concluded that the current requirement of 700 hours for Authorized Users does not adversely affect patient access to these radiopharmaceuticals

and that no change in the training and experience requirements was warranted.

The Subcommittee did note, however, that nearly 15 years had passed since the requirements had been updated and recommended that the ACMUI form a subcommittee to periodically review the training and experience requirements for all modalities currently in effect, and to make recommendations for changes as needed. The ACMUI accepted this recommendation, and the Subcommittee on Training and Experience Requirements for All Modalities was formed.

The Subcommittee developed a procedure for review of the training and experience requirements, and in order to optimize the review process, planned to begin with 10 CFR 35.100, followed by 35.200, 35.300, et cetera. Due to ongoing concerns about patient access, however, the Subcommittee was directed to prioritize the review of the training and experience requirements for use of unsealed byproduct material for which a written directive is required.

Current status. There have been two developments since the ACMUI recommended against changing training and experience requirements under 10 CFR 35.390. On January 26th, 2018, the United

States Food and Drug Administrative approved lutetium-177 dotatate for treatment of certain neuroendocrine tumors, given the encouraging results that had been obtained with this agent in clinical trials.

In contrast to other therapeutic radiopharmaceuticals which have been approved for very specific situations or indications, such as when other treatments have failed, the indications for lutetium-177 dotatate are much broader and include treatments of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumor, or GEP-NETs, N-E-T-S, including foregut, midgut, and hindgut neuroendocrine tumors in adults. And that is from the NDA 208700 approval letter from the FDA.

Given the excellent results obtained with lutetium-177 dotatate in clinical trials, the broad indications for its use, and the fact that neuroendocrine tumors are now the second most common gastrointestinal tumor, it is likely that there will be considerable demand for this agent.

In another interim development, the Subcommittee notes with some concern a precipitous decrease in the number of first-time candidates sitting for the certification examination of the

American Board of Nuclear Medicine. In 2016, fewer than 50 individuals sat for this examination, in contrast to 80 to 100 individuals in the past.

Furthermore, a review of the Accreditation Council for Graduate Medical Education database shows a steady decline over the past decade in both the number of nuclear medicine residency programs and the number of residents enrolled in those programs from 57 programs with 161 residents in academic year 2007-2008 to 41 programs with 75 residents in academic year 2017-2018. While it is difficult to judge the impact of this decline on patient access, the numerous letters that have been written and the discussions and presentations on this topic that have taken place over the past few years have focused on whether or not there is a sufficient number of Authorized Users. No data had been offered to suggest there is a surplus, nor have future needs been addressed. Thus, the Subcommittee views the decrease in the number of nuclear medicine physicians as a potentially serious problem, perhaps not immediately, but certainly in the future.

In view of the potential problems in patient access that could be created by an increase in the number of procedures, combined with a decrease

in the number of Authorized Users, the Subcommittee believes that it is time to reconsider the creation of an alternative pathway for Authorized Users for 10 CFR 35.390, training for use of unsealed byproduct material for which a written directive is required.

While the requirements of an alternative pathway are beyond the scope of this Interim Report, the Subcommittee offers the following items for consideration:

The length and scope of the training;

The minimum number of administrations that an individual must perform, and whether a total number is sufficient or a specific number per class, alpha and beta;

Written certification versus formal examination, and maintenance of competence.

The Subcommittee welcomes comments and suggestions.

And that concludes the report.

MS. HOLIDAY: So, at this time, are there any comments from members on this Subcommittee?

MEMBER SUH: This is John Suh.

I agree with what has been said in the report.

MEMBER METTER: This is Darlene Metter.

I agree, too. And I would also like to also mention that in Dr. Palestro's final sentence or near the end, the length and scope of training I think is going to be very important, too, as far as a curriculum development. And, again, assessment of competencies is going to be highly important.

MR. GREEN: This is Richard Green.

I'm very appreciative of the thorough report and the time taken by the Subcommittee.

It's interesting to note that, as stated, nearly 15 years have passed since this was last updated. And being a fan of history, it would be interesting to determine how these values were established. The world certainly has changed. The numbers of radiopharmaceuticals and prices and classes have changed. I think it's certainly time to reevaluate what these values were and what they might be going forward.

MEMBER PALESTRO: This is Dr. Palestro. If I can respond to Mr. Green's comment?

The answer is we have spent a good deal of time, and NRC staff has put in a lot of time, trying to ascertain how particularly the number of hours were established. And the answer is it just simply isn't clear from the historical data that are

available. I mean, I think we all agree that the numbers were established with the concept of ensuring the highest quality and safety of care, but why those numbers, in particular, were chosen simply is just not obvious.

VICE CHAIRMAN ZANZONICO: This is Pat Zanzonico.

I would like to ask a question. If I understood correctly, Dr. Palestro, the Subcommittee concluded that, at least at the moment, there was no shortage of Authorized Users that was currently restricting patient access to these procedures. And that's, obviously, an important criterion, among others, in evaluating whether training requirements, training and experience requirements need to be adjusted.

The specific question I have is, as long as the judgment is that there is no shortage of Authorized Users and no restriction in terms of patient access, is there any compelling reason, did the Subcommittee think there would be any compelling reason to offer the training and experience requirements? For example, assuming there is adequate access, patient access, would you still consider either decreasing or increasing the number

of hours and other training and experience requirements? Or is it necessarily tied to the issue of patient access?

MEMBER PALESTRO: Yes, this is Dr. Palestro.

In response to your question, the Subcommittee was formed with the express intention of going through each of the various 35 hundred parts to try to sort that out and determine what, if any, adjustments needed to be made. However, as I indicated in the report, we've been directed to focus specifically on 35.390 because, even though the previous Subcommittee had found no evidence of limiting patient access, these concerns were still expressed by various stakeholders. And now, it is complicated potentially by the fact that we have this new lutetium-177 dotatate coupled with a decrease in the number of nuclear physicians.

So, the answer to is there a shortage at the present time, based on what the Subcommittee presented and reviewed, and the ACMUI endorsed two, or maybe it's coming up on three years ago, not at the present time. But we are looking towards the future. I think there is, and I hope I conveyed it in the report, that the potential exists for a

shortage in the future. And I personally feel -- and I think the Subcommittee would agree with me -- that it would be better to be proactive rather than reactive, as these things take time to develop.

VICE CHAIRMAN ZANZONICO: Understood. Thank you.

MEMBER WEIL: If I may add -- this is Laura Weil -- while the Subcommittee's research found no evidence of shortage of Authorized Users, I think it would be a mistake to state that we found that there was demonstrable adequate numbers of Authorized Users in all healthcare settings and in all areas of the United States. We saw no evidence that there is shortage, but we can't say affirmatively that there are enough Authorized Users in all places.

MEMBER SHEETZ: This is Mike Sheetz.

I'd like to thank the Subcommittee for their work on this topic, and I understand it's a controversial issue.

However, I would be cautious in creating an alternative pathway for a use covered under 10 CFR 35.390. In my experience, this category includes a multitude of radiopharmaceutical therapies which requires a strong background and understanding in radioprotection, radionuclide handling, and clinical

patient care.

While some of these therapies may be relatively straightforward with minimal radiation safety issues, others such as the new lutetium-177 therapy involves a complex administration procedure, you know, with medical health physics and radiation safety concerns. So, again, therefore, we need to be cautious in reducing the training and experience requirements for this category of radiopharmaceutical therapy.

The current training requirements for 35.390 require an AU to be Board-certified in nuclear medicine or radiation oncology or, essentially, have completed the equivalent residency program training. I think it's essential for physicians to have this broad background and training provided by these medical specialties to be approved as an AU for 35.390 uses. So, I would look to these medical specialty boards to establish what the appropriate training and experience is to practice radiopharmaceutical therapy covered under 35.390.

And with respect to the potential patient access issue, I would also look to these medical specialty boards for them to address and make the determination for any changes in current regulatory

requirements.

Thank you.

MEMBER PALESTRO: This is Dr. Palestro.

Thank you for the comment. In response, I guess because there's been so much discussion about decreasing requirements and shortening the, quote/unquote, "number of hours," nowhere in the report, nor is it in the Subcommittee's concept, that the thoroughness of training be limited or that an insufficient amount of training and experience and education result. Whatever suggestions/recommendations made going forward would be made with the concept that any individuals going through the alternative or alternative pathway would have sufficient education, training, and experience.

MR. OUHIB: This is Zoubir Ouhib.

I will have to echo what was just said, and I think the idea that perhaps, while not proven, that there might be a shortage of Authorized Users, I think lowered the standards will be a huge mistake, in my opinion, which would potentially lead to some outcome that would not be desirable. So, I think the Committee has put a very solid document here to follow.

Thank you.

MEMBER DILSIZIAN: Vasken Dilsizian here.

I guess I just want to bring in the perspective of a cardiologist and non-nuclear medicine radiologist who happened to go beyond the cardio training to adequate training to be able to interpret nuclear medicine studies along with nuclear cardiology.

So, what I'm saying is that, if there are oncologists, cardiologists, endocrinologists, neurologists who are interested in contributing to the field of science, advancing medical care, providing patient care, after having fulfilled appropriate training as defined by the Committee or by these societies, then this alternative pathway should be available to those physicians. There's no reason why we should not have others who are interested in expanding the field like cardiologists have done. Nuclear cardiology has blossomed since nuclear cardiologists have had access to the imaging, has had a multitude of prognostic outcome data. The field has grown; patients have benefitted. I don't think that we should have a blind approach to not including other medicine subspecialties besides imaging.

So, I support the concept of defining what it would take to be a competent physician to administer the therapy dose and, then, allow any of the physicians or subspecialties to determine whether they're willing to go through that pathway.

MEMBER METTER: This is Darlene Metter.

What Vasken just said pretty much is what I believe, in my view, what an alternate pathway is. An alternate pathway is another pathway to achieve the same result. And so, these individuals should have the equal competence as someone who has been certified as a Diplomate of the ABR/ABNM or Radiation Oncology Board certification.

I think the problem that we were dealing with was, how do you assess competency in the sense of hours? You have to have a good curriculum for sure, but how do you assess competency? Is it going to be a formal exam or is it going to be just through Board certification? Or what are the pathways do we look at to assess an individual's competency for the radiopharmaceuticals that they'll be administering?

MR. GREEN: This is Richard Green.

I'd like to echo some of Dr. Palestro's comments. And just evaluation of the T&E requirements never has been equated with reducing;

it's evaluating. But we never had alpha emitters in commercial use, in commercial availability, as we do today. Fifteen years ago when these T&E requirements were evaluated, we never had a mixed beta-gamma emitter like lutetium administered in three courses of therapy at 200 millicuries each.

So, we need to evaluate whether what we have today is appropriate and, as Dr. Metter and Dr. Dilsizian have said, make sure that physicians who are supervising these therapies and treating these patients have the right training and experience that is now equated with a decrease. You have to evaluate the adequacy of training and what is really needed to treat patients and meet patients' needs, and they will go wherever that happens to go.

CHAIRMAN ALDERSON: This is Dr. Alderson.

Are there further comments from the Committee?

MEMBER PALESTRO: Yes, Dr. Alderson, it's Dr. Palestro.

I just want to reiterate -- and again, to eliminate any potential confusion -- that the Subcommittee, or that the alternative pathway is not necessarily equated with reducing the number of hours

or a shortcut to qualifying for being able to administer these various agents. It's simply just that an alternative pathway could turn out qualified, equally qualified, equally competent individuals.

CHAIRMAN ALDERSON: All right. Yes, good. Well said. Well said.

Are there further comments from members of the Committee before this goes to the open conference call, to the public?

MEMBER SHEETZ: This is Mike Sheetz.

I just have one thing to point out. In the current 35.390 requirements, there is an alternative pathway to Board certification, and it includes 700 hours, 200 of which have to be in didactic classroom radiation physics, protection, radiochemistry, radiobiology. So, there exists an alternative pathway to Board certification, but it requires 700 hours. So, I think the issue is, do we come up with a different set of alternatives or criteria than the 700 hours?

CHAIRMAN ALDERSON: Are there other comments from the ACMUI?

(No response.)

Hearing none, I think it's time, then, to go to the operator and see if we have people on the

phone who would like to make a comment.

OPERATOR: If you would like to ask a question, please press *1 from your phone, unmute your line, and speak your name clearly when prompted. If you would like to withdraw your question, please press *2.

One moment while we wait for the first question.

(Pause.)

Our first question comes from Cindy Tomlinson, ASTRO.

Your line is open.

MS. TOMLINSON: Thank you.

Chairman Alderson, this is Cindy Tomlinson with ASTRO. Can you hear me okay?

CHAIRMAN ALDERSON: Yes, fine.

MS. TOMLINSON: Okay. Great.

So, I just wanted to thank you for allowing to provide this statement on behalf of ASTRO in response to the Subcommittee's report discussed today. I did submit a written statement. So, I'm just going to summarize what we've stated there.

As we stated in October of 2016 to the ACMUI, ASTRO strongly opposes any reduction in the training and experience requirements found in 10 CFR

35.390. We believe that these requirements are appropriate, protect the safety of patients, the public, and practitioners, and should not be changed.

Radiopharmaceuticals are highly effective in treating cancer, but also potentially hazardous drugs with probable harmful effects to both the patient and the public if not used correctly and under the supervision of a highly trained physician.

The rigorous T&E requirements contribute to the excellent safety record of radiopharmaceuticals. We believe that it is important that the person administering the radiopharmaceuticals is appropriately trained in the safe handling, exposure risks, and the management of side effects of radiation.

In its report, the Subcommittee expressed its concerns with the decline in the number of nuclear medicine physicians sitting for the certification examination of the American Board of Nuclear Medicine. However, the Subcommittee does not discuss other AUs, including radiation oncologists.

The American Board of Radiology estimates that, between 2007 and 20017, approximately 1,650 radiation oncologists have been certified by the ABR with an Authorized User eligibility definition and

may become Authorized Users. In addition, ASTRO estimates that there are approximately at least 2200 radiation oncology facilities in the U.S., which means that, aside from nuclear-medicine-trained AUs nationwide, there are likely enough AUs just among the radiation oncologists.

We are not aware of a perceived shortage of radiation oncologists anywhere in the country. However, without being able to identify which AUs are licensed under 35.390 and 35.300, it is not possible to confirm whether there is an actual AU shortage or just a perceived one. Additionally, ASTRO has not heard what would be an ideal number of AUs. Our members are ready to care for patients needing any radiopharmaceutical.

In conclusion, for those reasons, we oppose reduction in the T&E requirements for 10 CFR 35.390, and we look forward to providing input to the Subcommittee as it continues its deliberations.

Thank you.

CHAIRMAN ALDERSON: Yes. Thank you for that statement.

Would anyone on the ACMUI like to comment?

MEMBER PALESTRO: Yes, Dr. Alderson, it's Dr. Palestro. I have a couple of questions, actually.

CHAIRMAN ALDERSON: Please.

MS. TOMLINSON: Okay.

MEMBER PALESTRO: Okay. Question No. 1, according to your letter, about 1,650 radiation oncologists have been certified with Authorized User eligibility over the past decade, which translates into 165 per year. And I'm just using an average. If we look at nuclear medicine AUs during that same time, based on Board certification, it's roughly about 80 per year. So, all together, over the past 10 years, we've been -- or I should say there are about 245 AUs being authorized between these two groups. And I'm not including diagnostic radiology because I really don't know those numbers.

However, if, in fact, the trend in nuclear medicine holds, where we've decreased from about 80 down to 40 or 45, that's a 16-percent decrease in incoming or newly authorized AUs, if you will, per year. I don't know how to judge that, but that, to me, is a substantial decrease. If we were to take a very critical view or a very severe view, if all nuclear medicine AUs disappear, and we're

talking 85 for those per year or 80 per year, that's a decrease of 35 percent in the total of new AUs, new individuals becoming AUs each year. So, again, those, to my way of thinking, really are numbers to be concerned about.

And then, the next question is, you said likely enough AUs just among the radiation oncologists. I would like to know, because this is something that we grappled with a couple of years ago and everyone continues to grapple with, on what basis can you conclude, or do you conclude, that there are, in fact, likely to be enough AUs just based on radiation oncologists alone?

MS. TOMLINSON: Right. So, when this issue came up a couple of years ago, we asked the NRC to see if we could get numbers for how many AUs are licensed under 35.390 and under 35.300. And the NRC is unable to do that with any certainty because of the way that they track Authorized Users and with the Agreement States. So, it's really hard for us to -- I mean, I think we're both in agreement that we just don't know, right?

MEMBER PALESTRO: Yes. Okay. Yes.

MS. TOMLINSON: Yes, we don't know. We don't know what an ideal number is, either.

MEMBER PALESTRO: That's correct.

MS. TOMLINSON: So, without knowing that, it's hard to say if a decline is okay or not okay.

MEMBER PALESTRO: Okay.

MS. TOMLINSON: So, I think it would be helpful if there were some way for the NRC to -- and I don't know, again, if this is something that they can -- I mean, I'm assuming it would take some time, but to figure out exactly who's licensed under which provision in the regs, because without that information, we're just not going to -- I don't know how you necessarily move forward.

MEMBER PALESTRO: The answer is I agree with you; it's really a complicated issue. I mean, if I'm going to misspeak, then, certainly, staff can correct me, but, as I recall, it's almost impossible to determine the number of AUs because, for example, we have a broad license and the AUs are really in-house. The state doesn't have numbers for each individual AU. So, it becomes very complicated. I agree with you there.

Would you agree with me that there's probably not a surplus they use for these procedures?

MS. TOMLINSON: I don't know that I can

agree or disagree with you on that.

MEMBER PALESTRO: Okay. And then, again, I'm just going to reiterate -- and I will continue to reiterate -- that the alternative pathway does not imply, at least not to me, not to my Subcommittee, or to the ACMUI, that less-well-trained, less-well-educated, less-well-experienced individuals will become AUs.

MS. TOMLINSON: I don't disagree with that. I think our concern is that, if you relax those requirements and there's not equal competency, as was mentioned earlier, then that would be concerning.

MEMBER PALESTRO: Yes, we agree with you. I think the hang-up or the issue that we get into is trying to equate hours with competency.

MS. TOMLINSON: Right.

MEMBER PALESTRO: And so, I think, potentially, the way around that is to decide what constitutes the knowledge base, if you will, that these individuals should have in order to be granted AU status, and devise a way to determine whether or not they possess that knowledge, whether or not they possess the competency. And I'm not convinced, and I think the educational paradigm of the 21st century

is not convinced, that necessarily hours are the way to do, that there are better ways to do it, examinations, and so forth.

MS. TOMLINSON: Right.

CHAIRMAN ALDERSON: Excellent comments. Further comments from the ACMUI?

MR. OUHIB: This is Zoubir.

I just have a question regarding the competency. Now, when you move forward and you have additional users or a larger number of users, and you have an Authorized User that's doing a procedure a year -- I'm going to exaggerate here for a second -- how do you define whether that individual is competent by performing one or two procedures a year, year after year?

CHAIRMAN ALDERSON: That's your question?

MR. OUHIB: Yes, that is my question.

CHAIRMAN ALDERSON: I'll try to step in on that one for a moment. We have to understand, and as part of this call, the scope of the ACMUI's position here. I think, ultimately, we, after much further study and input from the public, might advise the NRC in a particular way, but we would never be the organization responsible for establishing and

policing all of these kinds of documentation. As someone earlier said, I mean, it's probably going to roll back to the certifying boards or some other organizations that might be chosen to recommend or to employ such approaches. So, we're a long way from there.

And in the same way, since I'm on metrics for a minute, I do understand the discussion revolving around the number of AUs. Out of respect to some of our public input on this issue over the last couple of years, the input has been not simply the metric, but the distribution of the AUs and the concern that in certain areas of the country there was a significant dearth of AUs. So, that particular geographic issue can't be exactly related to the average number of AUs.

Would anyone like to comment on Zoubir's proposition?

(No response.)

Hearing none, then, I think we're ready for the next call.

MR. GREEN: Dr. Alderson, this is Richard. May I make a comment quickly?

CHAIRMAN ALDERSON: Certainly.

MR. GREEN: I appreciate the comments

made by the individual from ASTRO, representing ASTRO, and I apologize for forgetting her name. But I have to take a moment to -- there was a statement made that radiopharmaceuticals are highly effective in treating cancer, but are potentially hazardous drugs with possible harmful effects to both the patient and the public if not used correctly.

I agree with the statement with the exception of the term "hazardous drugs," which has a definition defined by the -- hazardous drugs is defined by the National Institute of Occupational Safety and Health, or NIOSH, of the Centers for Disease Control and Prevention, the CDC. They publish a NIOSH list of antineoplastic and other hazardous drugs in the healthcare setting that is updated annually. This is now, the standards for handling hazardous drugs is defined by USP Chapter 800, which was made official last year. And the definition, according to the Draft Hazardous Drugs Policy and Procedures, NIOSH defines a hazardous drug as "a drug that is approved for human use by the FDA and not otherwise regulated by the U.S. Nuclear Regulatory Commission". So, by definition, radiopharmaceuticals are not hazardous drugs. I acknowledge that they need to be understood, used

appropriately by trained individuals, but I just want to point out that, by definition, they are not hazardous drugs.

Thank you.

CHAIRMAN ALDERSON: Thank you for that comment, Mr. Green.

Further comments?

(No response.)

So, I think we'll thank ASTRO for its written statement and for its testimony.

And we'll go back to the operator and ask if there are further comments that would like to be made by the public.

OPERATOR: Dr. Carol Marcus, your line is now open.

DR. MARCUS: Thank you very much, and we would like to thank ACMUI for all its diligence in this area.

I want to make two points, one of which is the reason for the decreasing number of nuclear medicine residents, and the other point is going to be that I don't believe that the NRC is appropriately enforcing this 700-hour requirement.

As to the reason for the decreasing nuclear medicine residents, it's pretty obvious. NRC

is chopping up nuclear medicine into bits and pieces and letting other people do it. Hospital administrators, charged with saving money any way they can in today's reimbursement myth, simply tell those physicians who can be Authorized Users to do so and use that as an excuse to get rid of the well-qualified nuclear medicine physicians.

So, the reason for nuclear medicine physicians decreasing is simply that they can't get jobs. Obviously, a smart, young physician is not going to go into a field where he can't get a job, because it's being chopped up and given away to everybody else.

My second point has to do with the 700 hours. I'm not going to argue whether 700 hours is the ideal number. I think it's probably a good number. But, having taught for close to 40 years residents in nuclear medicine, in diagnostic radiology, and in radiation oncology, I would like to certainly challenge whether the diagnostic radiologists are getting 700 hours. And nobody ever checks.

The four months' residency that they do during their -- four months' rotation in nuclear medicine that they do during their radiology

residency is exactly 700 hours, assuming a 40-hour week. And almost all of that is diagnostic nuclear medicine and not therapy. I would probably doubt that more than 10 or 20 percent of it would be devoted to therapy.

And on top of that, they don't really do 700 hours total over the four months. When you deduct vacation time and time left the next day after doing general radiology night call, the time going to radiology lectures and time covering for other radiology residents who are sick or on maternity leave, one is down to, say, 500 hours in nuclear medicine total. And so, the amount of time spent in therapy is probably 1/10th of the required 700 hours.

And there have been many complaints about the quality of nuclear medicine therapy done by diagnostic radiologists by patients, to the point where an organization has been formed of thyroid cancer survivors complaining to the NRC about the quality of therapy that they're getting.

And I really think that that 700 hours should be checked, should be inspected, and made sure that the residency programs have 700 hours. Because it doesn't make any sense to argue for hours and hours about how many hours you need if the regulator isn't

going to check to make sure that those hours of training are being met.

Thank you.

CHAIRMAN ALDERSON: Would the ACMUI like to comment on that issue? Any comments from the ACMUI?

MEMBER METTER: This is Darlene Metter.

CHAIRMAN ALDERSON: Dr. Metter, please.

MEMBER METTER: So, I've been in academic medicine for over 20 years and been a supervising physician for nuclear medicine Fellows residents and radiology residents. And I understand Dr. Marcus' concern, but the ABR has an exam to assess the competency, if they've learned the information. Now everybody learns in a different way. Someone can learn something in one hour and it takes someone else 10 hours. So, I think the 700 hours is an appropriate number, as you said, but I think what I see is that you have certification boards that assess your competency and the assessment of your knowledge and experience and ability to translate that into, quote/unquote, "scenarios in care".

CHAIRMAN ALDERSON: Other comments, please, from anyone?

(No response.)

Hearing none, thank you, Dr. Marcus.

I think that we're ready for any other members of the public who would like to comment.

OPERATOR: We have Jeffry Siegel, and your line is now open.

DR. SIEGEL: Hi, Dr. Alderson, members of the ACMUI and NRC. Thank you for the opportunity.

All I want to do is make a couple of comments. I don't want to make any recommendations.

I want to remind everybody, since you're calling out 35.390 specifically and nothing else right now, that it was predated by -- and you can't be dyslexic for this -- 35.930, where all that was needed was 80 hours. So, during the revision of Part 35 in 2004, 390 came into being. And I don't want to argue whether the 700 is correct or not, but if you're not a Board-certified physician and decide to go the alternate pathway, which you're allowed to do, then this is for all four categories. Because if you only want one category, namely, the oral sodium iodide, you could go to 394, which was a carve out for endocrinologists, who only need 80 hours. So, one would, then, have to decide, is there really a difference in safety and protection between somebody administering 200 hours of sodium iodide versus

somebody who's administering 100 microcuries of an alpha emitter, as an example? So, there could be, instead of arguing over the alternate pathway in 390, additional carve outs for physicians who specifically want to limit their practice, just like an endocrinologist does, to a specific category of therapy.

And I thank you for allowing me to bring this up.

CHAIRMAN ALDERSON: Thank you. Thank you, Dr. Siegel. That is a good point. I'm glad that you made that point. It's not the first time it's been made. In fact, some of the previous input received by the ACMUI from specialty groups has been specifically to that point, that they would like another exception made regarding just the drug that they are interested in.

And there has been concern about getting into a situation where, for example, the ACMUI would recommend -- recall that all the ACMUI does is advise and recommend -- that we begin having these carveouts for a whole group of individual drugs one after the other. There's been some concern about that as an approach. But that idea does exist because of the I-131 carveout.

Would anyone else like to comment on this?

(No response.)

Anyone on the ACMUI who would like to comment on this issue?

(No response.)

Well, thank you for the comment, Dr. Siegel.

And we'll now go back to the operator and see if there are other members of the public who would like to comment.

OPERATOR: I have a Dr. Greenspan.

Your line is open.

DR. GREENSPAN: Thank you. This is Ben Greenspan. I am the current President of the Society of Nuclear Medicine and Molecular Imaging.

We submitted some comments, also, to the ACMUI, and they're fairly similar to those of ASTRO. We do think there should be a decrease in the number of hours.

Now I will say that that number, again, is somewhat nebulous. I know it requires 200 hours of didactic work and 500 hours of clinical experience. But I'm not sure that we can really tell competency by number of hours. I think what we need

to do is make sure people really know what they're doing, that they really are competent. And the best way to do that is provide excellent training and experience.

And to be honest, I don't think a certification board is sufficient. In diagnostic radiology, a lot of the residents watch from the back of the room and watch three therapies, and they figure they can go out and treat patients. And I don't think that's sufficient. I think we need to have better oversight of the training, and we need to have an exam to confirm that these people really are competent and know the basics of what they're doing, especially the basic science of radiation biology, radiation safety, and so on.

And I am planning to develop a task force to look at the amount of the training and the curriculum that should be required for all sorts of therapies with various radionuclides. I think there's going to be an explosion of these in the future with all sorts of radiopharmaceuticals, with lutetium-177, and a number of other isotopes, maybe actinium-225, and who knows what else?

And I think we need to be prepared for that. And so, like I said, I'm going to be starting

a task force to look at the curriculum that should be required for all nuclear medicine physicians, and potentially others, if they meet the appropriate training and qualifications, to handle these kinds of therapies in the future, because I think there's going to be an explosion of these.

Thank you very much.

CHAIRMAN ALDERSON: Thank you, Dr. Greenspan.

Comments from the ACMUI about Dr. Greenspan's position?

VICE CHAIRMAN ZANZONICO: This is Pat Zanzonico.

I'd like to agree. I think, as has been pointed out a number of times, the current training and experience requirements were drafted over a decade ago, and we all recognize and appreciate that there's been major changes in the clinical use of radionuclides with increasing targeted radionuclide therapies and now the use of, and likely increasing use of, alpha emitters. So, while training may or may not have been adequate when originally drafted, it certainly needs to be revisited and critically reevaluated in light of these ongoing advances and refinements in the field.

CHAIRMAN ALDERSON: Thank you, Dr. Zanzonico.

Would others like to comment?

MEMBER PALESTRO: Yes. This is Dr. Palestro again.

I certainly agree with Dr. Greenspan's comments about an examination, and so forth. And again, I'm just going to continue to reemphasize that, as we move forward, the Subcommittee and the ACMUI, and even the NRC, really need to focus on the educational components necessary to turn out qualified individuals, and then, eventually, if necessary, come up with hours. But you can't come up with hours -- it's putting the cart before the horse. We really need to define what is necessary to turn out or to develop competent individuals, and then, if necessary, sort of back the hours into it.

CHAIRMAN ALDERSON: Well, whether or not it's hours, I mean, all of us, any of us who have been involved with any of the ABMS boards know that the current thing for the last 15 years has been the development of maintenance of competence and how that is assessed. So, it's probably going to be something more complex even than hours, although hours may be a component of it. So, I think this is a very complex

issue and it's not getting any clearer as we move forward. I compliment the NRC and ACMUI on being engaged in this issue at this particular time, but I think we're far from being finished with our deliberations.

Are there other comments? Comments from the public or -- I'm sorry -- I should say, first, are there further comments on this particular statement by Dr. Greenspan?

MR. OUHIB: This is Zoubir.

CHAIRMAN ALDERSON: Yes?

MR. OUHIB: Just a quick question. It's regarding the examination component that you had stated. Can you elaborate on that a little bit more?

DR. GREENSPAN: Not a lot. First, we intend to develop the educational components necessary, all the basic sciences and clinical requirements, and so on. And then, from that, an exam can be made up that would test the basic requirements.

We are willing to draw up an exam. It's not clear who is actually going to be administering an exam like this, but the Society is willing to consider that. But the first step is to develop a curriculum that would handle all these therapies in

the future, and particularly, there may be combinations of alpha and beta emitters being given either simultaneously or consecutively for patients that may benefit them. And so, clinicians need to understand all this.

So, I'm sorry I can't give you more of an answer on the examination at this point. We'll have to wait and see how things develop.

CHAIRMAN ALDERSON: All right. Thank you. Thank you, Dr. Greenspan.

Other comments or questions for Dr. Greenspan?

(No response.)

Hearing none, to the operator, do we have other public comments?

OPERATOR: Next we have Michael Peters.

Michael Peters, your line is open.

MR. PETERS: Hi. This is Mike Peters with the American College of Radiology.

Just a quick comment. So, the latest Subcommittee recommendations pertaining to 390 raise some interesting concepts for contemplation. I might suggest soliciting written comments from the public by publishing a formal Request for Information. You could even include targeted questions for

stakeholders developed by this Subcommittee together with staff. Just some food for thought.

CHAIRMAN ALDERSON: Thank you, Mr. Peters.

Comments or questions for Mr. Peters?

(No response.)

Thank you.

Hearing none, Operator, further comments?

OPERATOR: We have Michael Guastella.

Your line is open.

MR. GUASTELLA: Thank you. Good afternoon. This is Michael Guastella from the Council on Radionuclides and Radiopharmaceuticals.

And I'd like to take the opportunity this afternoon to reiterate --

CHAIRMAN ALDERSON: You'll have to stay closer to your phone, please. Volume up.

MR. GUASTELLA: Is that better?

CHAIRMAN ALDERSON: Much better.

MR. GUASTELLA: Fantastic. Thank you.

I just wanted to reiterate some comments that CORAR has offered the ACMUI on this topic in the past. CORAR does support an alternative pathway and an alternative to the current 700 hours. We have

recommended a specific scope of training requirements for radioisotope handling and radiation safety for physicians that are wishing to administer intravenous therapeutic radiopharmaceuticals containing alpha- and beta-emitting radioisotopes, which -- and this is important -- which have been prepared by a licensed nuclear pharmacist in a state-licensed radiopharmacy and dispensed to physicians as patient-ready doses.

In determining the appropriate amount of time and scope of content for radioisotope handling and radiation safety training the physicians must have, and physicians such as medical oncologists and hematologists -- we haven't heard too much about these specialties today in the call -- they should receive the amount of training that will enable them to safely administer these types of therapeutic drugs.

And we've offered some of the following factors to the ACMUI to consider, such as: the limited role in handling these radiolabeled therapeutic drugs, which, again, would be dispensed and delivered to them in patient-ready doses from a licensed radiopharmacy; the radiological safety profiles of radiopharmaceuticals containing alpha- and beta-emitting isotopes, and, finally, physicians

experienced and trained handling toxic non-radioactive chemical therapies, such as cytotoxic chemotherapy agents.

Thank you.

CHAIRMAN ALDERSON: You're welcome.

Comments? Any comments regarding what was just said?

MR. GREEN: Dr. Alderson, this is Richard Green.

CHAIRMAN ALDERSON: Yes, Richard, please.

MR. GREEN: Mr. Guastella was bringing up concepts that I know that some of the NRC Commissioners have asked the NRC to evaluate, NRC staff to evaluate. Does the concept of mode of receipt have a role to play in the training and experience requirements? These beta-, gamma-, and alpha-emitting therapeutics -- and I agree with Dr. Greenspan, I think that's where the growth in the industry is going to be in these therapeutics -- do not require formulation, a kit, compounding, do not require imaging with a gamma camera or quality control of a gamma camera.

So, I think it's important that we evaluate not just the compounds and the 35.390, but

what is the manner of receipt? Because I think that may also play into the T&E requirements.

Thank you.

CHAIRMAN ALDERSON: Thank you. Yes. that is exactly what he was driving at.

Further comments on that issue?

(No response.)

Thank you.

Operator, are there further public comments?

OPERATOR: Dr. Carol Marcus, your line is open.

DR. MARCUS: Thank you very much.

I just wanted to make a comment about some of the other outside commenters.

CHAIRMAN ALDERSON: Please.

DR. MARCUS: I was on the ACMUI from 1990 to 1994. And near the end of my term, when NRC was contemplating redoing all the medical regulations, which it did in 1997, the ACMUI made two unanimous recommendations. One was to get rid of that two-week 80-hour endocrinology course for using I-131, which is a throwback to the old days of the AEC right after the Second World War. Because they did not feel that two weeks of training was enough to learn the basic

radiation and nuclear sciences that you really needed to know to handle I-131.

And the other recommendation that they made unanimously was to have an exam in basic nuclear and radiation sciences for anybody who wanted to practice any kind of nuclear medicine. And this requirement was actually in the first draft of the regulations, but at the very end this appeared. NRC reasoned that it would be too difficult to make a different basic radiation and nuclear science exam for each group of licensees. That was their excuse, but we had in mind only one exam for any licensee. And what we basically thought was that the NRC was afraid that the people it was selling licenses to wouldn't be able to pass the exam and they would lose a lot of user fee money, and they need that user fee money to support their staff.

This is always something that should be kept in mind that NRC has to raise user fees to support its regulatory program. And anything that decreases the number of users is a threat to its staff.

But the idea of the exam that Dr. Greenspan talked about was a unanimous recommendation of the ACMUI around 1994.

Thank you.

CHAIRMAN ALDERSON: Thank you, Dr. Marcus.

Would anyone like to comment on this comment by Dr. Marcus?

(No response.)

Well, I think the fact that these issues existed 20 years ago, and they still exist in different context today, speaks to their complexity.

Would anyone like to make a comment?

VICE CHAIRMAN ZANZONICO: This is Pat Zanzonico.

The notion that Dr. Marcus just raised of a single competency exam or competency metric, even if it weren't an exam, for all users I think is a compelling one because the implication would be, if prospective AUs did not take the same exam, what is it that they did not need to know that was covered in the exam, the compartmentalized exam they did take versus another subspecialist may take? I think that's a challenging question to answer. I mean, I think there is a knowledge base and a competency base that all physicians who work with radioactive materials, regardless of the specific application they are involved in, need to know. And if one starts

parsing the metrics of competency, whether by different exams, and so forth, it does beg the question, what is it that one physician who uses radioactive material does not need to know to use those materials safely and effectively?

CHAIRMAN ALDERSON: Thank you, Dr. Zanzonico.

Would others like to comment?

MR. OUHIB: Yes. This is Zoubir.

I'm not really sure whether my statement will be fair. But, if you have an individual, an Authorized User, who specializes in one particular element, wouldn't that provide less choices to patient care in comparison to somebody who is qualified and competent in providing all the others, for that matter? It is just a thought.

CHAIRMAN ALDERSON: Right. It's a difficult part of the problem.

Other comments?

VICE CHAIRMAN ZANZONICO: Well, just a follow-up to that last comment. This is Pat Zanzonico again.

CHAIRMAN ALDERSON: Yes, sure, Pat.

VICE CHAIRMAN ZANZONICO: Certainly I agree there may be differences in details of what

particular physicians specializing in certain applications may need to know, and that's an arguable point certainly. But my initial feeling is that there's much more in common that clinical users of radioactive materials need to know, regardless of their specific application, than there is different among those applications. But, again, I concede it's an arguable point, or at least that's my initial feeling.

CHAIRMAN ALDERSON: Thank you.

Further comments?

(No response.)

Hearing none, back to the operator for the next public comment.

OPERATOR: We have Jeffry Siegel.

Your line is open.

DR. SIEGEL: Hi. Sorry. I'm sure you're all aware of this, but I want to make sure you are, so we're not at 390 again five years from now. You all know that the categories of use are only two oral and two parenteral. So, my question is, since so many new agents are coming down the pike, what happens if this new agent is not oral or parentally administered?

Thanks very much.

CHAIRMAN ALDERSON: Oh, excellent question. Would someone on the ACMUI or the NRC like or the FDA like to answer that question?

MEMBER PALESTRO: Dr. Alderson, it's not Dr. Palestro.

CHAIRMAN ALDERSON: Yes?

MEMBER PALESTRO: The Subcommittee that is charged with reviewing the training and experience requirements was established specifically to conduct ongoing reviews in order to minimize the likelihood of falling out of step with the times. So that, as new agents become available, the Subcommittee would review them, or potentially available, if we know they're in the pipeline, review them and develop recommendations about what, if any, additional training would be required or perhaps a modification in the current rules.

DR. SIEGEL: Right. Is my line still open?

CHAIRMAN ALDERSON: Is this Dr. Siegel?

DR. SIEGEL: Yes.

CHAIRMAN ALDERSON: Yes, we can still hear you.

DR. SIEGEL: Oh, okay, great. Yes.

No, I realize that. I'm just saying that

there's no carve out or there's no way in 390 that one could even consider a different route of administration. You have to go through 1,000 and argue again what training and experience was necessary for this new form of administration. So, all I'm saying is maybe you want to not categorize these four categories the way you have. And this is an NRC question, I suspect.

MS. HOLIDAY: Dr. Alderson, this is Sophie, if I may?

CHAIRMAN ALDERSON: Please.

MS. HOLIDAY: So, Dr. Siegel is asking what happens if a radiopharmaceutical is neither oral or parenteral, but, in actuality, parenteral administration simply means that it's anything other than oral administration.

CHAIRMAN ALDERSON: That's the way that the NRC has defined that?

MS. HOLIDAY: Correct.

CHAIRMAN ALDERSON: Okay.

MS. HOLIDAY: And I actually looked up the definition, and the definition for "parenteral" is "administered or occurring elsewhere in the body, then the mouth and alimentary canal".

CHAIRMAN ALDERSON: And we have a

representative from the FDA with us. Is that consistent with what the FDA thinks?

MEMBER O'HARA: Yes, it is. I also can't say anything about any new form of delivery that may be being looked at by the FDA. It would be classified as something that is being reviewed by the FDA right now. So, I can't say anything, if there is something like that coming down the pike.

CHAIRMAN ALDERSON: So, given what Ms. Holiday has just said, and the agreement, or at least general agreement, from the FDA, I'll just make an example here to try to increase my own clarity on the issue. So, we all understand the oral part. It's the parenteral -- and that's how, generally, I was taught to say that word, "parenteral -- so, parenteral could be some sort of an intramuscular injection. What about inhalation? Would inhalation, if there was a drug that could be inhaled and would go in through the lungs, would that be considered parenteral?

MR. GREEN: Dr. Alderson?

CHAIRMAN ALDERSON: Yes?

MR. GREEN: As a pharmacist, I would have to defer to, you know, that's a different route. And I would also say that transdermal would be a different

route. It's not through the oral, you know, alimentary canal down the mouth.

CHAIRMAN ALDERSON: Correct.

MR. GREEN: And it's not injected through a layer of skin. But I would say that inhalation or transdermal are other routes that are not encompassed in today's regulatory status.

CHAIRMAN ALDERSON: So, you would not believe, Mr. Green, that those would be considered parenteral?

MR. GREEN: I would not classify them that way.

CHAIRMAN ALDERSON: Oh. So, we aren't going to resolve this discussion, but it just seems that we have, between the regulators and people who are really looking at these issues from other points of view, that even this definition would come under scrutiny. So, another example of the complexity of the issue.

And so, Dr. Siegel, thank you for bringing that issue up to us.

Further comments on this route-of-administration issue?

MEMBER PALESTRO: Dr. Alderson, it's Dr. Palestro.

CHAIRMAN ALDERSON: Yes?

MEMBER PALESTRO: Given the questions that have arisen, as the Subcommittee and the ACMUI and the NRC continue to move forward on the issues, I think it would be extremely important for us to receive clarification of any specific definition of what "parenteral" means to the regulators, not necessarily what is stated in Webster's dictionary, but the definition according to the regulators.

CHAIRMAN ALDERSON: Yes, very good. Very good. I think that's quite correct, and hopefully, some of our people from the NRC and the FDA can work with their groups on that particular issue and let us know how they -- well, I think we know how Sophie and the NRC feels. So, I guess we have to know of the FDA. We thought it seemed to agree, but Mr. Green said some other groups would not. So, we have to find out what's really out there and include that in future discussions.

MEMBER O'HARA: Dr. Alderson, I'll talk to the people on the drug side for the actual definition.

CHAIRMAN ALDERSON: Okay. That's good. That's good, too. And we'll try to see if we can get everyone to agree.

All right. Thank you.

Any further comments on this route-of-administration issue?

(No response.)

Hearing none, is there another comment from the public?

OPERATOR: There is no one else on the phone queue.

CHAIRMAN ALDERSON: All right. Operator, why don't you please ask for further comments from the public? And we'll give people a chance who haven't thus far gotten online.

OPERATOR: Again, if you would like to ask a question, please press *1 from your phone, unmute your line, and speak your name clearly when prompted. If you would like to withdraw your question, you can press *2.

One moment while we wait for any further questions.

(Pause.)

One moment. I do have someone that queued in. Just one moment, please.

(Pause.)

We have a question from David.

Your line is now open.

MR. BURPEE: Thank you.

David Burpee with Bayer Pharmaceuticals. I work for licensing customers to ultimately be able to legally ship product to them.

So, I want to thank the Committee and everyone involved. This is very, very important work because on the street level that I work with for finding Authorized Users and helping them to appropriately be a part of it, there's many difficulties. And several have been touched on in your discussion.

There is a geographic distribution problem. So, yes, there's plenty of Authorized Users that can work with this, with these products in Chicago, but in the Upper Peninsula of Michigan I have several accounts that have been struggling to have an Authorized User for over a year. And so, that means these patients have to travel many hours managing a great deal of pain. And so, this is a big problem. And so, thank you again for this work. It's vital.

The complexity that I'm hearing is what I see every day, too, and the differences in what is required to be an Authorized User. Jeff Siegel brought up the 394. There's also 396, which is

specifically for brachytherapy and eBr2 REDOX requiring 700 hours, including 80 hours. And so, it's a question about why the discrepancy of that versus the 200 and the 390. But I do believe it relates to the complexities of these isotopes that are coming down the road.

So, a suggestion may be, for determination perhaps of each isotope as to its safety and how complex it is for handling and working with, that there maybe be a baseline, like 396, and then, as the complexity goes up -- so, for example, comparing alpha at 100 microcuries of a typical dose to the lutetium products around 200 millicuries, that there would be different standards perhaps, maybe under 1,000, that would work for the right training and the competency. I like the comment one person had about how do we determine competency for each of these isotopes.

So, I hope those thoughts help, and again, thank you for your important work.

CHAIRMAN ALDERSON: Thank you.

Comments from the ACMUI on this last phone call?

MEMBER WEIL: This is Laura Weil. I would like to comment.

CHAIRMAN ALDERSON: Yes, Laura.

MEMBER WEIL: To the comment regarding the raw number of Authorized Users, it does not necessarily ensure patient access. The geographic distribution of those Authorized Users has to be taken into account.

Thank you.

CHAIRMAN ALDERSON: Yes. Good. Thank you, Laura.

Further comments from the ACMUI?

MEMBER PALESTRO: Yes, Dr. Alderson, this is Dr. Palestro.

Laura makes a very valid point. The problem is you can't legislate geographic distribution. And I don't know how that's overcome. I think that's a completely separate issue.

CHAIRMAN ALDERSON: Thank you, Dr. Palestro.

Further comments?

VICE CHAIRMAN ZANZONICO: This is Pat Zanzonico.

I think we all certainly understand and empathize with patients who really are put out to undergo a specific procedure, a specific procedure of any kind. And there are all kinds of medical

procedures from open heart surgery to whatever that are only done in specialized centers, likewise, some forms of cancer chemotherapy. And as unfair and as onerous as it may be, those procedures are performed only at centers where the practitioners are competent to perform them.

And while accessibility should be a consideration in using radiopharmaceuticals clinically, certainly in therapy, in particular, it just strikes me it can't be a decisive consideration, just as it can't be a decisive consideration in who can perform all sorts of very complex medical procedures that often are available only at tertiary care academic medical centers.

CHAIRMAN ALDERSON: Thank you, Dr. Zanzonico, for reminding us of that reality.

Further comments?

MEMBER WEIL: This is Laura Weil again. Just one further clarification.

I'm not suggesting that accessibility is in any way a substitute for competence. But I think when we try to make the argument that there's no need to look for an alternate pathway because there are plenty of Authorized Users already available, we have to be careful how we use the word "available" because,

then, it's a fallacy to say that every patient in the United States has access to an Authorized User, where there might be another way, if there's an alternate pathway, there might be a way to have people in the community who are perfectly competent and well-trained and able to offer those services to people in different geographic locations.

CHAIRMAN ALDERSON: Thank you, Ms. Weil.

Further ACMUI comments?

(No response.)

Hearing none, we'll go back to the operator and see if there are any more public comments.

OPERATOR: I have Munir Ghesani.

Your line is open.

DR. GHESANI: Thank you. Thank you to the Committee for giving the opportunity to speak. And thank you, ACMUI Committee, for putting this extensive work and coming up with the recommendations and report.

For disclosure, I'm the Human Relations Chair for SNMMI and I'm also a member of the American Board of Nuclear Medicine. But these opinions -- and we have formal comments submitted by SNMMI, and Ben Greenspan already mentioned earlier. But I would

like to add a few more, actually, two big comments.

One of them is about the discussion that we had about the geographic distribution and availability of Authorized Users based on geographic location. While that may be true in certain parts of the country, you have to also, as was mentioned by Pat Zanzonico, that he is going to look into the fact that that's the nature of the healthcare setup. And for the patients who are actually coming for this kind of treatment, they may also need a more extensive consult in post-treatment follow-up as well as handling of any complications.

So, in many ways, it is given, when you're looking at a very tertiary mode of treatment, that the patients are actually expected, and often willing, to look for the nearest alternative, which may not be next door in many instances. And practicing in New York, I see that many patients that we see in our daily practice do actually come from surrounding areas and travel quite extensively to come to a major tertiary center for their care. So, I think we should be careful in not looking at the geographic availability of the Authorized Users in isolation.

The second point I wanted to make was

that, based on the earlier discussions, I saw that there's quite a bit of uncertainty about the extent of Authorized Users and perceived shortage in the future. And I think we have plenty on it. Now anytime we think about preemptive, it's always a good idea because that avoids any catastrophe or crisis that may come up in the future. But, on the other hand, acting preemptively on data that's not sufficient, I don't see that could be justified, especially since there were comments made from the radiation oncology community about their availability of Authorized Users that has not decreased in number.

As far as the ABNM is concerned, in fact, I highly recommend that you look at the most recent data where not only the drop that occurred has now plateaued out, but, in fact, there's actually a slight, but certain, trend towards increased number of diplomates. Now it's not dramatic increase to the point that it meets the level that was seen in early 2000, but, nonetheless, it is an encouraging sign, not to mention that there is actually a second pool of residents who many of them -- as you know, the American Board of Radiology has created this alternate pathway, which ABNM has also supported, and that's available. So that there is an increasing

number of residents actually looking at that path. In fact, I was one of the first ones in the country who started this pathway, and within my very first year of offering it for residents, has stepped up.

And so, just to be careful about the number of Authorized Users, about perceived shortage. We do have another pool of residents from radiology who are training for 12 months of their 16. You know, they're training 16 months out of their four years of radiology residency, and many of them are offered an additional fellowship in nuclear FCT that allows them to become more competent in delivering these kinds of treatments.

And when you are talking about these treatments, they are not given in isolation. Oftentimes, there's a close correlation of imaging study that needs to be done. And you have to be very, very careful when you carve out a small section that only those trained properly administer these treatment. But the treatment is not given in isolation. There's a good part of training, whether it's in the nuclear medicine or in radiology that actually involves not just the radiation safety, but overall concepts of radiopharmacy physics as well as overall concepts of imaging, and combining the

imaging correlation with the treatment.

So, needless to say that it's very, very premature, and I think it's not advisable, to look at this treatment as something that happens in isolation in the care of the patient. It has to be taken into account a full spectrum of what goes on before you decide to give a treatment, and many of those who are in the audience right now know who are treating these patients that imaging plays a crucial role before you even think about administering the treatment, not to mention that after administering that treatment, you have to continuously follow these patients to make sure in which direction your treatment is going.

So, I highly advise that this whole concept of creating a new channel for treatment alone is not a good and advisable concept.

CHAIRMAN ALDERSON: Thank you. Thank you, Dr. Ghesani.

Comments on that?

MEMBER PALESTRO: Yes. This is Dr. Palestro. I have a couple of comments.

No. 1, getting back to the geographic distribution, the role of the Subcommittee and the ACMUI is to ensure that the rules and regulations and training and experience are sufficient that the

individuals who will be using these various radiopharmaceuticals are competent. We can't control which ones they choose to use, nor is it within our purview to do that. Similarly, it's not within our purview to control shortages that may be related to geographic distribution. We're simply there to ensure competence in these individuals and to ensure that our rules and regulations are not limiting access or keeping the numbers of individuals trained artificially down.

In terms of the numbers for nuclear medicine, you know what? I was on the American Board of Nuclear Medicine for seven years. I was Chair. I was on the ACGME Residency Review Committee for seven years. I was Chair. And there have been numerous various attempts at slowing the decreasing trend or the trend in decreasing numbers of residents and taking the board, and so forth, over that time. And the long and the short of it is, they have not met with very much success.

The new concept may or may not turn things around. I don't know. But I think, rather than sitting back and waiting to see what happens or anticipating that things are going to get better, when we've got 10 years of history that say they

haven't gotten better, is a mistake. And I think that we do need to be proactive and begin evaluating the future and see where we stand, to avoid any potential calamities.

And as far as having an adequate number of AUs at the present time, again, there's no basis in fact for any of that. It's a hypothesis. It may be an educated guess. But none of us can sit down and say that, yes, there are sufficient number of AUs with any degree of certainty.

And what, in fact, the Subcommittee said a couple of years ago was that there was nothing to suggest that the explanation for the decreasing use of one particular agent was related to a shortage or a lack of AUs. So, it's a little bit different.

DR. GHESANI: Is my line still open?

CHAIRMAN ALDERSON: Whoever you are -- we don't know who you are, but your line is open. We can hear you.

DR. GHESANI: Yes, this is Munir Ghesani.

Thank you, Dr. Palestro, for the detailed explanation, and I fully respect your judgment and your observation about the ABNM noticing the drop.

But I still am currently a member of the Board, and I just finished my tenure as the Chairman

of the Board. And we have acknowledged that the drop has been there, but the most recent data is suggesting that it has plateaued out. And as I indicated, the most recent one for this year has been a slight internal increase in the number of applicants.

And the other noticeable change that we have observed, and it is very much out in the public, is that amongst the increase, as well as overall, there are an increasing number of candidates who are dual-certified. So, the offer of the 16-month pathway occurred in 2010. Of course, when you offer a new track in a long residency program, it takes four or five years to notice the difference. And so, this would be the first few years that are showing a little bit of change. And I think that if the trend continues and if the dual pathway is offered at the same rate and, hopefully, at the increasing institutions, then you will clearly have the benefit of having more potential Authorized Users going into practice in the future.

With regards to your observation about the insufficient number of Authorized Users, you mentioned that the ACMUI -- in fact, I was on that call, and it was very clear that at that time it was noticed by the ACMUI Subcommittee that there was no

such issue with regards to geographic availability and overall shortage of the Authorized Users.

So, if that's the case, and if we don't have a handle on the total number of Authorized Users now or going into the future, I still maintain my position that it is a little bit premature to be preemptive without having a complete knowledge of data for analytics. In the business world, people would always rely on the data before making any future decisions. And I think the practice of medicine should be no different in that regard.

CHAIRMAN ALDERSON: Thank you, Dr. Ghesani.

Further comments?

MEMBER PALESTRO: Yes. This is Dr. Palestro. I would just like to respond briefly to Dr. Ghesani.

No. 1, in terms of preemptive, I don't think it's preemptive. I think it's more being proactive. It's not something that's going to occur overnight. As Dr. Alderson indicated, this is a slow process that takes a lot of work.

Getting back to your comment on business, they won't act until they have the data, again, I have 10 years of data for the ABNM that shows a

decreasing trend. And if I'm going to follow your suggestion on the way business would act, I would be acting on those 10 years of data before I would be sitting back and waiting for something hopefully to happen.

That's not to suggest that it's not going to happen. I hope it does. My whole career is built on nuclear medicine. There's nothing enjoyable about watching the number of individuals training in nuclear medicine decrease. But I do have 10 years of data that suggests that the numbers -- in fact, it doesn't suggest -- it confirms the numbers have continually decreased. And those are the data that I have in front of me. And I don't think -- I personally don't want to wait four or five years to see whether or not the trend has actually changed.

CHAIRMAN ALDERSON: Thank you, Mr. Palestro.

DR. GHESANI: Yes, Dr. Palestro, your point is very well-taken, and no doubt that this is an observation. But, while we are making a decision, it would be prudent to also see the most recent trends that have occurred.

And I fully agree that the process takes time. And if that's the case, then it may be even

more advisable to look at the most recent data and revisit the idea about where the trend is going. Because there's no question that the last 10 years have shown the trend to be in that direction, but, you know, the last couple of years have been somewhat different. And that should be strongly taken into account before putting it all together.

CHAIRMAN ALDERSON: Thank you. So, yes, the number of diplomates in one particular board are a component of the AU availability issue, but I would hope that we can stay off the details of the work of one particular board at this particular time. I think we've heard good comments on that, and thanks to all of you.

Are there other people online at this time who would like to make a new comment?

OPERATOR: We have no one else in the queue.

CHAIRMAN ALDERSON: No one is in the queue.

Are there other comments from members of the ACMUI?

MR. OUHIB: This is Zoubir.

Just a brief comment regarding item 1 that was brought up. I think it's a very important

one, as the healthcare business is looking into Centers of Excellence. And I really believe that these procedures are not just a matter of injecting a dose, or whatever. There's a comprehensive care that actually takes place, and I think that we need to keep that in mind. I fully understand that is not the scope of this Committee. However, that needs to be kept in mind.

CHAIRMAN ALDERSON: Thank you.

Further comments from the ACMUI?

(No response.)

Hearing none, and hearing that there are no people online, I believe that we can turn this back to Mr. Bollock and the NRC.

MR. BOLLOCK: Thank you, Dr. Alderson.

And I appreciate the time, and I appreciate all the comments and the Subcommittee's report, the discussion, and the public comments on all these. It is a very complex topic, a lot of different considerations in this area.

I just want to remind the Committee that the staff has been tasked by the Commission to evaluate whether it makes sense to establish tailored training/experience requirements for different categories of radiopharmaceuticals; how those

categories should be determined, such as by risks posed by groups of radionuclides or by delivery method; what the appropriate senior requirements would be for each category, and whether those requirements should be based on hours of training/experience or focused more on competency. So, we owe that to the Commission at the end of the summer.

We will be providing our Draft Evaluation to the ACMUI probably in about two months, give or take, when we've drafted it.

Again, this is the staff's, this is just the staff evaluation. It is not the Commission's. It's a draft. And we listened to all the comments we've heard. I think there was a comment that touched on almost every one of these categories I just said. So, we do appreciate all of that and the insights we've received, both by the ACMUI and the public.

CHAIRMAN ALDERSON: Excellent. Thank you.

Are there any other further issues to be brought before the group today?

(No response.)

I don't believe there's anything for us

to approve. I think this has been a broad-ranging discussion, and there are, as Mr. Bollock indicated just now, lots of open ends that need to be assimilated and summarized, which will be the work of the next several months.

Are there any other further comments before we adjourn?

MS. HOLIDAY: Dr. Alderson, this is Sophie again.

Just as I did during the last teleconference call, I would like to thank the Committee for their time on reviewing this topic and discussing it, including members of the public who also participated.

I'd also like to remind everybody that the ACMUI will be holding its spring meeting here at NRC Headquarters next Wednesday and Thursday. We look forward to having all of you here at Headquarters and participation via webinar.

Thank you.

CHAIRMAN ALDERSON: Okay. Thank you very much.

I think, hearing no other comments, unless there are any, I think we will stand adjourned.

(Whereupon, at 3:49 p.m., the Committee

was adjourned.)

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Statement of
The American Society for Radiation Oncology (ASTRO)
Before the Nuclear Regulatory Commission's Advisory Committee on the Medical Use of Isotopes
March 1, 2018

Chairman Alderson, members of the ACMUI and NRC staff, thank you for allowing me to provide this statement on behalf of the American Society for Radiation Oncology (ASTRO) in response to the Subcommittee on Training and Experience for all Modalities' report discussed today.

ASTRO is the largest radiation oncology society in the world, with more than 10,000 members who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, biology and physics, the Society is dedicated to improving patient care through education, clinical practice, advancement of science and advocacy. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

As we stated in our October 7, 2016 statement to the ACMUI, we strongly oppose any reduction in the training and experience (T&E) requirements found in 10 CFR 35.390, *Training for use of unsealed byproduct material for which a written directive is required*. Under this section, the NRC requires an authorized user (AU) to be certified by a medical specialty board recognized by either the NRC or an agreement state, or has completed 700 hours of T&E in "basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive." ASTRO believes that these requirements are appropriate, protect the safety of patients, the public, and practitioners, and should not be changed. Radiopharmaceuticals are highly effective in treating cancer, but also potentially hazardous drugs with possible harmful effects to both the patient and the public if not used correctly and under the supervision of a highly trained physician.

The rigorous T&E requirements contribute to the excellent safety record of radiopharmaceuticals. We believe that it is important that the person administering the radiopharmaceutical is appropriately trained in the safe handling, exposure risks, and the management of side effects of radiation.

In its report, the Subcommittee expresses concerns with the decline in the number of nuclear medicine physicians sitting for the Certification Examination of the American Board of Nuclear Medicine. However, the Subcommittee does not discuss other AUs, including radiation oncologists. The American Board of Radiology (ABR) estimates that between 2007 and 2017, approximately 1,650 radiation oncologists have been certified by the ABR with an Authorized User Eligibility designation and may become Authorized Users. In addition, ASTRO estimates that there are approximately 2,200 radiation oncology facilities in the United States, which means aside from the nuclear medicine trained AUs nationwide, there are likely enough AUs just among the radiation oncologists. Indeed, ASTRO is not aware of a perceived shortage of radiation oncologists anywhere in the country. However, without being able to identify which AUs are licensed under 35.390 and 35.300, it is not possible to confirm whether there is an actual AU shortage, or just a perceived one. Additionally, ASTRO has not heard what would be an ideal number of AUs. ASTRO members are ready to care for patients needing any radiopharmaceutical.

In conclusion, for the reasons stated above, ASTRO opposes a reduction in the T&E requirements for 10 CFR 35.390 and looks forward to providing input to the Subcommittee as it continues its deliberations.

SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

February 28, 2018

U.S. Nuclear Regulatory Commission (NRC)
11555 Rockville Pike
Rockville, MD 20852
Washington, DC 20555-0001

Re: Training and Experience Requirements

Dear members of the ACMUI:

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) appreciates the opportunity to provide comments on the Subcommittee's Draft Interim Report. SNMMI's more than 17,000 members set the standard for molecular imaging and nuclear medicine practice through the creation of clinical guidelines, sharing evidence-based medicine through journals and meetings, and leading advocacy on key issues that affect molecular imaging and therapy research and practice. SNMMI is pleased to offer comments on specific topics detailed below.

The Society of Nuclear Medicine and Molecular Imaging continues to believe that reducing the number of hours of training requirements to any less than 700 hours will significantly compromise the level of care for the patients receiving these treatments. We understand however that the ACMUI would appreciate a more detailed description of the training and experience that authorized users need. We will develop more detailed recommendations and expect to submit them to you in late June. We hope this will provide the subcommittee with enough time to consider our recommendations before the ACMUI's next meeting in the Fall.

As you are aware, clinical nuclear medicine practice requires not only deep fundamental knowledge of radiation biology and radiation safety but also of indications, contraindications and safety precautions of these treatments. In addition, the administering physician needs to be fully prepared to handle any minor or major radiation spills that may have patient and health personnel safety implications as well as major regulatory implications at the local, state and federal levels.

SNMMI appreciates the opportunity to comment on this report and looks forward to working with you as this process moves forward. As always, SNMMI is ready to discuss any of its comments or meet with NRC on the above issues. In this regard, please contact Caitlin Kubler, Senior Manager, Regulatory Affairs, by email at ckubler@snmmi.org or by phone at 703-326-1190.

Sincerely,

Bennett S. Greenspan, M.D., M.S.

Bennett S. Greenspan, MD, FACNM, FACR
President, SNMMI

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Feb. 21, 2018

Advisory Committee on Medical Uses of Isotopes (ACMUI)
U.S. Nuclear regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

c/o Ms. Sophie Holiday, Sophie.Holiday@nrc.gov

Dear Ms. Holiday and Members of the ACMUI:

Thank you for the opportunity to comment on the subject of training and experience (T&E) requirements for physicians to practice nuclear medicine therapy. I shared some of my thoughts with Dr. Metter on March 30, 2017, and will repeat some of my points here for the record.

Let me begin with a theoretical story to make the point that licensing physicians to do bits and pieces of nuclear medicine is a huge mistake.

Let us imagine that Dr. Brown takes a two week course in how to perform appendectomies and then goes to his hospital administrator wanting practice privileges to perform appendectomies. The hospital administrator agrees. Dr. White takes a two month course in how to perform hernia repairs, and asks the same hospital administrator for practice privileges to perform hernia repairs. The hospital administrator agrees. Dr. Black takes a one month course in how to perform cholecystectomies, and asks the same hospital administrator for practice privileges to perform cholecystectomies. The hospital administrator agrees. Dr. Green takes a four month course in how to perform lumpectomies and mastectomies, and asks the same hospital administrator for practice privileges to perform lumpectomies and mastectomies. The hospital administrator agrees. Drs. Brown, White, Black, and Green are family practice physicians, and when any of their patients come in with need of any of these procedures, they recommend themselves or each other to perform them. There was a board certified general surgeon on staff, but as his bread and butter business began melting away, he left and went elsewhere to practice. One night there is a

terrible auto accident, and severely injured victims are brought to the hospital. There is no general surgeon available to help these patients, and they die. **This is theoretical of course, because physicians are not given practice privileges to practice bits and pieces of general surgery. Generally speaking a physician must be board certified in general surgery to get practice privileges in general surgery. He/she may opt to specialize in breast surgery, or endocrine surgery, etc., but must be educated, trained, and experienced in all of general surgery. He/she may then opt to generally restrict his/her practice any way he/she wishes to do so.**

This is generally the case with all medical specialties. One cannot become a cardiologist, endocrinologist, pulmonologist, infectious disease expert, nephrologist, etc. without first becoming a general internist. Medical education, training, and experience start out broadly, and then become subspecialized. This is true of all medical specialties except nuclear medicine, and to my knowledge, only in the United States. **What happened in the United States to cause a balkanization of nuclear medicine?**

Part of the story is historical, part is political, and part is economic. Nuclear medicine began in the United States in 1936 with the use of P-32 sodium phosphate to treat polycythemia rubra vera. Before WWII, radionuclides were accelerator produced and their medical use was not regulated by anyone except generally by State Boards of Medicine. After WWII ended, I-131 sodium iodide was produced in the Oak Ridge reactor and became available for treating hyperthyroidism and differentiated thyroid cancer. Due to the fact that there was no specialty called "nuclear medicine", the fledgling Atomic Energy Commission ran a two week course in how to use I-131 sodium iodide to treat hyperthyroidism and differentiated thyroid cancer, and established an Advisory Committee on Medical Uses of Isotopes (ACMUI) to determine what radiopharmaceuticals could be used by physicians to diagnose and treat which conditions. At that time the FDA did not regulate radiopharmaceuticals (they didn't until 1975). When the Atomic Energy Commission was divided up into what became the Department of Energy (DOE) and the Nuclear Regulatory Commission (NRC), the ACMUI was retained by the NRC. When nuclear medicine finally became established as a board certifiable specialty, the NRC asked the ACMUI if NRC should restrict nuclear medicine licensure to physicians board certified in nuclear medicine. Due to the fact that there were many physicians practicing nuclear medicine who didn't take the early boards, the ACMUI decided against recommending a requirement for board certification in nuclear medicine in order to be licensed to practice it. As time went on, more and more board certified nuclear medicine physicians took positions in hospitals and in private practice.

The downturn in the building of nuclear power plants took place after the Three Mile Island accident in 1979, and the NRC looked to medicine to increase its regulatory activities. Then Congress put a User Fee provision into a law and the NRC had to raise its whole operating budget with User Fees, except for International Programs, which at the time was about 10% of its budget. The User Fee requirement stated that each class of NRC licensees had to take care of its own regulatory program. NRC could not use User Fees from the nuclear power side to fund its Medical Program, for example. NRC had hired many employees for its Medical Program, and its medical User Fees were high. The next year NRC tried to raise the fees even higher, and the

nuclear medicine community went to Congress and complained bitterly. The House Oversight Committee told NRC it could not raise its Medical User Fees.

The NRC was faced with two choices: lay off extraneous staff to keep the User Fees low, or sell more radioactive materials licenses in the medical sector to support its bureaucracy. It doesn't take a rocket scientist to figure out what happened. NRC started chopping up nuclear medicine into bits and pieces and selling more licenses. But the perfect storm occurred when Congress started putting the squeeze on hospital reimbursement. Hospital administrators were forced to cut costs wherever possible. So as cardiologists could be licensed to do nuclear cardiology, and diagnostic radiologists could be licensed to do diagnostic imaging and nuclear medicine therapy, and radiation oncologists could be licensed to do nuclear medicine therapy, the hospital administrators insisted that they do so and then laid off their board certified nuclear medicine physicians, or did not replace them when they left or retired. Today there are very few positions for board certified nuclear medicine physicians in the United States except for academic medicine. Most community hospitals will not take on a nuclear medicine physician unless he/she is also board certified in diagnostic radiology. Fewer medical school graduates choose nuclear medicine as a specialty, and nuclear medicine residency programs began decreasing. While the field is in good shape, the specialty is dying. At present we are down to 42 residency programs in the United States, with a total of 69 residents, 72.5% of whom are foreign medical graduates (1). And because of all this, the quality of nuclear medicine is often poor. Many radiologists and cardiologists expect their technologists to practice nuclear medicine, even to the point of reading out the scans, and no technologist is capable of practicing nuclear medicine. Many nuclear cardiologists contract out the reading of their scans to board certified nuclear medicine physicians, because the cardiologists are not competent to do so. **The NRC, which purportedly increased its regulation of nuclear medicine to keep America safe, has been the driving force in decreasing the safety of American patients by imposing poor quality nuclear medicine practice on them.** The patients are not endangered by the radiation in nuclear medicine. They are endangered because the studies are not optimally varied for individual patients with differing diagnostic questions, because the "nuclear medicine" physician does not even see the study until the end of the day when the tech has decided on the procedure and the patient is gone. The creativity in devising diagnostic nuclear medicine studies to get at difficult problems is gone. Many diagnostic procedures are misread or incompletely read. Most research and development in the United States is gone---just look at the Journal of Nuclear Medicine and see how most of the papers are coming in from other countries. Nuclear medicine technologist training programs run by nuclear medicine departments in hospitals are closing---the diagnostic radiologists have no interest or expertise to keep them going.

The situation with nuclear medicine therapy is even more problematic. Other than the use of Na I-131 to treat hyperthyroidism, all therapies at present are for cancer patients. Nuclear medicine therapies have side effects, sometimes moderate or severe, and many of the cancer patients are very ill, in pain, and have had prior treatments with chemotherapy, surgery, and/or radiation therapy. The patients and the patient's families have many questions, and physicians with minimal education, training, and experience often cannot answer their questions. Many of these physicians don't even want to talk to their patients and tell their technologists to take care of it. Technologists are unqualified to do so. A thyroid cancer survivor group apparently started by Peter Crane, a retired NRC lawyer, has complained to NRC about poor quality nuclear medicine

therapy care, expecting the NRC to fix the problem by regulation. Efforts by the NRC, with no medical competence whatsoever, to tell physicians how they must practice nuclear medicine are terrible. The problem is that these poorly competent physicians should not be practicing nuclear medicine therapy in the first place. My experience is that the worst group here is the diagnostic radiologists with no special training other than the supposed four month requirement for nuclear medicine during their diagnostic radiology residency. The radiation oncologists are generally somewhat better, but they usually have little training and experience as well. While theoretically each group receives 700 hours of training and experience, as promised by memos of understanding between their boards and the NRC, I think that it is highly unlikely that many of the residency programs for these groups actually offer such training, and that residents often do not attend many of the lectures and practice opportunities that are offered. To my knowledge, NRC has never inspected any of these programs to check whether residents actually receive 700 hours of training, and it might be a good idea for them to do so, and to check whether the residents actually come to the training offered. In January of 2018 Lu-177 Lutathera was approved by FDA for neuroendocrine tumors, and clinical trials are ongoing for Lu-177 prostate specific membrane antigen (for prostate cancer). These therapies can have significant side effects, and competent physicians must be present to take care of the patients. The problem of quality of the nuclear medicine therapy procedures may well worsen.

When I was on the ACMUI we unanimously voted to end the 80 hour T&E program for endocrinologists to use any quantity of I-131 NaI for hyperthyroid and thyroid cancer therapy. However, when NRC redid the medical regulations in 1997 it chose to ignore the ACMUI. In addition, the ACMUI unanimously voted to require a comprehensive examination in basic nuclear and radiation sciences for physicians who supposedly met the T&E requirements, to make certain that they actually internalized the needed information. The first draft of the 1997 regulations contained that requirement, but mysteriously disappeared in the final regulations with the lame excuse that making up a different examination for each group of nuclear medicine physicians was too difficult. The ACMUI never suggested a different examination for each group of physicians; only one examination was envisioned. However, it appears that the NRC realized that many of its authorized user physicians could not pass such an examination, and it would then lose the User Fees from these physicians, and that would mean laying off staff in the Medical Program.

It appears that some physicians in medical specialties that do not now have T&E programs for nuclear medical therapy are looking at profits from performing these therapies and want a limited T&E program like the endocrinologists have. Their excuse is “patient access”. I am absolutely opposed to this. It would only make the problem worse. **There is no limit to how low medical quality can sink, and we do not need a regulatory agency that purports to improve safety to continue to lower medical quality.**

So, what do we do to fix this T&E mess? The NRC needs to end the chopping up of nuclear medicine into multiple pieces and end the licensing of non-board certified nuclear medicine physicians for any of those pieces. This would restore a “critical mass” of procedures to a board-certified nuclear medicine physician, justifying a full-time person performing these procedures. After all, in radiation oncology the NRC requires board-certification in radiation oncology to perform any procedures using byproduct material (brachytherapy and some large sources in

Gamma Knife type procedures and I suppose a few Co-60 machines, although these are mainly defunct now). Why require board certification in radiation oncology but not nuclear medicine? **Politics and money!** The radiation oncology groups fought like cats when NRC was thinking about removing the requirement for board certification. Unfortunately, nuclear medicine has not yet mounted such a fight. **That is not a reason to destroy the specialty of nuclear medicine**. The use of unsealed radioactive material for nuclear medicine therapy is likely more dangerous than the use of sealed byproduct sources in radiation oncology.

A change such as this will take some time, so that more residents enter nuclear medicine and are available to be hired, replacing the part-time practitioners taking bits and pieces of nuclear medicine today. This could probably be accomplished over a 5-10 year period. In every first world country, and even a third world country like India, all nuclear medicine is practiced by board-certified nuclear medicine physicians. The United States is an outlier. We really do not need the NRC's Medical Program. In 1995, when the National Academy of Sciences Institute of Medicine (NAS-IOM) studied NRC's Medical Program under contract with the NRC, the NAS-IOM determined that NRC's Medical Program (including radiation oncology as well as nuclear medicine) was so dysfunctional, and such a danger to patients, that it recommended that Congress remove NRC's statutory authority in all of medicine and medical research. The standard of medical practice is determined by the specialties of nuclear medicine and radiation oncology, not the NRC. We do not need the NRC Medical Program at all. A requirement that any or all of nuclear medicine be practiced by board-certified nuclear medicine physicians and a continuation of the requirement that any or all of radiation oncology be practiced by board-certified radiation oncologists would replace all of Part 35, including all the NRC's Medical Program staff. This needs to be accomplished by the NRC Commissioners, and perhaps the Congress. But, for the benefit of patients, it is high time that it was accomplished.

Thank you for your attention and consideration.

Sincerely,

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