

**Official Transcript of Proceedings**  
**NUCLEAR REGULATORY COMMISSION**

Title: Draft Report of the ACMUI Training  
and Experience Requirements for All  
Modalities Subcommittee

Docket Number: N/A

Location: Teleconference

Date: February 26, 2019

Work Order No.: NRC-0148

Pages 1-84

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UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

TELECONFERENCE

+ + + + +

TUESDAY

FEBRUARY 26, 2019

+ + + + +

The meeting convened by teleconference at  
10:00 a.m., Christopher J. Palestro, M.D., ACMUI  
Chairman, presiding.

MEMBERS PRESENT:

CHRISTOPHER J. PALESTRO, M.D., ACMUI Chairman;  
Nuclear

Medicine Physician

DARLENE F. METTER, M.D., ACMUI Vice Chairman;  
Diagnostic Radiologist

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

RONALD D. ENNIS, M.D., Radiation Oncologist  
(Brachytherapy)

RICHARD L. GREEN, Nuclear Pharmacist

MELISSA C. MARTIN, Nuclear Medicine Physicist

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

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ZOUBIR OUHIB, Therapy Medical Physicist

A. ROBERT SCHLEIPMAN, Ph.D., Health Care Administrator

MICHAEL SHEETZ, Radiation Safety Officer

MEGAN L. SHOBER, Agreement State Representative

LAURA M. WEIL, Patients' Rights Advocate

NON-VOTING MEMBER PRESENT:

HARVEY B. WOLKOV, M.D., Radiation Oncologist (GSR)

STAFF PRESENT:

ANDREA KOCK, Director, Division of Materials Safety, Security, States, and Tribal Programs (MSST)

CHRISTIAN EINBERG, ACMUI Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Designated Federal Officer

KELLEE JAMERSON, ACMUI Designated Federal Officer;  
ACMUI Coordinator

MARYANN AYOADE, NMSS/MSST/MSEB

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

LISA DIMMICK, Medical Radiation Safety Team Leader,  
NMSS/MSST/MSEB

SARA FORSTER, R-III/DNMS/MLB

ROBERT GALLAGHAR, R-I/DNMS/MLAB

EDWARD HARVEY, R-III/DNMS/MIB

ESTHER HOUSEMAN, OGC/GCLR/RMR

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

IAN IRVIN, OGC/GCLR/RMR

DONNA JANDA, R-I/DNMS/MLAB

SARAH LOPAS, NMSS/MSST/MSEB

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PATTY PELKE, R-III/DNMS/MLB

ZAHID SULAIMAN, R-III/DNMS/MIB

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

MEMBERS OF THE PUBLIC PRESENT:

MICHAEL BAXTER, American Pharmacists Association

KENDALL BERRY, Fox Chase Cancer Center

JANET BUKOVCAN, British Technology Group (BTG)

MARY BURKHART, Illinois Emergency Management Agency

(IEMA)

WILLIAM CHEN, *unaffiliated*

JOHN CHIPPO, Pennsylvania Department of

Environmental Protection (PDEP)

THOMAS CONLEY, University of Kansas Medical Center

WHITNEY COX, IEMA

DAVID CROWLEY, North Carolina Department of Health

and Human Services, Radiation Protection

Section

ARIEL DOUCET, Virtua Health

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WENDY GALBRAITH, University of Oklahoma Health  
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BENNETT GREENSPAN, M.D., Medical College of Georgia,  
Augusta University

MIGUEL de la GUARDIA, Cook Children's Medical Center

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

STANLEY HAMPTON, Eli Lilly

DAN HILL, Cardinal Health

DANIEL JANUSESKI, Virtua Health

TRACY JUE, California Department of Public Health

SUE LANGHORST, Ph.D., *unaffiliated*

RALPH LIETO, St. Joseph Mercy Health System

CINDI LUCKETT-GILBERT, Shertech Pharmacy

CAROL MARCUS, Ph.D, M.D., University of California  
at Los Angeles (UCLA)

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

SAMUEL MEHR, M.D., Nebraska Cancer Specialists

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GEORGE SEGALL, M.D., American Board of Nuclear  
Medicine (ABNM)

BEN SEIBER, PDEP

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and Conservation

JEFFRY SIEGEL, Ph.D., Nuclear Physics Enterprises

DANIEL STROHMEYER, *unaffiliated*

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Oncology (ASTRO)

MICHAEL UJHELYI, BTG

PAUL WALLNER, M.D., 21<sup>st</sup> Century Oncology, Inc.

MATTHEW WILLIAMSON, Memorial Sloan Kettering Cancer  
Center

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MELONIE WISSING, VDH

JOHN WITKOWSKI, United Pharmacy Partners (UPPI)

1

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

2 (10:15 a.m.)

3 MR. EINBERG: Thank you. This is Chris  
4 Einberg. I am the Branch Chief of the Medical Safety  
5 and Events Assessment Branch, and I wanted to  
6 apologize for the technical difficulties that we have  
7 been having right now getting the webinar running.

8 As Sophie mentioned, the slides will be  
9 available on the ACMUI public website. So we're going  
10 to try to get the webinar running, but if you cannot  
11 access the -- or if we can't get the webinar running,  
12 then please access the slides from the -- from the  
13 public SharePoint -- or from the public website.

14 So I am going to start with the opening  
15 remarks here. As the Designated Federal Officer for  
16 this meeting, I am pleased to welcome you to the  
17 public meeting of the Advisory Committee on the  
18 Medical Uses of Isotopes.

19 Once again, my name is Chris Einberg. I'm  
20 the Branch Chief of the Medical Safety and Events  
21 Assessment Branch, and I have been designated as the  
22 Federal Officer for this Advisory Committee in  
23 accordance with 10 CFR Part 7.11.

24 Present today as the Designated Officer  
25 is Sophie Holiday. And, likewise, as a Designated

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1 Federal Officer, I would like to introduce Kellee  
2 Jamerson, who was assigned to the role of the ACMUI  
3 Coordinator in December.

4 This is an announced meeting of the  
5 committee. It has been held in accordance with the  
6 rules and the regulations of the Federal Advisory  
7 Committee Act and the Nuclear Regulatory Commission.  
8 This meeting is being transcribed by the NRC and may  
9 also be transcribed or recorded by others.

10 The meeting was announced on -- or in the  
11 February 4, 2019, edition of the Federal Register,  
12 Volume 84, page 1521.

13 The function of the committee is to  
14 advise the staff on issues and questions that arise  
15 on the medical use of byproduct material. The  
16 Committee provides counsel to the staff, but does not  
17 determine or direct the actual decisions of the staff  
18 or the Commission. The NRC solicits the views of the  
19 Committee and values their opinions.

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

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1           At this point, I would like to perform a  
2           roll call of the ACMUI members participating today.  
3           First is Dr. Christopher Palestro, Chairman, Nuclear  
4           Medicine Physician.

5           CHAIR PALESTRO: Present.

6           MR. EINBERG: Dr. Darlene Metter, Vice  
7           Chairman, Diagnostic Radiologist.

8           VICE CHAIR METTER: Present.

9           MR. EINBERG: Dr. Vasken Dilsizian,  
10          Nuclear Cardiologist.

11          MEMBER DILSIZIAN: Present.

12          MR. EINBERG: Dr. Ronald Ennis, Radiation  
13          Oncologist.

14          MEMBER ENNIS: Here.

15          MR. EINBERG: Mr. Richard Green, Nuclear  
16          Pharmacist.

17          MEMBER GREEN: Present.

18          MR. EINBERG: Ms. Melissa Martin, Nuclear  
19          Medicine Physicist.

20          MEMBER MARTIN: Present.

21          MR. EINBERG: Dr. Michael O'Hara, FDA  
22          Representative.

23          MEMBER O'HARA: Present.

24          MR. EINBERG: Mr. Zoubir Ouhib, Radiation  
25          Therapy Physicist.

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1 MEMBER OUHIB: Present.

2 MR. EINBERG: Dr. A. Robert Schleipman,  
3 Health Care Administrator.

4 MEMBER SCHLEIPMAN: Present.

5 MR. EINBERG: Mr. Michael Sheetz,  
6 Radiation Safety Officer.

7 MEMBER SHEETZ: Present.

8 MR. EINBERG: Ms. Meghan Shober, State  
9 Government Representative.

10 MEMBER SHOBER: Present.

11 MR. EINBERG: Ms. Laura Weil, Patients'  
12 Rights Advocate.

13 MEMBER WEIL: Present.

14 MR. EINBERG: Okay. We have a quorum.

15 On the phone we also have Dr. Wolkov.  
16 Dr. Wolkov has been selected as the ACMUI Radiation  
17 Oncologist. He is pending a security clearance, but  
18 may participate in the meeting. However, he does not  
19 have voting rights at this time.

20 And I now ask that NRC staff members who  
21 are present to identify themselves. I'll start with  
22 individuals in the room here. And, Sophie, if you  
23 want to go first.

24 MS. HOLIDAY: Hi. Sophie Holiday,  
25 Medical Radiation Safety Team.

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1 MS. JAMERSON: Kellee Jamerson, Medical  
2 Radiation Safety Team.

3 MS. HOUSEMAN: Esther Houseman, OGC.

4 MS. LOPAS: Sarah Lopas, Medical  
5 Radiation Safety Team.

6 MR. IRVIN: Ian Irvin, OGC.

7 DR. TAPP: Katie Tapp, Medical Radiation  
8 Safety Team.

9 MR. EINBERG: Donna-Beth Howe is here as  
10 well. And now I'll go to the NRC staff members on  
11 the phone. Can you please identify yourselves?

12 MS. AYOADE: Maryann Ayoadé, Medical  
13 Radiation Safety Team.

14 MR. EINBERG: Okay. Thank you. Members  
15 of the public who notified Ms. Jamerson that they  
16 would be participating on the teleconference will be  
17 captured in the transcripts. Those of you who did  
18 not provide prior notification, please contact Ms.  
19 Jamerson at kellee.jamerson@nrc.gov, and that's K-E-  
20 L-L-E-E dot J-A-M-E-R-S-O-N at nrc.gov, or at (301)  
21 415-7408.

22 We have a bridge line available, and that  
23 phone number is (888) 790-6447. The passcode to  
24 access the bridge line is 3279476#. Once again,  
25 3279476#.

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1                   This meeting is also using the  
2                   GoToWebinar application to view the presentation  
3                   handouts real time. Hopefully, we are getting that  
4                   up.

5                   Maryann, have you been able to get that  
6                   going?

7                   MS. AYOADE: Yes. It's up and running.

8                   MR. EINBERG: Okay. Thank you so much.

9                   MS. AYOADE: If anyone on the line can't  
10                  see it, let me know.

11                  MR. EINBERG: And you can access the  
12                  webinar by going to [www.gotowebinar.com](http://www.gotowebinar.com) and searching  
13                  for meeting ID 657537587. Once again, that's  
14                  657537587.

15                  The purpose of this meeting is to discuss  
16                  the draft report of the ACMUI Training and Experience  
17                  Requirements for All Modalities Subcommittee. In its  
18                  report, the subcommittee provides recommendations  
19                  with respect to the T&E requirements for all  
20                  modalities under 10 CFR Part 35, Medical Use of  
21                  Byproduct Material, with specific focus on Part  
22                  35.300 uses.

23                  Individuals who would like to ask a  
24                  question or make a comment regarding a specific issue  
25                  the Committee has discussed should dial star one to

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1 signal the operator that you wish to speak. Please  
2 clearly state your first and last name for the record.  
3 Comments and questions are usually addressed by the  
4 Committee near the end of the presentation after the  
5 Committee has fully discussed the topic. We will  
6 notify the operator when we are ready for the public  
7 comment period of the meeting.

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

11 At this time, I ask that everyone on the  
12 call who is not speaking to place their phones on  
13 mute. If you do not have the capability to mute your  
14 phone, please press star six to utilize the conference  
15 line mute and unmute functions.

16 I would also like to ask everyone to  
17 exercise extreme care to ensure that background noise  
18 is kept at a minimum as any stray background sounds  
19 can be very disruptive on a conference call this  
20 large.

21 At this point, I would like to turn the  
22 meeting back to Dr. Palestro.

23 CHAIR PALESTRO: Thank you, Mr. Einberg.  
24 This is Dr. Christopher Palestro, Chair of the ACMUI,  
25 and I will now turn the meeting over to Dr. Darlene

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1 Metter, who chairs the Subcommittee for Training and  
2 Experience for All Modalities for presentation of the  
3 subcommittee's report. Dr. Metter?

4 VICE CHAIR METTER: Thank you, Dr.  
5 Palestro, and thank you for letting us use this  
6 conference call to present our Subcommittee report.  
7 And before I start, I would like to thank the work by  
8 Subcommittee members Dr. Ronald Ennis, Dr. Robert  
9 Schleipman, Mr. Michael Sheetz, Ms. Megan Shober, and  
10 Ms. Laura Weil.

11 While I present this presentation for our  
12 document that we submitted, you will have slides that  
13 will help point out the key points of this document.

14 The Subcommittee charge. In 2016, the  
15 U.S. NRC ACMUI's Subcommittee on Training and  
16 Experience Requirements for All Modalities was  
17 charged to periodically review the training and  
18 experience requirements for the medical use of  
19 unsealed byproduct material under Title 10, Code of  
20 Federal Regulations, Part 35, Subparts D to H, to  
21 make recommendations for changes as needed.

22 Subcommittee subcharge. The Subcommittee  
23 should reprioritize its work such that the review of  
24 the T&E requirements for 10 CFR 35.300, Uses, is  
25 conducted prior to the review of the T&E requirements

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1 for 10 CFR 35.200. As part of the reprioritized work,  
2 and in light of the NRC's tasking, the Subcommittee  
3 should consider the development of a limited scope AU  
4 pathway.

5 Now I will review some of the background.  
6 In March 2016, the ACMUI held a public teleconference  
7 meeting to discuss the report of the Subcommittee on  
8 the Training and Experience Requirements authorized  
9 users of alpha, beta, and gamma emitters under 10 CFR  
10 35.390.

11 During this teleconference meeting, the  
12 Committee unanimously endorsed the subcommittee's  
13 report and recommendations, which included  
14 maintaining the existing 700-hour training and  
15 experience requirements also termed the alternate  
16 pathway.

17 Additionally, it was recommended that a  
18 separate subcommittee be formed to conduct periodic  
19 reviews of the training and experience requirements  
20 for all modalities under 10 CFR Part 35.

21 The subcommittee developed a data-driven  
22 standardized review template that would provide a  
23 comparative format for future review and  
24 reassessment. To optimize this review process, the  
25 subcommittee intended to begin the review with

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1 35.100, followed by 35.200, 35.300, and so on. The  
2 subcommittee completed its review of 10 CFR 35.100  
3 with no suggested revisions.

4 However, because of ongoing concerns  
5 about patient access to unsealed byproduct material  
6 for which a written directive is required, the  
7 subcommittee was directed to review the T&E  
8 requirements for 10 CFR 35.300 before reviewing  
9 35.200.

10 In August 2017, the Commission voted on  
11 the 10 CFR Part 35 rulemaking package and included  
12 direction to the NRC staff to review 10 CFR 35 Subpart  
13 E and evaluate the possibility of tailored training  
14 and experience with different categories of  
15 radiopharmaceuticals, delineate how these categories  
16 would be created, recommend the appropriate training  
17 and experience requirements, and whether these  
18 requirements would be satisfied based on hours of  
19 training or would require a formal assessment of  
20 competency.

21 In January 2018, the U.S. Food and Drug  
22 Administration approved a therapeutic  
23 radiopharmaceutical, lutetium-177 dotatate, with the  
24 potential for greater use than previously approved  
25 therapeutic radiopharmaceuticals.

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1           In addition, there was a decrease in the  
2 first-time candidates sitting for the American Board  
3 of Nuclear Medicine or the ABNM certification exam.  
4 These two observations go to concerns about a  
5 potential authorized user or AU shortage in the  
6 future. Thus, the ACMUI proposed the reconsideration  
7 of an alternate AU pathway for 10 CFR 35.390.

8           Now, what I'll do is give the  
9 Subcommittee review, comments, and recommendations,  
10 and this was divided into three topics. The first  
11 topic is a potential AU shortage. To address concerns  
12 about a potential future shortage of AU, the  
13 subcommittee reviewed the current pathways for AU  
14 certification.

15           Traditionally, nuclear medicine, nuclear  
16 radiology, diagnostic radiology, and radiation  
17 oncology graduates of Accreditation Council for  
18 Graduate Medical Education, or ACGME, approved  
19 residencies, seek board certification; and, hence,  
20 authorized user status, by the NRC-deemed Status  
21 Boards with the American Board of Radiology, ABR;  
22 Nuclear Medicine, ABNM; and Osteopathic Radiology.

23           In 2016, the ABR supported a redesigned  
24 AU eligibility pathway consisting of 16 months of  
25 nuclear radiology or nuclear medicine training

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1 incorporated into the 48-month or four-year ACGME-  
2 accredited diagnostic radiology residency.

3 This revised program is a redesigned ABR  
4 pathway and would satisfy the NRC's training and  
5 experience requirements for 10 CFR 35.390 via the  
6 alternate pathway.

7 Upon completion of the radiology  
8 residency, the graduate trainee is then eligible to  
9 sit for the board certification exams for the ABR in  
10 nuclear radiology and/or the ABNM.

11 Now, to explore the concern for potential  
12 AU shortage, the Subcommittee reviewed the 2018 and  
13 2019 ACGME website, which provided the following  
14 information on the current number of potential future  
15 AUs in training. And the slide you have listed the  
16 total number of residents in training and the  
17 estimated graduates per year. The first is nuclear  
18 medicine, which has 40 programs. The peculiar aspects  
19 about that residency is that it has a one-, two-, and  
20 three-year pathway, with the one-year pathway taken  
21 by radiologists, which are the majority of the total  
22 residents.

23 So the number 79 is the total number of  
24 residents currently in training with an estimate of  
25 approximately 50 graduates, 40 to 50 graduates per

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1 year.

2 For nuclear radiology, total residents  
3 11, with 11 graduates per year. The redesigned  
4 pathway, which has -- I just went over -- currently  
5 has 56 residents, and the graduates won't be coming  
6 up for a few more years because this just started  
7 about a year or so ago. So when it does mature, it  
8 will be approximately with this current number of 14  
9 per year, but likely it is likely to increase in  
10 number.

11 Radiation oncology, 775 total residents  
12 with 194 graduates per year. The diagnostic radiology  
13 and osteopathic radiology residents are large in  
14 number, with certain graduates per year. However,  
15 the majority of them do not satisfy 35.390  
16 qualifications.

17 So in the current pipeline for AUs in  
18 training for 35.390, it's over 900, which includes  
19 trainees in nuclear medicine, nuclear radiology,  
20 diagnostic radiology, and radiation oncology. As of  
21 2018, the ABNM reported 2,591 practicing ABNM  
22 diplomates. And along with the current practicing  
23 authorized users, the nearly 270 annual 35.390 AU  
24 graduates, and counting for the retiring AUs, the  
25 Subcommittee concluded that there is no objective

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1 data to support an authorized user shortage at the  
2 present time.

3 And if you think about it, if you have  
4 about 250, 270 graduates per year in the next four  
5 years, you will add another 1,000 AUs for 35.390.

6 Topic 2, the limited scope AU pathway.  
7 Although there is no evidence that there is a current  
8 AU shortage, these are the likelihood of the number  
9 of available therapeutic radiopharmaceuticals, and  
10 the demand for these therapies will increase. The  
11 subcommittee explored whether the NRC should consider  
12 developing a limited scope AU pathway tailored to  
13 specific radiopharmaceuticals.

14 Radionuclide therapy possesses the  
15 highest risk and the highest impact of all nuclear  
16 medicine procedures. And if doses are not properly  
17 handed or administered, these therapies can cause  
18 unintentional, serious organ or tissue injury. The  
19 newer therapeutic radionuclides have become  
20 increasingly more complex administrations. And with  
21 the potential for multi-organ or tissue toxicities,  
22 and, hence, this requires a basic competency in  
23 radiation therapy and radiation safety.

24 A potential limited scope AU pathway for  
25 radionuclide therapy must ensure that the basic

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1 knowledge topics in 10 CFR 35.390 are obtained thereby  
2 obtaining an equivalent level of therapeutic  
3 competency and competency in radiation safety.

4 When investigating the feasibility of a  
5 limited scope AU pathway for 10 CFR 35.390, the NRC  
6 staff, with ACMUI input, proposed a list of required  
7 basic knowledge topics for AUs involved in  
8 radionuclide therapy. The proposed curriculum began  
9 with the knowledge topics of 10 CFR 35.390.

10 But due to the complexity and overlap of  
11 these basic knowledge topics, the Subcommittee  
12 concluded that it is not feasible to tailor the T&E  
13 requirements for a limited scope authorized user for  
14 each specific radiopharmaceutical, nor is it feasible  
15 to create categories for specific therapeutic  
16 individual radionuclides because each such category  
17 would encompass nearly all of the knowledge topics in  
18 10 CFR 35.390.

19 The NRC staff, with external stakeholder  
20 input from the medical community, and the  
21 Subcommittee, agreed that the knowledge topics in 10  
22 CFR 35.390 are the basic minimum knowledge required  
23 for any radionuclide therapy.

24 In considering the above, the  
25 subcommittee does not recommend a limited scope AU

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1 pathway for radionuclide therapy requiring a written  
2 directive. Unlike the iodine I-131 sodium iodide,  
3 limited scope authorized user, under 10 CFR 35.392  
4 and 35.394, which are for endocrinologists, the  
5 emerging radionuclide therapies have multiple  
6 contraindications and more toxicities versus the I-  
7 131 sodium iodide, which is specific to one organ,  
8 the thyroid gland for thyroid therapy.

9 It would be too cumbersome to develop and  
10 provide oversight for specific training and  
11 experience requirements within the regulations to fit  
12 each radionuclide therapy. All of the classroom  
13 laboratory training areas and work experience topics  
14 contained in 35.390 are applicable to any  
15 radionuclide therapy and are essential for radiation  
16 safety of the patient, personnel, and public.

17 It would be difficult in defining a  
18 limited scope authorization and what radionuclides or  
19 radiopharmaceuticals are to be included. Each  
20 therapeutic radiopharmaceutical has unique radiation  
21 safety issues, which require a comprehensive  
22 understanding of all of the training and experience  
23 topics in 35.390, regardless of the types of radiation  
24 emissions, chemical properties, or mode of  
25 administration.

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1           During a public NRC meeting held on  
2           December 11, 2018, a novel team approach was proposed  
3           where an onsite authorized nuclear pharmacist, or  
4           ANP, who had prepared the radionuclide for therapy  
5           and handled the radiation safety components, while  
6           the limited scope authorized user would administer  
7           the patient-ready dose and manage patient care.

8           The perceived benefits of an AU  
9           partnership should be carefully reviewed. Although  
10          well intended, a fragmented approach to a therapeutic  
11          procedure can have the unintended consequence of  
12          making things worse. Furthermore, if an onsite ANP  
13          or authorized nuclear pharmacist is available, a  
14          fully trained authorized user is also likely  
15          available for the entire radionuclide therapies,  
16          which are generally not on an emergent basis.

17          There are also fewer authorized nuclear  
18          pharmacists than authorized users, and authorized  
19          nuclear pharmacists are generally concentrated, as  
20          are authorized users, in urban and not-rural areas.

21          The safe and effective administration of  
22          radionuclide therapy is best accomplished by a  
23          comprehensively trained physician authorized user who  
24          is responsible for the entire therapeutic procedure  
25          and who has a thorough knowledge and understanding of

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1 the therapy, to include the various factors and  
2 potential toxicities and serious hazards that can  
3 occur to the patient, the personnel, and the public.

4 Topic 3, competency assessment for the  
5 limited scope authorized user pathway. In the initial  
6 limited stakeholder outreach, the majority of  
7 respondents favored using an examination to confirm  
8 the successful acquisition of 10 CFR 35.390 outreach  
9 topics and to confirm the individual's competency to  
10 independently function as comprehensive or limited  
11 scope authorized user under 10 CFR 35.390. It is  
12 also critical to validate that the proposed  
13 curriculum was successfully attained.

14 For this confirmation and proficiency,  
15 the NRC staff and the subcommittee agree that a  
16 competency assessment is necessary. This assessment  
17 should not be based on hours of preceptor  
18 attestations, but, rather, on an initial and  
19 continued competency evaluation over time.

20 The subcommittee supports broader input  
21 from the medical community to create an AU competency  
22 assessment with final approval by the NRC. The  
23 subcommittee further supports the periodic  
24 reassessment of authorized user competency,  
25 particularly in relation to the frequent or

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1 infrequent performance of radionuclide therapy. This  
2 infrequency concept has raised similar concerns in  
3 board certification/ recertification process, and the  
4 recertification process is generally seven to ten  
5 years between recertification exams.

6 The American Board of Medical  
7 Specialties, or the ABMS, is a nonprofit organization  
8 of 24 medical specialty boards which serves the public  
9 in quality health care to professional and  
10 educational standards. And the ABMS has supported a  
11 program of continuing professional certifications for  
12 physician lifelong learning and self-assessment.

13 The American Boards of Radiology and  
14 Nuclear Medicine are ABMS member boards. And to  
15 promote continued professional competency for their  
16 diplomats, the ABR and ABNM have transitioned or are  
17 transitioning to this continuous longitudinal  
18 assessment.

19 In regards to radionuclide therapy, this  
20 infrequency concept and procedure performance was  
21 also reviewed by the subcommittee. Because of the  
22 ability to eliminate and destroy tissue, therapeutic  
23 radionuclide procedures pose a much higher risk to  
24 the patient, personnel, and public than do diagnostic  
25 procedures. The potential for limited scope AUs, and

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1 the higher likelihood that the infrequent performance  
2 for radionuclide therapy in rural areas would make it  
3 difficult for physicians to retain basic AU  
4 competency in radionuclide therapy.

5 To attest to the successful acquisition  
6 of the authorized user knowledge topics in 10 CFR  
7 35.390, the overall limited stakeholder input and the  
8 subcommittee support a formal competency  
9 certification and a continuous certification process.

10 The goal of certification is to validate  
11 that an authorized user candidate has achieved a  
12 predetermined level of competence, and the current -  
13 - this certification is to confirm the acquisition of  
14 a basic knowledge curriculum and the ability to  
15 independently function as an authorized user for  
16 specific radionuclide therapy or therapies.

17 Although the subcommittee does not  
18 recommend adoption of a limited scope AU pathway for  
19 therapy, if the NRC pursues such a pathway, the  
20 subcommittee strongly recommends an initial formal  
21 competency assessment and competency reassessment to  
22 ongoing longitudinal reassessment with specific  
23 emphasis on radiation safety.

24 The entity or entities that will  
25 administer this formal competency assessment and

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1 reassessments must develop a methodology that ensures  
2 that passing these examinations is empirically  
3 determined. This latter aspect is the Angoff Method,  
4 which is a widely used standard in test development  
5 and creates a test that will be legally defensible  
6 and meet the standards for educational and  
7 psychological testing.

8 So, in summary, the ACMUI Subcommittee on  
9 Training and Experience Requirements for All  
10 Modalities addressed the NRC staff request to assess  
11 the feasibility of a limited scope authorized user  
12 pathway for 10 CFR 35.390, which was initially  
13 predicated on the concern about a potential future  
14 shortage of authorized users.

15 At the present time, there are no  
16 objective data to support an authorized user  
17 shortage. The subcommittee does not recommend the  
18 development of a limited scope AU pathway for the  
19 administration of unsealed byproduct material where  
20 a written directive is required.

21 If the NRC moves forward in pursuing an  
22 alternative limited scope authorized user pathway,  
23 the subcommittee strongly recommends that the limited  
24 scope authorized user must successfully acquire the  
25 knowledge topics in 10 CFR 35.390, which would be a

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1 minimum requirement for all authorized users involved  
2 in radionuclide therapy.

3 The subcommittee also conclude that due  
4 to the complexity and overlap in these basic knowledge  
5 topics, it would be difficult to safely and  
6 practically create specific categories for  
7 therapeutic radiopharmaceuticals.

8 Despite the ACMUI Subcommittee  
9 recommendation against this action, if the NRC  
10 chooses to pursue the creation of a limited scope  
11 authorized user pathway for unsealed byproduct  
12 material where a written directive is required, the  
13 subcommittee strongly recommends that the authorized  
14 user candidate must acquire the basic knowledge  
15 topics in 10 CFR 35.390 and satisfactorily complete  
16 a formal competency assessment.

17 Furthermore, the individual's continued  
18 status as a limited scope authorized user is dependent  
19 on successfully maintaining a formal periodic  
20 reassessment of competency. This final and most  
21 critical component, and the attainment and  
22 maintenance of any authorized user status, will  
23 optimize patient care while ensuring the protection  
24 of the public's health and safety.

25 So the Subcommittee position and four

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1 recommendations are the following. First, the  
2 subcommittee strongly supports and reaffirms the  
3 committee's 2016 position on maintaining the current  
4 and existing authorized user pathway, which are the  
5 board certification and alternate pathways as  
6 codified in the regulations, which are adequate for  
7 protecting public health and safety. Radionuclide  
8 therapy poses the highest risk and the highest impact  
9 of all nuclear medicine procedures.

10 Two, the Subcommittee concludes that  
11 there is no objective status to confirm an authorized  
12 user shortage.

13 Three, the Subcommittee does not  
14 recommend a limited scope authorized user pathway for  
15 unsealed byproduct material for which a written  
16 directive is required.

17 And, four, the Subcommittee unanimously  
18 agrees that in order to ensure the safety of patients,  
19 personnel, and the public, if the NRC chooses to  
20 pursue the creation of a limited scope authorized  
21 user pathway for unsealed byproduct material, where  
22 a written directive is required, the authorized user  
23 candidate must acquire the basic knowledge topics in  
24 10 CFR 390 and satisfactorily complete a formal  
25 competency assessment.

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1           Furthermore, the individual's continued  
2           status as a limited scope authorized user is dependent  
3           on successfully maintaining a formal periodic  
4           reassessment of competency.

5           And that is the end of my report, and,  
6           Dr. Palestro, I turn the meeting over to you.

7           CHAIR PALESTRO: Thank you, Dr. Metter.  
8           This is Dr. Palestro again. I now open this report  
9           to comments by members of the Subcommittee.

10          MEMBER DILSIZIAN: Vasken here. Great  
11          presentation, Dr. Metter. I guess, to me, I'm just  
12          going to summarize, if I get this correctly, what we  
13          are proposing is to maintain the current AU pathway  
14          training for 35.390. And not only maintain it, but  
15          add not just training based on hours and attestation  
16          alone, but additional competency assessment in this  
17          formal test that would be concluding in a certificate,  
18          which would be maintained subsequently by some number  
19          of years where you have to be recertified. Is that  
20          -- would that be the conclusion then?

21          VICE CHAIR METTER: That would be a  
22          recommendation right now. The subcommittee was  
23          looking at the feasibility of a limited scope  
24          authorized user pathway. And these are some of the  
25          recommendations we would make, and that would have to

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1 be for a future subcommittee investigation.

2 MEMBER DILSIZIAN: Thank you.

3 CHAIR PALESTRO: Any other comments from  
4 members of the subcommittee?

5 MEMBER SHEETZ: This is Mike Sheetz. I  
6 have a comment.

7 CHAIR PALESTRO: Go ahead, Mr. Sheetz.

8 MEMBER SHEETZ: I want to thank Dr. Metter  
9 for pulling all of this together. I have a couple of  
10 comments. One, in consideration of the limited scope  
11 AU/ANP partnership, while the ANP could help as an  
12 RSO, we feel that the AU must have a comprehensive  
13 knowledge and understanding of the entire therapeutic  
14 procedure.

15 This includes all of the radiation safety  
16 issues associated with the procedure from package  
17 receipt, dose assay surveys, radioactive waste  
18 disposal, instrument QA, radiation safety training,  
19 personal monitoring, and others.

20 In the United Pharmacy Partners AU/ANP  
21 partnership proposal, there was no delineation of  
22 tasks of who would be responsible for the aspects of  
23 this therapy. You know, would the ANP be physically  
24 present during the administration of the procedure?  
25 Would they be onsite for a person to do special

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1 surveys and waste disposal?

2 So the details of the shared  
3 responsibility have not been addressed, so it's  
4 difficult to make a determination of whether it is  
5 really feasible. While there was a team approach  
6 with other types of radiation therapy and medical  
7 uses, such as the Y-90 microsphere therapy, gamma  
8 radiosurgery, radioactive seed localization, the AU  
9 really is knowledgeable in all of the areas and  
10 supervises the other team members.

11 In one of the United Pharmacy Partners'  
12 letters, they say that this limited scope AU status  
13 is only being requested for alpha and beta therapies  
14 and not high-risk materials. I feel this, in itself,  
15 is just a limited understanding of the radiation  
16 physics and radiation safety associated with all  
17 radiopharmaceuticals used for therapy.

18 Most of these radionuclides also emit  
19 photons, gamma rays, or X-rays, you know, very strong,  
20 and the alpha and/or beta particles also present a  
21 radiation risk, you know, if not handled or  
22 administered properly.

23 In my personal experience here at the  
24 University of Pittsburgh Medical Center, before the  
25 FDA approval of Lutathera, we were one of the only

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1 sites in the western PA region who offered this  
2 therapy. At that time, we had quite a few referrals  
3 that came from distant locations, roughly 40 percent.  
4 However, now a year after FDA approval, we don't get  
5 those referrals. Almost all of our patients are from  
6 the local area.

7 Also, our volumes have plateaued and  
8 slowly dipped as many patients have been -- who have  
9 been waiting for the therapy have received their  
10 treatments. The point is, patients travel to get  
11 medical care. Another important factor that needs to  
12 be considered is that the lack of Lutathera  
13 availability in many places is not because of an end  
14 use shortage but the reluctance of many hospitals or  
15 clinics to do Lutathera therapy because of its upfront  
16 cost, which is upwards of \$200,000 per patient in  
17 drug cost for the four treatment, which obviously can  
18 easily break the bank for smaller community entities,  
19 even with one or two insurance ties.

20 In addition, the manufacturer of  
21 Lutathera, AAA, if necessary with their applications,  
22 if selective and a good institution, it will help set  
23 up a program based somewhat on the expected volume of  
24 patients.

25 So I believe the core program on

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1 availability is really the extremely high cost of  
2 these drugs and not the availability of AUs.

3 Thank you.

4 CHAIR PALESTRO: Thank you, Mr. Sheetz.

5 Any other comments from members of the  
6 Subcommittee? Ron?

7 MS. HOLIDAY: Dr. Ennis, before you speak  
8 -- this is Sophie Holiday -- for everybody else on  
9 the phone, I just want to let you know that the  
10 information that Mr. Sheetz was referring to was a  
11 letter submitted to the NRC on February 20th from  
12 UPPI, and that comment letter will be made publicly  
13 available when it is appended to the meeting  
14 transcript as part of the official record.

15 Thanks. I'll turn it back to you now,  
16 Dr. Ennis.

17 MEMBER ENNIS: Thank you. Just kind of  
18 a reflection. In these recommendations that people  
19 have put forward, I see a very lack of the  
20 understanding of the biological issues surrounding  
21 radiotherapy and the complications thereof.

22 There seems to be some kind of implicit  
23 understanding or -- that these are trivial drugs that  
24 anyone can learn how to do, and it's just a technical  
25 application and a technical issue of this injection

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1       rather than understanding the complex biology and how  
2       radiation interacts with a variety of tissues.

3               Its interaction with each tissue is  
4       unique. The complications that can cause -- that it  
5       can cause, both acutely and chronically, are unique.  
6       It's a level of subspecialization that [inaudible],  
7       the full education, has listed in the listing of  
8       topics. To imply otherwise would be somewhat similar  
9       to suggesting that a primary care doctor could do  
10      chemotherapy. The analogy is really quite similar,  
11      but obviously possible.

12              Thank you.

13              CHAIR PALESTRO: Thank you, Dr. Ennis.

14              Any other comments from members of the  
15      subcommittee?

16              MEMBER WEIL: Yes, please. This is Laura  
17      Weil.

18              CHAIR PALESTRO: Go ahead, Ms. Weil.

19              MEMBER WEIL: The primary role of  
20      regulation is to ensure safety. And it's true that  
21      the -- that regulation can limit access to some people  
22      who can't travel for care, and that is a legitimate  
23      barrier. However, it's not a question of whether  
24      those barriers exist. It's more a question of whether  
25      the regulatory standards that create those barriers

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1 are unnecessarily restrictive or ethically  
2 responsible -- or nor is it the role of the regulator  
3 to attempt to increase access by compromising  
4 necessary safeguards that protect patients, their  
5 families, health care providers, and the public.

6 Thank you.

7 CHAIR PALESTRO: Thank you, Ms. Weil.

8 Any other comments from other members of  
9 the Subcommittee? Comments from members of the ACMUI?

10 MEMBER MARTIN: This is Melissa Martin.  
11 Again, I would like to refer to the letter that was  
12 submitted from the UPPI. A couple of comments after  
13 reviewing that letter. As presented earlier, one of  
14 the requests was that we look at the distribution of  
15 authorized -- number of authorized users and the  
16 geographic distribution.

17 In the letter from the UPPI, they  
18 suggested that there would be a better geographic  
19 distribution of nuclear pharmacists than there would  
20 be of authorized users. Again, there has been no  
21 data submitted to support that statement. I think we  
22 would need to see some kind of data that shows where  
23 the nuclear pharmacist would be distributed.

24 I know the NRC is working on collecting  
25 the data for where the authorized users are located.

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1 But, again, if we have 4,000 authorized users, I think  
2 there is a better geographic distribution already. I  
3 think -- my impression is most of those authorized  
4 users are connected to relatively moderate to large  
5 size cities, and the patients -- again, that was  
6 stated earlier -- the ones that live in the rural  
7 areas are used to traveling and getting  
8 accommodations to get their therapy.

9 So I don't see that that has been a big  
10 -- I don't think that is the impediment to receiving  
11 some of these treatments.

12 The proposal is that it would increase  
13 access to the rural access -- rural areas, but there  
14 has been no proposed limitation on these procedures  
15 being performed by the team approach, limited to the  
16 rural areas. So it would assume that a lot of these  
17 procedures would be performed in the same geographic  
18 mid-to-large sized cities that is currently being  
19 performed.

20 So I don't see that that would -- I don't  
21 understand how that would be restricted to rural  
22 access.

23 One of the other questions I had was,  
24 what is meant by minimally trained physician that  
25 would be administering the isotope in the proposed

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1 team approach? Thank you very much.

2 CHAIR PALESTRO: Thank you, Ms. Martin.

3 Any other comments from the ACMUI?

4 MEMBER GREEN: Dr. Palestro?

5 CHAIR PALESTRO: Yes.

6 MEMBER GREEN: This is Richard Green.

7 CHAIR PALESTRO: Yes, Mr. Green. Go  
8 ahead.

9 MEMBER GREEN: The Subcommittee's  
10 position and recommendations are four bullets on the  
11 document. The last bullet says that the Subcommittee  
12 unanimously agrees, in that fourth bullet. Were the  
13 three prior bullets unanimous decisions?

14 VICE CHAIR METTER: This is Darlene. Yes,  
15 the Subcommittee -- actually, every member was given  
16 the document and they all agreed and we could actually  
17 add that, too, unless there is -- I misunderstood the  
18 Subcommittee, and that when they submitted their  
19 comments they did not agree, but I -- they did not  
20 relate that, but we wanted to make an emphasis on  
21 that last point because that is a very important  
22 point.

23 I mean, they're all important, but that  
24 was a key component in assessing the competency of  
25 the individual who is going to be an authorized user.

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1           And can I just ask the Subcommittee, was  
2           that correct or was it -- I mean, is that a correct  
3           reflection of our decision?

4           PARTICIPANT: Absolutely.

5           MEMBER SCHLEIPMAN: Robert Schleipman. I  
6           totally agree. I think we all -- including for  
7           myself, I fully agree with the recommendations.

8           PARTICIPANT: Yes, it was unanimous from  
9           our discussions.

10          VICE CHAIR METTER: Thank you.

11          MEMBER GREEN: Thank you, Dr. Metter.  
12          Another question I have. I agree completely that the  
13          requirements for complete knowledge of all aspects of  
14          10 CFR 35.390 are required for any physician who  
15          administers radionuclide therapy. I don't think  
16          there is any ability to skimp on that full, complete  
17          knowledge.

18                 It is my understanding that during the  
19          course of training through one of the approved  
20          pathways to become a diplomate in nuclear medicine,  
21          nuclear radiology, radiation oncology, or diagnostic  
22          radiology, that that training period encompasses more  
23          than the 10 CFR 35.390.

24                 Can you give an estimate of what time is  
25          spent on 35.200 and other nuclear medicine

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1 techniques, imaging, uptake, dilution, and excretion,  
2 other than radionuclide therapy?

3 VICE CHAIR METTER: Well, they have -- as  
4 far as it's all incorporated into 48 months of  
5 diagnostic radiology. But looking at the authorized  
6 user status, we are really mainly just looking at the  
7 equivalent training and experience requirements for  
8 35.390, which his for the use of unsealed sources for  
9 therapy and not for imaging and localization or  
10 dilution and excretion.

11 MEMBER GREEN: Yeah. I thought the  
12 charter --

13 VICE CHAIR METTER: Yeah. I'm sorry.  
14 The other thing, too, we're not looking at hours. As  
15 I mentioned in the report, we're not looking at hours.  
16 We're looking at level of competency and ability to  
17 acquire that knowledge and use that knowledge safely  
18 for our patients.

19 MEMBER GREEN: All right. I'm just trying  
20 to -- you know, I thought the challenge to the  
21 Subcommittee was to discern in the training and  
22 experience for all modalities. And so this is what's  
23 required to successfully do 35.200, 35.100, 35.300  
24 applications for radiopharmaceuticals.

25 And I -- I think I am seeing a resounding

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1 support of the existing pathway, but I don't really  
2 think I see a dissection of really what training and  
3 education is required for this 35.300 versus 35.200  
4 versus 35, you know 100. And that's what I thought  
5 was the charge to the Committee -- to the  
6 Subcommittee.

7 VICE CHAIR METTER: Mr. Green, the  
8 Subcommittee is supposed to look at 35.300, but this  
9 specific report addresses 35.390 and not the entire  
10 35.300.

11 MEMBER GREEN: Thank you.

12 VICE CHAIR METTER: And that is  
13 throughout the report, by the way.

14 MEMBER DILSIZIAN: Vasken here. Can I  
15 have a comment?

16 VICE CHAIR METTER: Yes.

17 MEMBER DILSIZIAN: So, Dr. Metter, you  
18 know, I think I know what you're intending to say,  
19 but looking at this slide, and then in your statement  
20 when you say, We are not looking for our self-  
21 competency. I think what you wanted to say is, we're  
22 not just looking for hours and attestation alone, but  
23 an added competency assessment.

24 I think that it's important to just say  
25 -- because the way it comes out both in the slide and

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1 your verbal statement, that if there is no minimum  
2 hours, I think we -- we will understand there has got  
3 to be some number of hours of training, and then it  
4 falls with the competency test. Is that correct,  
5 what I'm hearing, because that's not very clear.

6 VICE CHAIR METTER: No. Exactly what I  
7 said, that we are not looking at hours because hours  
8 can be - it's different for different individuals.  
9 We're looking at the final result.

10 It's sort of like -- I believe I made the  
11 same analogy during our meeting last year in the sense  
12 of if you -- if you are taking your driver's license  
13 -- you wanted to obtain a driver's license, and the  
14 way you obtain it is -- the final result is going to  
15 be the driver's license.

16 And whether you obtain it by going to a  
17 driving school or going to a course with your parents  
18 or with a different individual, if you -- if you learn  
19 the basic requirements and the basic fundamental  
20 knowledge and experience that you need to pass an  
21 exam to get your certification, is what this is  
22 implying. This is a new pathway in the  
23 sense, if it's a limited scope, it's not like a  
24 traditional one that we've done before. So I think  
25 we need to really look at it very seriously because

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1 hours can be, you know, different for your number of  
2 training hours. You can learn quicker than I can,  
3 but I want to know the final result, that you are a  
4 competent individual for the administration of the  
5 radiopharmaceutical therapy for the patient and for  
6 those involved with -- and the public.

7 And so, to me, the final result is that  
8 you are able to do what is needed for our patients.

9 MEMBER DILSIZIAN: Well, the problem I  
10 guess I have is that any ACGME training program, where  
11 you're doing internal medicine, you're doing  
12 radiology, or radiation oncology, has, first, a  
13 minimum number of years of training or hours of  
14 training for/by board certification.

15 You can't possibly ignore the 700 hours  
16 requirement, plus competency. This is what you -- or  
17 what I'm hearing you say is that let's forget about  
18 the 700 hours. Some people can do it in 50 hours, as  
19 long as they pass the test, and I'm having trouble  
20 with that. I think my recommendation would be to  
21 maintain a certain number of hours, years, or whatever  
22 it takes for an average person to be trained for/by  
23 a competency test. Otherwise, I think that 700 --  
24 what you are proposing, 700 hours, doesn't mean  
25 anything. Maybe someone can do it in 50 hours.

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1                   VICE CHAIR METTER: I understand what  
2                   you're saying.

3                   CHAIR PALESTRO: Dr. - I'm sorry, Dr.  
4                   Dilsizian?

5                   MEMBER DILSIZIAN: Yes.

6                   CHAIR PALESTRO: Yeah. Hi. Dr. Palestro  
7                   speaking now. At this point, your comments are sort  
8                   of moot because the Subcommittee has recommended  
9                   against the creation of the limited scope authorized  
10                  user status.

11                  But going back a bit -- and do you  
12                  remember this -- this committee and these discussions  
13                  have been evolving over time. The concept was to --  
14                  if and when a program is -- a limited AU program is  
15                  in fact developed, to develop and to create a  
16                  curriculum, if you will, with all of the competencies  
17                  that need to be met, and then after that to go back  
18                  and determine hours that would be required to complete  
19                  it, because as I think we all agree at this point, we  
20                  have no idea how the 700 hours was arrived at.

21                  And so rather than focusing on hours, the  
22                  concept would have been develop a program, make sure  
23                  it has all of the elements necessary to educate and  
24                  to develop a competent AU, and then after that figure  
25                  out how to -- how to translate that into hours.

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1                   MEMBER DILSIZIAN:    So, again, I guess I  
2                   just wanted to -- I think Mr. Green said this before  
3                   me. I guess I would have expected the subcommittee  
4                   to actually designate some hours to the current  
5                   curriculum that would sum up to some number that may  
6                   be 700 or 500 or 550, so that we can be reassured, as  
7                   would be the NRC staff, that these numbers are in the  
8                   cost ballpark of what it would take for someone to be  
9                   adequately trained.

10                  CHAIR PALESTRO:    Dr. Metter, would you  
11                  like to respond to that?

12                  VICE CHAIR METTER:   I would defer to you.

13                  CHAIR PALESTRO:    Thank you, Mr. Metter.

14                  VICE CHAIR METTER:   Anytime.

15                  CHAIR PALESTRO:    The answer is, again, I  
16                  think right now for the moment it is a moot point,  
17                  since the subcommittee has recommended against it.  
18                  Should the NRC decide to go forward with it, as the  
19                  subcommittee has indicated, they clearly would like  
20                  the opportunity to actively participate in the  
21                  development of such a program.

22                  MEMBER GREEN:    Dr. Palestro?

23                  CHAIR PALESTRO:    Yes.

24                  MEMBER GREEN:    This is Mr. Green again.

25                  So with the recommendation not at this time to do a

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1 limited AU status, will the subcommittee, or the  
2 committee as a whole, take the challenge, as Dr.  
3 Dilsizian has asked, to actually dive into the concept  
4 and figure out how many hours -- what does it take to  
5 learn this concept, that concept, this fact, this  
6 methodology, so that we can actually better  
7 substantiate that engraved-in-stone sort of -- we  
8 don't know where it came from, but if we are asked by  
9 staff or by the Commissioners to develop other  
10 pathways or to validate the existing pathway, are we  
11 going to be going through the exercise?

12 CHAIR PALESTRO: The answer is, when the  
13 subcommittee was originally formed -- and, in fact,  
14 if you look at the title of the subcommittee -- it is  
15 training and experience for all modalities. And the  
16 concept was -- and as Dr. Metter enumerated in her  
17 report, we developed a template. We looked at 100,  
18 and our plan was to go to 200, and then 300, but we  
19 were -- or the subcommittee, I should say, was  
20 redirected to focus on 390.

21 So the answer is, the concept for the  
22 subcommittee is at some point to return to its  
23 original charge and begin to look at the various  
24 categories. And I would presume that the subcommittee  
25 will take into account hours and necessary, for lack

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1 of a better term, items that individuals need to be  
2 knowledgeable in.

3 MEMBER GREEN: Dr. Metter, you are  
4 currently the chair of the subcommittee. Would you  
5 agree with that?

6 VICE CHAIR METTER: Yes, Dr. Palestro, I  
7 do. And I also think, as far as if we do look back  
8 at how these 700 hours were obtained, it may actually,  
9 with the increasing complexities of the radionuclides  
10 that are coming out for therapy, that the - we're  
11 assuming that the hours are going to decrease.

12 The hours may -- we don't know what the  
13 hours will do. They may actually increase because  
14 you now have to know more about what -- about the  
15 newer therapies and their toxicities and adverse  
16 effects and effects on the patient and their -- and  
17 the long-term consequences.

18 So that would be something we'd have to  
19 look at. But at this point in time, I don't think we  
20 are looking at that because, as you said, we did not  
21 support a limited scope AU pathway.

22 CHAIR PALESTRO: Thank you, Dr. Metter.

23 Any other comments from the ACMUI?

24 MEMBER DILSIZIAN: Vasken here. I just  
25 want to go on the record just to kind of let us know

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1 that despite -- I agree with all of what was stated  
2 so far. It would have been nice to have an  
3 approximation of the hours dedicated to the current  
4 required training -- current, not the -- not the  
5 shortened pathway.

6 That would be close to 700 hours, and so  
7 it would then reassure all of us on this call, as  
8 well as the NRC Commissioners and the staff, that we  
9 are not that far apart from what is currently  
10 required.

11 CHAIR PALESTRO: Thank you, Dr.  
12 Dilsizian. But, again, I just want to point out that  
13 was not the charge or the subcharge that was given to  
14 the subcommittee.

15 Any other comments/questions from the  
16 ACMUI?

17 MEMBER OUHIB: Yes. This is Zoubir Ouhib.  
18 My comment is really we seem to be focusing a little  
19 bit on the numbers, and I'm a little bit concerned  
20 about that because, really, going back and seeing  
21 what it takes in -- you know, on the big picture, you  
22 know, in terms of patient evaluation, pre-treatment,  
23 and so on and so forth, and then the treatment itself,  
24 it's not just an injection. There is a lot more that  
25 goes into it than that, and then the patient

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1 management after the fact, and so on and so forth.

2 So I think looking at what an authorized  
3 user has to go through in terms of education,  
4 training, and so on and so forth, and exams and so  
5 on, I think that number is -- well, is irrelevant in  
6 my opinion because it's very easy to look at that and  
7 figure out that it takes a lot more than the 700  
8 perhaps.

9 CHAIR PALESTRO: Thank you, Mr. Ouhib.

10 Any other comments or questions from the  
11 ACMUI? Dr. Metter, I have a question for you. The  
12 subcommittee concluded that there are no objective  
13 data to support an AU shortage at the present time.  
14 We have a list of data, table of data, in which we  
15 have about 270 new graduates per year.

16 How did you come to that conclusion? In  
17 other words, what data did you use? Did you attempt  
18 to determine the number of AUs throughout the United  
19 States and then look at the number per 100,000 people  
20 and determine that's sufficient or insufficient?  
21 Exactly how did you arrive at that conclusion?

22 VICE CHAIR METTER: Well, there is -- you  
23 know, those are the numbers that we have. And as we  
24 had previously stated, most of these are concentrated  
25 in urban areas and where the facilities and resources

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1 are available for the safe use of the radionuclides.

2 And there is really no objective data for  
3 that, and it was -- it was -- there is no objective  
4 for that -- objective data regarding your question.

5 CHAIR PALESTRO: Okay. So this was sort  
6 of I guess an intuitive approach or an intuitive  
7 conclusion based on discussions among members of the  
8 subcommittee?

9 Types of things that I would be  
10 interested in that would make me feel more comfortable  
11 with this sort of conclusion would be the following.  
12 What are the trends over time if we look at the  
13 specialties? Have the number of individuals being  
14 certified, are they increasing, decreasing? Are they  
15 remaining the same?

16 You mentioned briefly individuals  
17 retiring, but did you do any -- any sort of  
18 calculations, for lack of a better word, to see  
19 whether or not the number of new graduates or newly  
20 certified individuals are compensating for retirees,  
21 that sort of thing?

22 And then the other issue, of course, that comes  
23 up, and we have talked about lutetium-177, and there  
24 has also been another agent that was approved last  
25 July, the I-131 MIBG, what about the numbers of these

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1 unsealed source radiopharmaceutical therapies?

2           Where are they in terms of total numbers?  
3 Are they decreasing? Are they plateauing? Are they  
4 increasing? Those are the sorts of data that would  
5 make me feel more comfortable about accepting the  
6 conclusion that there is nothing to suggest an  
7 authorized user shortage at this time.

8           VICE CHAIR METTER: Those are very good  
9 points, Dr. Palestro. I think looking at numbers can  
10 be for or against an argument. And if you say you  
11 have one authorized user for X number of patients,  
12 that would be assuming that the distribution of  
13 patients is equal and homogeneous throughout that  
14 territory, which of course, as I mentioned earlier,  
15 it's not because they're generally concentrated in  
16 urban areas.

17           So, in itself, the distribution of the  
18 population is not equal. And as far as the number of  
19 retirees, that is not available, and I don't know how  
20 that could be available. But as far as we know, I  
21 can give you the number of practicing authorized users  
22 by the American Board of Nuclear Medicine that they  
23 obtained -- that I obtained from them, and we can  
24 look at the number of authorized user graduates from  
25 these programs.

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1           We do not know -- and I don't believe the  
2           NRC collects data on exactly what authorized users do  
3           what therapies. And, you know, that, unfortunately,  
4           is not available. It would be my desire to have that  
5           available, so we can be -- make a more educated  
6           summary of what your questions pose. But at this  
7           point in time, the data is not available.

8           CHAIR PALESTRO:    Okay.    That doesn't  
9           surprise me because we -- this has come up on numerous  
10          occasions in the past. And that is one of the reasons  
11          that I am concerned, because as we all know, there is  
12          -- it takes a long time to effect changes in rules  
13          and regulations, and so forth.

14          And my concern has been, continues to be,  
15          that I would much prefer to be proactive rather than  
16          reactive. And by that I mean I would not like to  
17          find out two or three or four years from now that, in  
18          fact, there is a shortage, and now we need to do  
19          something about it, rather than potentially being  
20          proactive and working on developing a plan to prevent  
21          that, if you will, a preemptive plan.

22          So that's my concern about your  
23          conclusion, and it may be that there is no way to get  
24          more substantive data, and that's the way it is. But  
25          thank you.

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1                   VICE CHAIR METTER: So as far as numbers  
2 go, there are an increasing interest for -- I know  
3 for at least radiology residents to enter the pathway,  
4 the redesigned pathway into nuclear radiology  
5 positions, because of the increasing therapy.

6                   The other thing is I believe your data,  
7 you know, is something that we need to look at. But,  
8 again, it's unavailable, and I think that if you look  
9 at the number of authorized users that are going to  
10 be coming out of the next four years, there will  
11 actually be another 1,000 at least. And so that is  
12 going to increase it by, you know, another 1,000 for  
13 the 3,600 currently available.

14                   And is there -- there is no objective  
15 data, like you said, that there is a potential --  
16 that there is a current authorized user shortage.

17                   And we do have to remember our patients.  
18 As Ms. Weil mentioned that, you know, there is,  
19 unfortunately, a perhaps geographic barrier regarding  
20 the accessibility of certain therapies and  
21 treatments, but that's not the specifics for nuclear  
22 medicine. It's for any medical and health therapy.

23                   And, you know, it's our responsibility as  
24 regulators to protect the public, and I think  
25 protecting the public is to have a confident

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1 individual who understands the entire therapy to be  
2 the one that is going to be responsible for the  
3 patient.

4 CHAIR PALESTRO: Well, I certainly agree  
5 with that and your comment that over the next four  
6 years there is going to be an increase of 1,000  
7 authorized users, give or take. Again, that comment  
8 fails to take into account retirees. There are  
9 clearly people who are retiring, and I have no idea  
10 what that number is. So while it may remain the same,  
11 it may increase by a couple hundred, it may decrease  
12 by a couple hundred. I'm not sure, but, again,  
13 without those data, I would not assume that the number  
14 is going to increase by 1,000 over the next four  
15 years.

16 VICE CHAIR METTER: Well, all that you  
17 know is that the number of authorized users coming  
18 out will be another 1,000. We don't know, like you  
19 said, how many are going to retire. But at least the  
20 number -- you know, there is an increasing number of  
21 available authorized users.

22 CHAIR PALESTRO: Okay. Any other  
23 comments from the ACMUI?

24 MEMBER ENNIS: Yes. Dr. Palestro, this  
25 is Ron.

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1 CHAIR PALESTRO: Yes, Dr. Ennis.

2 MEMBER ENNIS: So just -- I have a little  
3 more specific information about the radiation  
4 oncology piece in terms of distribution, and ASTRO is  
5 actually putting together a heat map of distribution  
6 across the country.

7 And for the part of our radiation  
8 oncology practices that involves the external  
9 radiation and treatments, those are, as you might  
10 imagine, even more challenging in the sense the  
11 patients have to come for daily treatments as opposed  
12 to a single or a periodic injection, and yet we are  
13 not seeing, you know, any groundswell of concern of,  
14 you know, tremendous shortages in the rural areas.

15 Although there are challenges to  
16 practices in radiation oncology in rural areas, there  
17 is no overwhelming sense of lack of access, so that  
18 that would suggest that there are AUs even in the  
19 more rural parts available for the nuclear medicine  
20 aspects of radiotherapy as well.

21 CHAIR PALESTRO: Thank you, Dr. Ennis.

22 Any other comments from the ACMUI?

23 MEMBER GREEN: Dr. Palestro, this is  
24 Richard Green. I just want to, again, repeat your  
25 concerns about being proactive versus reactive.

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1 Personally, I am involved in seven radionuclide  
2 therapy investigational agents that are across the  
3 gambit from AML to two for prostate cancer, non-  
4 Hodgkin's lymphoma, and there is -- again, I am  
5 dealing with seven.

6 So there is a high likelihood that we're  
7 going to see multiple radionuclide therapies coming  
8 out for a multitude of different targets, cancers, in  
9 the next two or three years.

10 Thank you.

11 CHAIR PALESTRO: Thank you, Mr. Green.

12 Any other comments from the ACMUI?

13 MEMBER OUHIB: Yes. Hi. This is Zoubir  
14 Ouhib. Just a general comment looking at, you know,  
15 can you imagine having 1,000 users doing one case  
16 every six months versus having, you know, 500  
17 qualified authorized users that will do multiple  
18 cases regularly? Their expertise, their skills, and  
19 all of that, will be much, much better, and, sure  
20 enough, will most likely have less issues and  
21 complications. So that's my take.

22 CHAIR PALESTRO: Thank you, Mr. Ouhib.

23 Any other comments from the ACMUI?

24 MEMBER SHEETZ: This is Mike Sheetz.

25 CHAIR PALESTRO: Yes, Mr. Sheetz.

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1                   MEMBER SHEETZ: The availability of AUs  
2                   is one issue. But, really, the issue is the number  
3                   of institutions or licensees, and so one of the  
4                   questions would be, is the current number of  
5                   institutions or licensees, you know, insufficient to  
6                   provide these therapies?

7                   And, again, I'll go back to a comment  
8                   made earlier. These new targeted therapies are very  
9                   expensive. They are complex. They require a program  
10                  to be developed and set up, you know, usually with  
11                  the manufacturer. And so it's not something that can  
12                  be set up at every clinic. It's going to be set up  
13                  at existing hospitals that have nuclear medicine and  
14                  radiation oncology programs, for which I assume there  
15                  will be a sufficient number of AUs, you know, who  
16                  will meet the requirements.

17                  Thank you.

18                  CHAIR PALESTRO: Thank you, Mr. Sheetz.

19                  Any other comments from the ACMUI?  
20                  Hearing none, at this point, I would like to open up  
21                  the phone lines to the public.

22                  MS. AYOADE: Dr. Palestro?

23                  CHAIR PALESTRO: Yes.

24                  MS. AYOADE: This is Maryann Ayoadé from  
25                  NRC. I just wanted to clarify, and I would put up a

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1 slide with regards to the NRC specialty boards that  
2 are recognized, as I know you are aware. But I just  
3 wanted to clarify that the current certification  
4 boards that recognize the NRC for 390 training are  
5 the American Board of Nuclear Medicine Certification,  
6 the American Board of Radiology for Radiation  
7 Oncology, and the American Osteopathic Board of  
8 Radiology for Radiation Oncology.

9 With that being said, with regards to  
10 this next slide, there is -- there are a number of  
11 authorized users in training. We would be looking at  
12 -- currently, the ones that recognize the NRC would  
13 be the nuclear medicine and the radiation oncology.

14 CHAIR PALESTRO: Correct.

15 MS. AYOADE: For the nuclear radiology,  
16 they still have an application with it, so they are  
17 not -- they are still not recognized.

18 And then, like Dr. Metter mentioned, the  
19 redesigned DR is still in the works. I just wanted  
20 to clarify that.

21 CHAIR PALESTRO: Okay. Thank you.

22 OPERATOR: Okay. Thank you. We will now  
23 begin the question and answer session. If you would  
24 like to ask a question, please press star followed by  
25 one, unmute your phone, and record your name clearly.

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1 If you need to withdraw your question, press star  
2 followed by two.

3 Again, to ask a question, you would press  
4 star followed by one. It will take a moment for the  
5 questions to come through. Please stand by.

6 MS. HOLIDAY: Before we turn it over to  
7 the public comment -- this is Sophie from the NRC,  
8 and I'd like to ask a question for clarification.

9 OPERATOR: Sure.

10 MS. HOLIDAY: Earlier, Dr. Dilsizian, you  
11 made a comment regarding if the subcommittee's  
12 recommendation was that there would be a number of  
13 training and experience hours in addition to  
14 competency, and Dr. Palestro stated that the  
15 subcommittee's recommendation was that we would  
16 maintain the current and existing AU pathways, but  
17 that if the NRC decided to move forward with the  
18 limited scope AU pathways, then the subcommittee  
19 would recommend that there be a competency  
20 assessment.

21 However, Dr. Palestro, he went forward in  
22 saying that the subcommittee's recommendation was  
23 that there would be a curriculum developed, and then  
24 based on the topics being covered in the curriculum,  
25 a number of hours would be determined as a result of

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1 that curriculum.

2 So my question is, if that is indeed the  
3 recommendation from the Subcommittee, that is not  
4 reflected in the subcommittee report. What the report  
5 does say is that if -- you know, like as I said, NRC  
6 decides to move forward with this, there should be  
7 competency assessments, which should not be based on  
8 hours or separate attestations.

9 So I think maybe this goes to what Dr.  
10 Dilsizian was saying, if this is in fact what the  
11 subcommittee is recommending, that there be a  
12 curriculum, and then from the curriculum a  
13 delineation of hours, then the report would need to  
14 be revised to reflect that.

15 Is that, in fact, the Subcommittee's  
16 position?

17 CHAIR PALESTRO: Sophie, this is Dr.  
18 Palestro. Thank you for pointing that out to me.

19 And, Dr. Metter, really this question is  
20 for you and the subcommittee.

21 VICE CHAIR METTER: Well, that part of it  
22 has not been discussed with the subcommittee. And  
23 right now, this report is that right now we don't  
24 recommend hours. But we do recommend that the  
25 curriculum be established, and right now we do not

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1 recommend the limited scope AU pathway.

2 We would be happy to work with NRC staff  
3 if the NRC decides to go on a limited scope pathway,  
4 and that will be determined at that time.

5 MS. HOLIDAY: So my understanding is that  
6 you are saying, again, that the subcommittee does not  
7 recommend the development of the limited AU pathway.  
8 However, should the NRC move forward, then the ACMUI  
9 would like to work with the NRC to develop such a  
10 curriculum?

11 VICE CHAIR METTER: Yes.

12 MS. HOLIDAY: Okay. Thank you.

13 MEMBER DILSIZIAN: Vasken here. Just --  
14 can I just add one comment? A curriculum has been  
15 forwarded I think to us -- by the Society of Nuclear  
16 Medicine and Molecular Imaging of what entails to  
17 have the training to be an authorized user, correct,  
18 a 700-hour pathway? It's just that the curriculum  
19 hasn't been assigned hours; is that correct? We do  
20 have a curriculum in hand.

21 VICE CHAIR METTER: The subcommittee will  
22 have to look at that curriculum and review it.

23 MEMBER DILSIZIAN: Okay.

24 CHAIR PALESTRO: All right. There being  
25 no other comments, if we can move ahead to comments

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1 from the public?

2 OPERATOR: Our first question is coming  
3 from Carol Marcus. Your line is now open. You may  
4 begin.

5 DR. MARCUS: Thank you very much. I am  
6 a nuclear medicine physician from UCLA. I have two  
7 comments. One is, since the SNMMI, the ACNM, the  
8 ACR, ASTRO, and the ACMUI have all recommended against  
9 this NRC rulemaking, it would be very strange to me  
10 if the NRC, which has no medical competence  
11 whatsoever, would go against the unanimous opinion of  
12 the medically competent groups involved. That's my  
13 first comment.

14 My second comment is that most of these  
15 therapies require sophisticated imaging studies ahead  
16 of time to ascertain whether the patients are good  
17 candidates for the therapies. And this kind of  
18 sophisticated imaging is found in urban areas. It is  
19 not found in rural areas either. And since the  
20 patients are going to have to have sophisticated  
21 imaging procedures in urban areas, they certainly  
22 might as well get their therapy there.

23 Nobody has talked about how they would  
24 get these sophisticated imaging studies in a rural  
25 area with some limited-competence doctor giving the

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1 therapy. And it doesn't make sense. They have to  
2 have the diagnostic tests first, in most cases.

3 That's the end of my comment.

4 CHAIR PALESTRO: Thank you, Dr. Marcus.

5 Other comments from the public?

6 OPERATOR: Yes, sir. Our next question  
7 is going to come from Dr. Paul Wallner. Your line is  
8 now open.

9 DR. WALLNER: Thank you. My name is Dr.  
10 Paul Wallner. I'm a practicing radiation oncologist.  
11 I'm speaking today on behalf of the American College  
12 of Radiology.

13 The ACR represents approximately 38,000  
14 members, including diagnostic and interventional  
15 radiologists, nuclear medicine physicians, radiation  
16 oncologists, and medical physicists, many of whom are  
17 authorized users, authorized medical physicists, or  
18 radiation safety officers.

19 We commend the ACMUI Subcommittee for its  
20 thoughtful review of this controversial topic, and we  
21 generally concur with the subcommittee's analysis and  
22 recommendations.

23 I would like to make three comments  
24 related to some of the discussion earlier today. One  
25 is that there is definitely an increase in the number

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1 of nuclear radiologists, diagnostic radiologists, who  
2 are authorized user-eligible, and radiation  
3 oncologists. And that number is based on increasing  
4 actual real numbers and increasing number of training  
5 programs. Those numbers do exceed the number of  
6 retirees.

7 Secondly, related to the issue of hours,  
8 I would urge the Commission to avoid placing specific  
9 hours on any of these core competencies. The ACGME  
10 requires that all of its training programs review  
11 core competency of all trainees at least twice a year.  
12 Residents cannot advance to the next level of training  
13 unless they have fulfilled all of those competencies.

14 And a third issue related to the new --  
15 potential new agents in the pipeline, I would suggest  
16 that history would suggest that many of these agents  
17 will never reach the marketplace, number one. And,  
18 number two, as we are seeing over the last 30 or 40  
19 years, except for iodine-131, many of these agents  
20 enter the marketplace and then are quickly changed -  
21 - it is quickly eliminated by disruptive technologies  
22 or interventions.

23 With regard to topic 3 of the  
24 subcommittee report, I would note that the American  
25 Board of Radiology and the American Board of Nuclear

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1 Medicine currently employ maintenance and  
2 certification programs to facilitate career-long  
3 assessments for its diplomates, and their previous  
4 issues are evaluated and assessed on an ongoing basis.

5 We strongly agree with the subcommittee  
6 recommendation against adoption of a limited scope AU  
7 pathway mechanism that we believe would fail to  
8 provide reasonable assurance of the adequate  
9 protection of health and safety. Moreover, any such  
10 regulatory changes would greatly increase risk and  
11 introduce unintended consequences, conflicts, and  
12 burdens that would far outweigh the theoretical and  
13 unrealistic rural access improvements suggested by  
14 drug manufacturers.

15 We hope that the NRC staff future  
16 recommendations will prioritize health and safety in  
17 radiopharmaceutical therapy, and follow the advice of  
18 the ACMUI members and patient care experts.

19 Thank you for this opportunity.

20 CHAIR PALESTRO: Thank you. Other  
21 comments?

22 OPERATOR: Yes, there is. Our next  
23 comment is coming from Bennett Greenspan. Your line  
24 is now open.

25 DR. GREENSPAN: Thank you. Can you hear

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1 me?

2 CHAIR PALESTRO: Yes.

3 DR. GREENSPAN: I just want to make a few  
4 comments. First of all, I agree with the assessment  
5 from the subcommittee, and I agree with their  
6 recommendations. I also agree that a competency  
7 assessment is a far better approach than number of  
8 hours. I also agree that the NRC is charged with  
9 protecting the public, and that's good, and that's  
10 why in rural areas with people with limited abilities,  
11 that's really not sufficient, and I think patients  
12 would not be protected being treated by physicians  
13 who don't really understand what they are dealing  
14 with.

15 As far as a curriculum, I am not  
16 representing the Society here, but I did formulate a  
17 curriculum for the Society of Nuclear Medicine and  
18 Molecular Imaging, which was submitted last summer,  
19 and that is one -- one example of a curriculum. I  
20 think the ACMUI may be developed one also.

21 Numerous societies are against having a  
22 limited scope pathway. As Carol Marcus suggested,  
23 that includes now ACMUI and the board certifications  
24 ABM and ABR, but also SNMMI, ACNM, ACR, ASTRO, which  
25 you all mentioned previously, and also AAPM, the

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1 American Association of Physicists in Medicine.

2 I'm not specifically representing them  
3 here either, but all of these societies recommend  
4 against a limited scope authorized user pathway, and  
5 I agree with that as well.

6 Thank you very much.

7 CHAIR PALESTRO: Thank you. Other  
8 comments?

9 OPERATOR: We do have another comment.  
10 This next participant, we do not have your name  
11 recorded, but your line is open.

12 DR. RAZMARIA: Hello? Can you hear me?

13 CHAIR PALESTRO: Yes.

14 DR. RAZMARIA: Hi. Yeah. My name is  
15 Aria Razmaria. I am a senior resident training in  
16 nuclear medicine. As training physicians, we  
17 appreciate the efforts by the ACMUI to provide insight  
18 into the concerns of shortage of authorized users and  
19 bring data into the discussion rather than just  
20 assumption.

21 As to just physicians, our primary  
22 obligation is toward the patients. Radionuclide  
23 therapies are highly proven therapies with high  
24 potential for serious side effects. We appreciate a  
25 strong recommendation towards maintaining the

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1 training and experience requirements, but are puzzled  
2 by discussion of the option of a possibility of NRC  
3 -- (telephone interference).

4 NRC is charged with radiation safety of  
5 the public. As physicians, we are tasked with a  
6 responsibility towards each and every patient, and  
7 high quality of care. We have undermined the  
8 authority and it causes confusion in the  
9 recommendation. If there is a clause mentioned in  
10 the staff recommendation, it is not solid.

11 As physicians, our primary concern is  
12 towards patients, and above all to maintain the  
13 patient interest, above all -- despite all economic  
14 pressures and insights. We strongly maintain that  
15 radionuclide therapies are highly individualized  
16 therapeutic modality and require thorough and in-  
17 depth trainings that are already established by  
18 specialty boards. Creating new competency-assessing  
19 tools would be a significant undertaking, going above  
20 NRC's purview and undermine existing competency  
21 assessment mechanisms in place by specialty boards.

22 In summary, the subcommittee report  
23 sufficiently underlines the fact that there is no  
24 shortage of authorized users, which are the original  
25 arguments of creating alternate pathways.

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1           If NRC decides to pursue the creation of  
2           new pathways with limited training requirements, as  
3           physicians we cannot share responsibility for any  
4           consequences a physician might have, the health of  
5           the patients, and NRC has to be the sole bearer of  
6           responsibility to the public for any competencies  
7           this rulemaking might have.

8           Thank you for your attention.

9           CHAIR PALESTRO:     Thank you.     Other  
10          comments?

11          OPERATOR:   Yes.   Our next comment comes  
12          from George Segall.   Your line is now open.

13          DR. SEGALL:   Thank you very much.   I am  
14          the Executive Director of the American Board of  
15          Nuclear Medicine, as well as a practicing physician,  
16          and I'd like to state that the Board strongly  
17          recommends -- strongly supports the recommendation of  
18          the Training and Education Subcommittee.

19          A few interesting questions came up  
20          during the conference today.   There was one question  
21          regarding the distribution of authorized users in the  
22          United States.   I think the NRC is best positioned to  
23          answer this question.   However, in the comment letter  
24          submitted by the American Board of Nuclear Medicine,  
25          we did give you the distribution data of our

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1       diplomates who are the largest block of diplomates  
2       who are authorized users. And the numbers are in the  
3       letter, but I can say that we have authorized users  
4       in all 50 states and territories.

5                   Dr. Palestro, during his public  
6       conference call, queried about the number of retiring  
7       diplomates and whether the pipeline would more than  
8       offset the number of retired diplomates. I think all  
9       specialty boards keep track of this information. The  
10      ABNM can certainly supply it.

11                   I can tell you, just as I was looking up  
12      while listening to these proceedings, that in the  
13      past four years the ABNM has had an average number of  
14      retirees of 48 per year, which is below the average  
15      number of new diplomates for this period of time,  
16      which is 63.

17                   So we do not see any sort of attrition in  
18      the total number of diplomates, and has -- and as has  
19      been brought up by other participants in this call,  
20      there are new training pathways that are encouraging  
21      increasing numbers of young professionals to seek the  
22      training necessary to become authorized users.

23                   During this conference call, there was an  
24      interesting proposal that the limited authorized user  
25      pathway would be predicated on having an authorized

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1 nuclear pharmacist to be responsible for the nuclear  
2 safety aspects of treatment. This just wouldn't work.  
3 The authorized nuclear pharmacist would not be onsite  
4 and could not provide the level of coordination  
5 necessary of all of the personnel that is required in  
6 handling a spill of radioactive materials that do  
7 occur.

8 And the coordination of these personnel  
9 involve physicians, technologists, as well as  
10 physicists. So the authorized user responsible for  
11 the radiation safety must be actually physically  
12 present in the department.

13 Then the other question came out about  
14 de minimis standards for the duration of training,  
15 and let's say all education met de minimis standards  
16 in terms of duration, which is a practical necessity.

17 In terms of radiation safety,  
18 particularly with skills, these are unexpected events  
19 that are relatively uncommon. The best training  
20 occurs on -- when an event like this happens and the  
21 training is present. The likelihood of acquiring  
22 this training is directly proportional to the  
23 duration of training.

24 Similar events involving radioactive  
25 materials used in -- used for diagnosis occur more

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1 frequently, and though they are still uncommon. The  
2 likelihood of gaining the necessary experience to  
3 fully and effectively respond to these situations  
4 cannot be gained in a short period of time.

5 To directly answer the question of one of  
6 the committee members regarding how much time is  
7 devoted to 35.390 training, in the ACGME-accredited  
8 residency training programs that lead to  
9 certification by boards who have dean status from the  
10 NRC, the minimum training -- the minimum -- is 16  
11 months, and as has been noted earlier, up to three  
12 years.

13 And training is gaining the experience to  
14 handle spills and other unexpected events throughout  
15 their training period. It is a continuous educational  
16 process. And as a practical matter, there must be  
17 de minimis standards, and my expert opinion is that  
18 700 hours is really a minimum requirement to obtain  
19 the experience necessary for competency.

20 Thank you.

21 CHAIR PALESTRO: Thank you. Other  
22 comments?

23 OPERATOR: We show no other comments at  
24 this time. As a reminder, if you would like to make  
25 a comment, or if you have a question, please press

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1 star followed by one.

2 CHAIR PALESTRO: Ms. Holiday?

3 MS. HOLIDAY: Yes, Dr. Palestro.

4 CHAIR PALESTRO: Yes. Next, the ACMUI  
5 needs to vote on the draft report; am I correct?

6 MS. HOLIDAY: That is correct. If there  
7 are no additional comments from members of the public,  
8 you are free to go ahead and make a motion to vote on  
9 the report.

10 CHAIR PALESTRO: The report itself, am I  
11 correct, isn't that the motion and we need a second?

12 MS. HOLIDAY: Correct. And that would be  
13 the report including all of the recommendations  
14 within the report.

15 CHAIR PALESTRO: Yes. All right. So do  
16 we have a second for the subcommittee's report?

17 MS. HOLIDAY: Well, is there a motion?

18 CHAIR PALESTRO: Well, the report itself  
19 is the motion; is it not?

20 MS. HOLIDAY: No. Generally, a member on  
21 the committee --

22 CHAIR PALESTRO: I'm sorry. I  
23 misunderstood.

24 MS. HOLIDAY: That's okay.

25 CHAIR PALESTRO: All right. Can we have

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1 a motion?

2 MEMBER ENNIS: Motion to approve the  
3 report.

4 MEMBER O'HARA: Second.

5 CHAIR PALESTRO: Second?

6 MEMBER O'HARA: Yes. Second.

7 CHAIR PALESTRO: All right. Dr. Ennis  
8 made the original motion; am I correct?

9 MEMBER ENNIS: Yes.

10 CHAIR PALESTRO: And who made the second,  
11 for the transcriptionist?

12 MEMBER O'HARA: Michael O'Hara.

13 CHAIR PALESTRO: Dr. O'Hara seconded.

14 Any discussion?

15 VICE CHAIR METTER: This is Darlene. I  
16 would like to -- Sophie, you had made a comment about  
17 developing the curriculum. Would that need to be in  
18 this report?

19 MS. HOLIDAY: If that is a recommendation  
20 from the Subcommittee, at this time, you would need  
21 to make a vote on that before the overall vote on the  
22 report. So my suggestion would be that a motion be  
23 put forward for the subcommittee report to be amended  
24 to include language reflecting that the subcommittee  
25 recommends or maintains its recommendation that it

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1 does not support a limited scope AU pathway. However,  
2 should the NRC move forward with developing such a  
3 pathway, that the NRC staff and the ACMUI work  
4 together to develop the core topics in the curriculum.  
5 Is that the recommendation?

6 VICE CHAIR METTER: That is exactly the  
7 recommendation. I move that that be introduced as  
8 the motion, to make that recommendation.

9 CHAIR PALESTRO: Do we have a second?

10 MEMBER SCHLEIPMAN: Robert Schleipman. I  
11 second that.

12 CHAIR PALESTRO: All right. All in favor?

13 (Chorus of ayes.)

14 CHAIR PALESTRO: Any opposed?

15 All right. Now we will go back and vote  
16 on the original motion.

17 MS. HOLIDAY: Dr. Palestro --

18 CHAIR PALESTRO: Yes.

19 MS. HOLIDAY: -- if I may, were there any  
20 abstentions?

21 CHAIR PALESTRO: I'm sorry. Yes. Any  
22 abstentions?

23 MS. HOLIDAY: Thank you.

24 CHAIR PALESTRO: Now we will go back to  
25 vote on the original motion. All in favor?

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1 (Chorus of ayes.)

2 CHAIR PALESTRO: Any opposed? I am going  
3 to oppose it for the reasons that I expressed  
4 initially. My concerns -- and I do thank Dr. Segall  
5 for his input on retirees. That was certainly very  
6 helpful. But before I am comfortable with saying  
7 there is no shortage, or there is no potential for a  
8 shortage, I would like to see more substantive data.

9 And, again, my biggest concern is the  
10 long lag time between initiation and completion of  
11 rules changes, and so forth. So I am going to go on  
12 the record as being opposed.

13 Any abstentions? All right.

14 MS. HOLIDAY: Okay. Thank you. So I  
15 have that the motion passes to approve the report  
16 with the amendment regarding the development of the  
17 curriculum between the NRC staff and the ACMUI, and  
18 that the ACMUI approved the report with one opposing  
19 vote.

20 VICE CHAIR METTER: Correct.

21 CHAIR PALESTRO: Correct.

22 MS. HOLIDAY: Okay.

23 CHAIR PALESTRO: We can adjourn the  
24 meeting, Ms. Holiday?

25 MS. HOLIDAY: That is correct. So, at

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1 this time, I would like to thank all of the ACMUI  
2 members, particularly the ACMUI Subcommittee members,  
3 for developing this subcommittee report and for  
4 discussing it today.

5 Thank you to the Committee members, NRC  
6 staff, and members of the public who have participated  
7 and provided thoughtful comment and feedback during  
8 this time.

9 As I said earlier in this meeting, the  
10 letter that was submitted to the NRC staff from UPPI  
11 will be appended to the meeting transcript as part of  
12 the official record.

13 If you joined this call after the call  
14 started, please make sure that you send an email to  
15 Kellee Jamerson, K-E-L-L-E-E dot J-A-M-E-R-S-O-N at  
16 nrc.gov, and myself, Sophie Holiday, S-O-P-H-I-E dot  
17 H-O-L-I-D-A-Y at nrc.gov, so that we may  
18 appropriately capture you as a participant of the  
19 meeting.

20 With that being said, thank you for your  
21 time, and the meeting is adjourned.

22 CHAIR PALESTRO: Thank you.

23 (Whereupon, the above-entitled matter  
24 went off the record at 11:49 a.m.)

25



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## Advisory Committee on the Medical Uses of Isotopes

Submitted Feb. 20, 2019

Comments to the Tuesday, February 26, 2019 ACMUI teleconference to discuss “Training and Experience (T&E) Draft Subcommittee Report regarding the requirements for authorized users under Title 10 Code of Federal Regulations (10 CFR) 35.300, ‘Use of unsealed byproduct material for which a written directive is required.’”

As the author of the “novel ‘team approach’” concept to enable an Authorized Nuclear Pharmacist (ANP) partnership highlighted in the ACMUI’s Feb. 7 Draft Report,<sup>1</sup> UPPI would like to address the “concerns” raised by the ACMUI about this proposal, and clear up some of the misconceptions contained in the ACMUI’s summary of the proposal.

To reiterate, UPPI is proposing that an Authorized Nuclear Pharmacist (ANP), who has the same 700 hours of training as an Authorized User (AU), be permitted to “team” with a limited trained AU. The AU would cover the patient safety aspects of the treatment, and the ANP would handle the nuclear safety aspects of the treatment.

This would enable ANPs to extend services and availability of treatment physically well beyond the current locations of AUs, but would also more than double the number of individuals that are authorized to provide these treatments, significantly expanding patient availability without sacrificing safety.

We sincerely appreciate the ACMUI urging the NRC to give this proposal adequate consideration. Unfortunately, however, the ACMUI’s “consideration” of this proposal falls far short of that goal. Therefore, because UPPI has worked extensively with the NRC staff during their consideration of the T&E standards, including providing extensive testimony, comments and descriptions of the proposal, how it would work, and what the benefits are, we urge the ACMUI to give this proposal the consideration it deserves instead of the fleeting consideration and injudicious dismissal, and urge the NRC to conduct their own examination of this proposal if that does not occur without regards to the ACMUI’s comments.

---

<sup>1</sup> <https://www.nrc.gov/docs/ML1903/ML19039A113.pdf>

This concept has the benefit that it advances patient safety and treatment availability, does not change current standards, does not require additional training, and meets all of the patient and radiation safety requirements mandated by the NRC. There may be some down-sides to this approach, but we do not think that the ACMUI draft report's objections and concerns should derail this opportunity because it does not raise any substantive concerns or objections.

Specifically, the ACMUI Report states:

- 1) "A fragmented approach to a therapeutic procedure can have the unintended consequence of making things worse." The Report cites to an American Psychological Association (APA) website for "The Standards for Educational and Psychological Testing," <https://www.apa.org/science/programs/testing/standards>, as the sole basis for this claim.

We assume that this is the incorrect cite, but regardless, this unsupported statement should clearly not be the sole basis for a policy determination of this magnitude.

Instead, UPPI would argue that any potential adverse consequences should be considered and addressed, as opposed to assuming that there will be any unintended consequences that cannot be overcome.

Specifically, it appears that the ACMUI cannot articulate ANY substantive objections to this proposal, and so rather than seek to critique it by using substantive arguments that can be evaluated on the merits, the ACMUI is simply relying on some vague notion of unknown concerns as their basis for seeking to dismiss this proposal. This is not the type of "reasoning" that the NRC should rely upon in determining whether this proposal has merit or not.

In other words, if ACMUI does have concerns about unintended consequences, the burden should be on the ACMUI to clearly articulate the concerns that they have so that the NRC can make an informed decision as to whether or not to move forward on this proposal, instead of an arbitrary dismissal based on a cliché and incorrect citation.

- 2) "If an onsite ANP is available, a fully trained physician AU is also likely available."

Even if true, this statement clearly is not an objection. Instead, it implies that there is no need to change the rules because a physician could handle the cases. That ignores the fact that a physician can only handle a limited number of cases at one time, so even if true, the UPPI proposal would still expand treatment opportunities for patients by making more treatment options available.



This statement also implies that a physician AU would be better able to provide services to the patient than the “teaming” approach suggested by UPPI, though there is no evidence to support that implication.

However, that statement that a physician would “likely” be available fundamentally misunderstands the way that ANPs operate. While some larger providers may have their own NPs and facilities on site, for the most part ANPs operate in a central location and deliver radiopharmaceuticals to off-site locations.

For example, one of UPPI’s members operates a central nuclear pharmacy in Tampa, Florida, and delivers radiopharmaceuticals up and down the Florida coast, from Tallahassee to Fort Myers. This means that every hospital and imaging center could have access to radiopharmaceuticals if there is a partially trained AU available. We have not seen evidence that AUs would be willing to travel to relatively remote areas on a regular basis outside of a few select instances.<sup>2</sup>

Further, the ACMUI has not articulated any objections or concerns to having ANPs provide the nuclear safety coverage demanded by the NRC.

In other words, the second concern raised by the ACMUI is also an easily debunked cliché.

3) “There are also far fewer ANPs than AUs”

Even if true, this does not make any sort of case for why this proposal should not move forward. If part of the NRC’s goal is to consider how to expand access to these services without sacrificing safety, this proposal satisfies that need, even if there were only a handful of ANPs.

However, there are approximately 1200 ANPs, and so enabling them to provide these services would double patient access.

4) “ANPs are generally concentrated (as are AUs) in urban and not rural areas.”

This is the first acknowledgement by the ACMUI that we have seen that there is an uneven geographic distribution of AUs. (The geographic distribution of AUs does not appear to be part of the consideration by the ACMUI as to whether additional AUs are necessary, though it seems to us that geographic distribution should be a major factor in that determination.)

However, even if this statement is accurate, doubling the number of providers, even if all located in the same area, will increase patient access. Therefore, this again is NOT an argument

---

<sup>2</sup> This appears to be part of the evaluation that the NRC staff is undertaking to determine if there is a shortage of AUs, so perhaps the ACMUI could wait for that evaluation to be completed before making such unsubstantiated judgements.

against this proposal. Specifically, if the ACMUI is correct and that there is not a *shortage* of AUs, that does not mean that adding more AUs would be problematic. Instead, such an increase would increase patient access without harming patient safety or increasing risk. This could also lower patient costs, which should not be a consideration that impacts the NRC, and nor should those issues impact the decision of an unbiased Advisory Committee like the ACMUI which is tasked with advising the NRC on “policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy.”<sup>3</sup>

However, as discussed above, this statement is not only incorrect, but represents a fundamental misunderstanding of how the centrally located nuclear pharmacy operates and delivers products across rural and urban areas.

First, as you can see from the enclosed map,<sup>4</sup> the distribution of nuclear pharmacies includes both major urban *and* rural areas. Therefore, extending this plan to ANPs will extend coverage beyond urban centers.

Second, as discussed above, this ignores the fundamental benefit of nuclear pharmacies in this respect in that they are not tied to a particular location, but can deliver nuclear materials to locations that are up to three hours away. That means that the ANP could travel to provide these services, significantly expanding the access of these services without sacrificing safety.

- 5) “The safe and effective administration of radionuclide therapy is best accomplished by a comprehensively trained AU who is responsible for the entire therapeutic procedure, and who has thorough knowledge and understanding of the therapy to include the various factors and potential toxicities and serious hazards that can occur to the patient, personnel and the public.”

This appears to be the only remotely substantive concern raised by the ACMUI about this proposal, but again the concern is based on a failure to study and understand the roles of each provider in the process and the overall training provided to an ANP.

Let’s unpack this:

- “A comprehensively trained AU”

An AU under 35.59 receives the same training and requirements as a Authorized Nuclear Pharmacist under 35.55(a) – the same 700 hours of training in the same issues. Of nuclear

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<sup>3</sup> <https://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html>

<sup>4</sup> <https://nuclear.pharmacy.purdue.edu/nukeinus>

safety, patient safety, etc. UPPI is not suggesting that the ACMUI consider reducing those vigorous standards in this case.

- “who is responsible for the entire therapeutic procedure”

UPPI is not suggesting that the ANP perform the specific procedure – that would be performed by the accompanying limited trained physician who would provide the entire therapeutic procedure to the patient.

- “who has thorough knowledge and understanding of the therapy to include the various factors and potential toxicities and serious hazards that can occur to the patient, personnel and the public.”

The limited trained AU physician has detailed knowledge and understanding of the therapy, including the possible problems and side effects that may arise. The ANP would provide the overall understanding of the larger risks that could occur.

While the ACMUI implies that sharing this responsibility is somehow risky, there has clearly been no investigation of this question, which is what we are seeking by raising this issue. We do not believe that there is a risk, and that if there is a risk that it is minimized, but we would like the ACMUI to more fully articulate what these risks and concerns are so that we can determine if this is a viable proposal. Simply stating that there are risks without undertaking even an elementary exploration or explanation of what those risks are, how they might be addressed or minimized, and whether the potential risks outweigh the benefits strikes us as an arbitrary decision that does not meet the requirements of the NRC in assessing the use of radiotherapies.

Further, this concern by the ACMUI ignores the part of the UPPI suggestion that this application *only* apply to alpha and beta therapies. We are not suggesting that higher risk materials be used. That limitation should factor into the ACMUI’s analysis, as well.

Any therapy could be called high risk. We think some therapies do not carry the same risk and could be handled by limited trained AU.

Finally, a note on the need for additional AUs.

First, it is clear that the ACMUI subcommittee did not undertake any sort of detailed analysis of the need for additional AUs. For example, with regards to the geographic disparity in the distribution of AUs, the ACMUI acknowledges that AUs “are generally concentrated in urban and not rural areas.” That determination in and of itself should trigger a more detailed investigation as to whether that geographic disparity has any adverse impact on patient care, as the Comment from the National Rural Healthcare Association suggests. However, the

geographic distribution is not even considered in dismissing whether there may be a shortage of AUs.

This lack of investigation ignores the concerns of ACMUI Member Wiel<sup>5</sup>, who has suggested that just because there are adequate numbers does not mean that they are evenly distributed:

“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... The geographic distribution of those Authorized Users has to be taken into account... it's a fallacy to say that every patient in the United States has access to an Authorized User.”

This also shortchanges and ignores the examination of that very question by the NRC staff, who in December of 2018 indicated that they were going to carefully consider this question as part of their inquiry into this matter.<sup>6</sup>

This summary dismissal of the geographic distribution of AUs also ignores a Freedom of Information Act (FOIA) request submitted by UPPI to seek to ascertain whether there is a shortage of AUs based on geographic distribution.<sup>7</sup>

Further, even if the geographic distribution was not a factor, the ACMUI ignores the coming flood of new and exciting radionuclear therapies that are in the development process that could significantly increase the demand for these procedures.

In conclusion, we urge the ACMUI to more fully consider the opportunities that the UPPI proposal creates to expand patient care and make these therapies far more widely available. The cursory and arbitrary dismissal of the UPPI proposal contained in the draft report does not provide adequate consideration for the Commission to make a decision as to whether or not to move forward, and we urge the ACMUI to provide more substantive advice for the Commission to consider. The ACMUI acknowledges that this is a proposal that is “novel” and “should be carefully reviewed.” The summary dismissal of this proposal with no detailed analysis should not be considered to be a “careful review.”

Thank you very much for your consideration, and we are available to provide any additional comments or clarifications desired by the ACMUI.

Sincerely,

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<sup>5</sup> <https://www.nrc.gov/docs/ML1808/ML18082A687.pdf> (Emphasis added)

<sup>6</sup> <https://www.nrc.gov/docs/ML1900/ML19002A566.pdf>, P. 19 (Emphasis added).

<sup>7</sup> Id, P. 36.

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John Witkowski,

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