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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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TUESDAY

FEBRUARY 26, 2019

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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

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

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

IAN IRVIN, OGC/GCLR/RMR

DONNA JANDA, R-I/DNMS/MLAB

SARAH LOPAS, NMSS/MSST/MSEB

KATHY MODES, NMSS/MSST/ASPB

JANICE NGUYEN, R-I/DNMS/MLAB

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

BRIAN ERASMUS, BTG

LYNNE A. FAIROBENT, *unaffiliated*

SHERRIE FLAHERTY, Minnesota Radioactive Materials Unit

MIKE FULLER, Virginia Department of Health (VDH)

SANDY GABRIEL, *unaffiliated*

WENDY GALBRAITH, University of Oklahoma Health Sciences Center

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

ASHLEY MISHOE, University of California, San Francisco

MARY MOORE, VDH

JOSHUA MYERS, PDEP

CHRISTOPHER OTT, PDEP

BRANDON PATERSON, *unaffiliated*

RICHARD PEROS, New Jersey Department of Environmental Protection (NJDEP)

MICHAEL PETERS, American College of Radiology (ACR)

CARMINE PLOTT, Novant Health

ARIA RAZMARIA, M.D., UCLA Medical Center

GLORIA ROMANELLI, ACR

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

BEN SEIBER, PDEP

BETH SHELTON, Tennessee Department of Environment and Conservation

JEFFRY SIEGEL, Ph.D., Nuclear Physics Enterprises

DANIEL STROHMEYER, *unaffiliated*

CINDY TOMLINSON, American Society of Radiation Oncology (ASTRO)

MICHAEL UJHELYI, BTG

PAUL WALLNER, M.D., 21st Century Oncology, Inc.

MATTHEW WILLIAMSON, Memorial Sloan Kettering Cancer Center

MELONIE WISSING, VDH

JOHN WITKOWSKI, United Pharmacy Partners (UPPI)

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

(10:15 a.m.)

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

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

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

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

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

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

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

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

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

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

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

CHAIR PALESTRO: Present.

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

VICE CHAIR METTER: Present.

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

MEMBER DILSIZIAN: Present.

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

MEMBER ENNIS: Here.

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

MEMBER GREEN: Present.

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

MEMBER MARTIN: Present.

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

MEMBER O'HARA: Present.

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

MEMBER OUHIB: Present.

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

MEMBER SCHLEIPMAN: Present.

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

MEMBER SHEETZ: Present.

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

MEMBER SHOBER: Present.

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

MEMBER WEIL: Present.

MR. EINBERG: Okay. We have a quorum.

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

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

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

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

MS. HOUSEMAN: Esther Houseman, OGC.

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

MR. IRVIN: Ian Irvin, OGC.

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

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

MS. AYOADE: Maryann Ayoade, Medical Radiation Safety Team.

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

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

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

Maryann, have you been able to get that going?

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

MR. EINBERG: Okay. Thank you so much.

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

MR. EINBERG: And you can access the webinar by going to www.gotowebinar.com and searching for meeting ID 657537587. Once again, that's 657537587.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

year.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

minimum requirement for all authorized users involved in radionuclide therapy.

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

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

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

So the Subcommittee position and four

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

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

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

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

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

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

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

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

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

be for a future subcommittee investigation.

MEMBER DILSIZIAN: Thank you.

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

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

CHAIR PALESTRO: Go ahead, Mr. Sheetz.

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

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

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

surveys and waste disposal?

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

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

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

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

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

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

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

So I believe the core program on

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

Thank you.

CHAIR PALESTRO: Thank you, Mr. Sheetz.

Any other comments from members of the Subcommittee? Ron?

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

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

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

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

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

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

Thank you.

CHAIR PALESTRO: Thank you, Dr. Ennis.

Any other comments from members of the subcommittee?

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

CHAIR PALESTRO: Go ahead, Ms. Weil.

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

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

Thank you.

CHAIR PALESTRO: Thank you, Ms. Weil.

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

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

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

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

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

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

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

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

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

team approach? Thank you very much.

CHAIR PALESTRO: Thank you, Ms. Martin.

Any other comments from the ACMUI?

MEMBER GREEN: Dr. Palestro?

CHAIR PALESTRO: Yes.

MEMBER GREEN: This is Richard Green.

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

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

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

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

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

PARTICIPANT: Absolutely.

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

PARTICIPANT: Yes, it was unanimous from our discussions.

VICE CHAIR METTER: Thank you.

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

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

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

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

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

MEMBER GREEN: Yeah. I thought the charter --

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

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

And I -- I think I am seeing a resounding

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

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

MEMBER GREEN: Thank you.

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

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

VICE CHAIR METTER: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

MEMBER DILSIZIAN: Yes.

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

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

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

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

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

VICE CHAIR METTER: I would defer to you.

CHAIR PALESTRO: Thank you, Mr. Metter.

VICE CHAIR METTER: Anytime.

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

MEMBER GREEN: Dr. Palestro?

CHAIR PALESTRO: Yes.

MEMBER GREEN: This is Mr. Green again. So with the recommendation not at this time to do a

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

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

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

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

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

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

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

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

CHAIR PALESTRO: Thank you, Dr. Metter.

Any other comments from the ACMUI?

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

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

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

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

Any other comments/questions from the ACMUI?

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

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

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

CHAIR PALESTRO: Thank you, Mr. Ouhib.

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

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

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

are available for the safe use of the radionuclides.

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

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

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

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

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

unsealed source radiopharmaceutical therapies?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIR PALESTRO: Yes, Dr. Ennis.

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

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

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

CHAIR PALESTRO: Thank you, Dr. Ennis.

Any other comments from the ACMUI?

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

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

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

Thank you.

CHAIR PALESTRO: Thank you, Mr. Green.

Any other comments from the ACMUI?

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

CHAIR PALESTRO: Thank you, Mr. Ouhib.

Any other comments from the ACMUI?

MEMBER SHEETZ: This is Mike Sheetz.

CHAIR PALESTRO: Yes, Mr. Sheetz.

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

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

Thank you.

CHAIR PALESTRO: Thank you, Mr. Sheetz.

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

MS. AYOADE: Dr. Palestro?

CHAIR PALESTRO: Yes.

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

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

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

CHAIR PALESTRO: Correct.

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

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

CHAIR PALESTRO: Okay. Thank you.

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

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

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

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

OPERATOR: Sure.

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

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

that curriculum.

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

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

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

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

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

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

recommend the limited scope AU pathway.

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

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

VICE CHAIR METTER: Yes.

MS. HOLIDAY: Okay. Thank you.

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

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

MEMBER DILSIZIAN: Okay.

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

from the public?

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

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

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

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

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

That's the end of my comment.

CHAIR PALESTRO: Thank you, Dr. Marcus.

Other comments from the public?

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

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

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

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

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

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

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

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

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

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

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

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

Thank you for this opportunity.

CHAIR PALESTRO: Thank you. Other comments?

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

DR. GREENSPAN: Thank you. Can you hear

me?

CHAIR PALESTRO: Yes.

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

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

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

American Association of Physicists in Medicine.

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

Thank you very much.

CHAIR PALESTRO: Thank you. Other comments?

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

DR. RAZMARIA: Hello? Can you hear me?

CHAIR PALESTRO: Yes.

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

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

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

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

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

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

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

Thank you for your attention.

CHAIR PALESTRO: Thank you. Other comments?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you.

CHAIR PALESTRO: Thank you. Other comments?

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

star followed by one.

CHAIR PALESTRO: Ms. Holiday?

MS. HOLIDAY: Yes, Dr. Palestro.

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

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

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

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

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

MS. HOLIDAY: Well, is there a motion?

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

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

CHAIR PALESTRO: I'm sorry. I misunderstood.

MS. HOLIDAY: That's okay.

CHAIR PALESTRO: All right. Can we have

a motion?

MEMBER ENNIS: Motion to approve the report.

MEMBER O'HARA: Second.

CHAIR PALESTRO: Second?

MEMBER O'HARA: Yes. Second.

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

MEMBER ENNIS: Yes.

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

MEMBER O'HARA: Michael O'Hara.

CHAIR PALESTRO: Dr. O'Hara seconded.

Any discussion?

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

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

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

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

CHAIR PALESTRO: Do we have a second?

MEMBER SCHLEIPMAN: Robert Schleipman. I second that.

CHAIR PALESTRO: All right. All in favor?

(Chorus of ayes.)

CHAIR PALESTRO: Any opposed?

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

MS. HOLIDAY: Dr. Palestro --

CHAIR PALESTRO: Yes.

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

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

MS. HOLIDAY: Thank you.

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

(Chorus of ayes.)

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

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

Any abstentions? All right.

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

VICE CHAIR METTER: Correct.

CHAIR PALESTRO: Correct.

MS. HOLIDAY: Okay.

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

MS. HOLIDAY: That is correct. So, at

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

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

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

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

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

CHAIR PALESTRO: Thank you.

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

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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,[1] 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.

[1] 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 radiopharmeudicals up and down the Florida coast, from Tallahassee to Fort Myers. This means that every hospital and imaging center could have access to radiophariceudicals 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.[2]

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

[2] 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." [3]

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,[4] 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

[3] https://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html

[4] https://nuclear.pharmacy.purdue.edu/nukeinus

safety, patent 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[5], 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.[6]

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.[7]

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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[5] https://www.nrc.gov/docs/ML1808/ML18082A687.pdf (Emphasis added)
[6] https://www.nrc.gov/docs/ML1900/ML19002A566.pdf, P. 19 (Emphasis added).
[7] Id, P. 36.

/S/

John Witkowski,

President, UPPI