UNITED STATES

NUCLEAR REGULATORY COMMISSION

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MEETING WITH THE ADVISORY COMMITTEE ON THE

MEDICAL USES OF ISOTOPES

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THURSDAY,

APRIL 27, 2017

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ROCKVILLE, MARYLAND

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The Commission met in the Commissioners' Hearing Room at the Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, at 10:00 a.m., Kristine L. Svinicki, Chairman, presiding.

COMMISSION MEMBERS:

KRISTINE L. SVINICKI, Chairman

STEPHEN G. BURNS, Commissioner

JEFF BARAN, Commissioner

ALSO PRESENT:

ANNETTE VIETTI-COOK, Secretary of the Commission

MARGARET DOANE, General Counsel

AMCUI PANEL:

PHILIP ALDERSON, M.D., ACMUI Chair

SUE LANGHORST, Ph.D., ACMUI Radiation Safety Officer

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

JOHN SUH, M.D., ACMUI Radiation Oncologist

LAURA WEIL, ACMUI Patients' Rights Advocate

10:01 a.m.

P R O C E E D I N G S

CHAIRMAN SVINICKI: Well, good morning everyone.

The Commission convenes this morning to have a meeting that I know personally, as a Member of the Commission, I always derive great value from the meeting that we have with the Advisory Committee on the Medical Uses of Isotopes.

And, today, we will hear views on a number of medical related topics from Members of the Committee, so I welcome everyone here today.

I would as if my colleagues have any opening comments?

(NO AUDIBLE RESPONSE)

CHAIRMAN SVINICKI: Okay.

So, we will hear one panel of presentations today, again, Members of the Advisory Committee.

We will hear from Dr. Philip Alderson. Also, we will hear from Dr. Christopher Palestro. We'll hear from Ms. Laura Weil, Dr. Susan Langhorst and Dr. John Suh.

So, I would ask that, after you present, you could just hand off to the next panelist.

So, thank you very much and we will begin with Dr. Alderson.

DR. ALDERSON: Chairman Svinicki, Commissioners Baran, Burns, it's a pleasure for the ACMUI to be here today and to talk to you about the important topics that we've been engaged in recently.

The topics that have been selected for this discussion are here

because we think that each of them is an important issue for patient and public safety.

Next slide, please?

So, I will be giving an overview of these activities and most of the things that I mention to you in the next few minutes will be discussed in more detail by some of the speakers who follow me.

These will include things such as the purpose of the ACMUI, the membership, the topics we've been working on in the past and that we'll work on in the future.

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To review, the purpose of the ACMUI is to advise the NRC staff and, thus, you, the Commission, on policy and medical uses of radionuclides and to provide technical assistance and serve as consultants.

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This slide shows the membership positions on the ACMUI. When fully staffed, 13, but we are not fully staffed at this time. And, we have both a nuclear pharmacist and a medical physicist who have been in queue for some time now.

We, unfortunately, lost one of our members, the state organization representative, Mr. Frank Costello recently. Frank passed away.

We briefly commemorated his service at our meeting yesterday, but we will do something more formal on his behalf in the fall.

So, that's another position that needs to be filled and, next September, our radiation safety officer will end her term.

So, we are looking forward to being able to repopulate the

Committee.

Next slide, please?

The topics addressed in the last year include the training and experience requirements for alpha and beta emitters. And, in fact, for all modalities. This is now a standing committee of the ACMUI. So, we will consistently hear about issues related to training and experience. And, Dr. Palestro will describe these in more detail in a few moments.

Another topic is the impact of medical event reporting in the people in the field and the creation of a true safety culture within the ACMUI and user community.

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The clarification of what is a patient intervention and how should that relate to reporting requirements?

The licensing of those who would be involved in the placement of radioactive seeds for localization.

The licensing guidance for the germanium/gallium-68 generator which is used in the preparation of an important FDA approved radiopharmaceutical that tracks neuroendocrine tumors.

Next slide, please?

Additional topics include the impact of Category 3 sources in medical practice and what security measures need to be considered for those sources and how that would impact medical practice. You will hear more about that in one of the subsequent reports.

And, progress and improving ACMUI internal and external communications.

I would like to specifically commend the Agency on the fact that I think they have worked hard, we have worked hard on improving our internal and external communications. And, I'll say just a bit more about that on my last slide.

Next slide, please?

Current ACMUI topics include continuing discussion, as I mentioned a moment ago, of the training and experience for authorized users in all modalities, medical event reporting for all modalities, review of medical events and the issue of patient release.

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Additional current topics, again, radioactive seed localization, licensing guidance, the specific decommissioning funding plan requirements for the use of the generator that I mentioned a moment ago and the licensing guidance for who should be present at the new Icon Leksell Gamma Knife.

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And, finally, then, again, a current topic, ways to enhance communications.

So, as I mentioned a moment ago, I commend the NRC staff and the Members of the ACMUI for working very hard on this particular issue.

We have received guidance in the details of process so that we understand that process more carefully. We are able to discuss it openly at our meetings.

We've also reached out to the user community in what we eventually decided was the most cost-effective way, which is that our Members, in fact, go regularly to the meetings of their own subspecialty groups.

And so, they have reached out and have scheduled actual sessions, training, discussion, Q&A sessions at these national meetings that relate to the NRC.

So, just -- there are at least seven of these now that have been scheduled in the last year.

And so, coming up, we'll be represented the NRC and the ACMUI will be represented at the American College of Radiology, the Society of Nuclear Medicine, ASTRO, which is the Radiation Oncology Society, the American Pharmacologic Association, and others.

So, we are really reaching out and working hard to communicate with the user community on behalf of the NRC.

Next slide, please?

We currently have a number of these issues under discussion. And, as new issues arise and they may include emerging new technologies, we will address and provide advice on those issues that are relevant to the safe handling of radioactive sources.

The next presentation will be by Dr. Palestro.

DR. PALESTRO: Thank you, Dr. Alderson.

Over the next few minutes, I'm grateful for the opportunity to be able to update the Commission on the activities of the Standing Subcommittee on Training and Experience.

In 2016, the ACMUI created a Standing Subcommittee on Training and Experience.

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The charge of this Committee was to periodically review training

and experience requirements currently in effect for all modalities and to make recommendations for changes as needed.

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The Standing Subcommittee is in the process of reviewing training and experience requirements currently affect for the uses of unsealed byproduct materials, including 10 CFR 35.100, 35.200, 35.300 and 35.1000 as well as sealed byproduct materials, 35.400, 35.500, 35.600 and 35.1000.

Next slide, please?

The issues that the Committee needs to address and is in the process of addressing is the periodic review, the training and experience requirements, competency and, of course, patient access.

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In terms of periodic review, what is a reasonable time interval between reviews? It's been 15 years and, perhaps, a bit longer since the training and experience requirements were reviewed and modified.

And, that simply is too long a time interval. Even more so today with the ever-increasing rapid new developments.

One year, on the other hand, is simply impractical.

So, the Subcommittee has determined that five years is a reasonable, practical and achievable interval to review the various training and experience requirements.

That, however, doesn't preclude us from accelerating that interval if conditions warrant.

For example, the introduction of a new procedure, an increase in the number of medical events or radiation safety events or perhaps some other

factor that might trigger an accelerated review.

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In beginning our review, it became clear to us that we really need to develop a template to review these training and experience requirements.

And, the reason for this are twofold. Number one, so that we have consistency as we go through the requirements.

We understand or we develop a classification for these requirements and methods of evaluation.

But, equally important for the future, because, as you know, the Members of the ACMUI rotate on and off the Committee so that, as we who are working with this now are gone from the Committee, those our successors, those who'll be here in the future understand the rationale behind our actions.

They may or they may not agree with what we recommended and what we did, but nevertheless, they'll understand why we did it.

So, this template is as follows, in terms of training and experience requirements for 35-whatever part.

Next slide, please? Previous slide, I'm sorry, thank you.

In terms of classification, these requirements can be classified as appropriate, as inappropriate or perhaps even obsolete.

If, for example, there are no authorized users, no authorized users, the procedures are no longer performed.

But, to arrive at that classification, we need to develop some sort of systematic evaluation. And, we are looking at medical events and radiation safety events and, of course, patient access.

Next slide, please?

In terms of medical and radiation safety events, we are looking at numbers and trends. Are they stable? Are they increasing? Are they decreasing?

And, particularly when there are large numbers of medical and/or radiation safety events and the trends of these events are increasing, it requires more than just recognizing that. It requires an investigation and an explanation.

What's the cause of this increase in number? Is it the procedure? Is the introduction of a new procedure or has something changed in a procedure that's already established?

It also might be due to competency. Is there a deficiency in a competency structure? Again, has something changed that requires additions to what constitutes competency? It can also be a combination of these factors.

A word about competency -- next slide, please?

The general definition of competency is that it is the ability to do something, to perform a task, especially when measured against a standard.

The medical definition of competency is that it is a principle of professional practice identifying the ability of a provider to consistently administer safe, reliable care.

Next slide, please?

Having defined competency, the next step is to try to determine how to -- or try to determine how to establish competency of an individual.

In the majority of cases, this is done by virtue of the fact that individuals become authorized users, having obtained certification by one or

more Boards, such as the American Board of Nuclear Medicine, the American Board of Radiology, that have been granted Dean status by the Nuclear Regulatory Commission.

What about alternative pathways? Well, certainly a question comes up, should there be an alternative pathway? And, that's an issue that certainly needs to be addressed. But, for the moment, assuming that there are alternative pathways, what is the best structure? How should they be structured?

One potential way is to use didactics with an examination perhaps and hands on experience with preceptor certification. Which is analogous or similar to what's available now in which we have prescribed components of the educational process along with prescribed numbers of hours.

An alternative, somewhat novel, and some might say radical approach would be to do away with hours. Simply have a list of components that are necessary for an individual to master to become an authorized user and allow that individual or those individuals to take a practical examination administered by an independent examining committee.

And, by a practical examination, it certainly could have a written component but perhaps, more importantly, take place with simulated scenarios, medical events, radiation safety events that might provide a more comprehensive review and estimate of the individual’s competency.

Next slide, please?

Having said that, however, it's important that we keep in mind, and this is an issue that has come up in the past, patient access.

So, we need to remember or we need to look at the question of,

do current proposed regulations limit patient access to procedures?

We also have to balance that with radiation safety. So, do those current or proposed regulations provide adequate protection from unintended radiation exposure?

And, finally, are the pathways for obtaining authorized user status accessible and reasonable?

Next slide, please?

The Subcommittee recognizes the keen interest in 10 CFR 35.300. However, we also recognize that the charge of the Subcommittee -- with the responsibilities that the Subcommittee has been charged with are quite extensive, complicated and require a slow, methodical approach.

So, rather than attempting to dive in head first, as it were, Subcommittee chose to look at a much narrower category for our first go round, and that is 10 CFR 35.190, training for uptake, dilution, and excretion studies.

In terms of the evaluation, there have been no medical events for this category reported over the last past ten years.

Data on radiation safety events, unfortunately, was not available. And, the reason for that is that there are so few individuals who are authorized only for 35.190, that these events are incorporated into the 35.200 group.

Finally, with respect to patient access, we were unable to identify any issues, any concerns about patient access. And, based on the data available to us, we conclude that the current training and experience requirements for CFR 35.190 are appropriate.

At this point, we will then move forward to 10 CFR 35.200,

identify perhaps any shortcomings in the template, any additions, input that we get from stakeholders.

And, once we finish with 35.200, we should be ready to move on to 35.300.

Next slide, please?

It's important, and I can't emphasize enough, the importance of stakeholder input to this process.

And, there are two ways to obtain stakeholder input. One is informal and the other, of course, is formal.

The informal method is simply to solicit input on an individual basis by Members of the Subcommittee to individuals whom we know organizations with which we are familiar and ask them for their suggestions and recommendations.

So, that's certainly expedient and we've already begun to do that.

The disadvantage to that is that there's a potential for bias because I am most likely to contact individuals that I know, organizations that I'm familiar with and who probably have a viewpoint similar to my own.

On the other hand, once we move forward and it becomes clear, perhaps, that there are going to be recommendations for rule changes, then the formal process will be -- will, of course, will have to be commenced.

And, while that's a slower process, it will, of course, have the advantage of offering a broader respondent base.

Next slide?

Thank you and now, I will turn the microphone over to Ms. Laura

Weil, Patient Rights Advocate.

MS. WEIL: Thank you, Dr. Palestro.

Thank you to the Commission for allowing me to offer a few observations from a patient advocacy perspective on the issue that Dr. Palestro has been discussing.

I find it useful to use the lens of clinical ethics when trying to evaluate the impact of Nuclear Regulatory Commission regulation of the medical uses of isotopes.

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And, these three ethical principles can be easily adopted for this use.

Beneficence requires that the effects of regulation should promote the welfare of patients and reduce harms.

Justice refers to equalizing the burdens and benefits among those affected.

And, autonomy protects patients' rights to exercise free will and personal preferences in their choice of medically appropriate treatment options.

Next slide, please?

The central purpose of regulation is to promote safety for patients, the public, and for the clinicians.

This safety test, if you will, is a way to assess the essential tension that exists in all regulatory limits.

And, it comprises these two considerations, does existing or proposed training and experience regulation adequately protect clinicians, patients and the public from harm?

Or, is the existing or proposed training and experience regulate unnecessarily restrictive such that it inhibits patients' access to necessary care?

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So, if we drill this down a little more specifically to the 700 hours required for the use of -- to become an authorized user for the use of radiopharmaceuticals, this training and experience requirement effectively limits designation as authorized user to a fairly narrow subset of clinical specialties.

And, these physicians cover these 700 hours in residency training and have been Board certified.

Is this depth of knowledge acquired in residency training for these particular clinical subspecialties necessary for the safe use of all radiopharmaceuticals?

This tension raises some additional questions. Will the highly restrictive 700 hour requirement inhibit both the use and development of new treatment modalities?

Will pharmaceutical research and development be discouraged?

Will existing treatment options be withdrawn for lack of profitability?

And, does this restriction, therefore, limit choice for some patients?

New treatment options have and will become available such as the single-dose shielded patient-ready infusions which were sent from and returned directly to the manufacturer or centralized nuclear pharmacy.

These new delivery systems may be amenable to more nimble

or less restrictive regulation.

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So, here are two examples of the extremes.

We have yttrium-90 in the form of Zevalin which is recently been discussed a fair amount which requires 700 hours of training and experience. Is that too much?

We have iodine-131 which requires 800 hours -- 80, I'm sorry, 80 hours. Is that too little?

In the case of Zevalin, the 700 hour training and experience requirement for the use of all radiopharmaceuticals is not about a barrier to access to patients in most urban and suburban areas. There is no shortage of clinicians available and authorized to administer these radiopharmaceuticals.

But, it's important to acknowledge that this condition may not hold true for all community settings, particularly where non-Hodgkin lymphoma patients often receive treatment.

Non-Hodgkin lymphoma patients often survive multiple recurrences of disease over many years and require a varied armamentarium of therapies to address each subsequent recurrence for which previously used therapies may no longer be effective.

Many of these patients are elderly, some are unable to travel, they may have very limiting insurance networks and they may be too frail to tolerate the debilitating effects of cytotoxic therapy.

To assert that all patients have access to radio-immunotherapy like Zevalin is to ignore the logistical barriers that exist, for those who are limited to receiving therapy in the rural or isolated community setting.

The 700 hour training and experience requirement effectively limits authorized users to those medical specialties that cover the requirements in residency training.

These specialists may simply not be available in the community setting and, thus, creating a real barrier to access for those patients who are unable to seek treatment in a larger medical center.

The central question here is whether or not this restriction is justifiable due to safety reasons?

That assessment rests with further evaluation by the Subcommittee, as chaired by Dr. Palestro.

In the past, let's talk about iodine-131 now. In the past, endocrinologists were singled out to be able to receive authorized user status to administer oral iodine-131 in the non-hospital or the hospital setting with a reduced number of only 80 training and experience hours.

This number of hours of training may contribute to the potential for limited knowledge on the part of authorized users, particularly with respect to the need for careful evaluation of patients' living situations and instructions for the immediate post-treatment period to limit radiation exposure to family, caregivers and the public. Is 80 hours adequate?

Again, this needs to be evaluated by the Subcommittee.

These two examples demonstrate the inevitable tension between assuring broad access to radiopharmaceuticals and ensuring their safe usage.

One-size-fits-all regulation is not amenable to the nuances of each situation. But, on the other hand, a system that allows multiple exceptions

to the general rule creates an atmosphere that fosters problems of compliance for regulators and users alike.

Continual overview, periodic overview, and adjustment of the training and experience requirements, in the context of current clinical environment is likely the only logical process that can balance the tension of regulatory constraint versus maximal access for patients and their physicians.

Thank you. I'd like to turn the microphone over to Dr. Langhorst.

DR. LANGHORST: I appreciate the opportunity to speak with you today regarding the NRC's evaluation of need to revise regulations or add processes regarding Category 3 sources.

The existing regulations and processes currently in place provide robust accountability and security for Category 3 sources, especially in regard to those in medical use.

And, thus, the changes NRC staff is evaluating will impose unnecessary regulatory burden.

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If the proposed Category 3 changes are limited to those radioactive materials currently listed in 10 CFR Part 20 Appendix E table, then the only medical use sources impacted by these changes will be those in high dose rate, remote afterloaders, also called HDRs.

The wire sources contain 74-day half-life irridium-192. The new sources are typically between 10 and 11 curies when transferred from the HDR vendor to the licensee.

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HDRs are used to provide internal radiation therapy where the HDR source is placed close to or inside the cancer tumor.

The types of cancers treated by HDRs include breast, esophagus, gynecologic, head and neck, lung, prostate, rectum and skin cancers.

These ACMUI's last receive of the annual U.S. numbers of radiation therapies indicted there were approximately 33,000 HDR therapies administered in 2010.

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Because iridium-192 has a half-life of 74 days, the HDR source must be replaced about every three months because of source decay.

One of the HDR vendors also has limitation on the number of cable runs per source. So, depending on the case load of cancer therapies for a given HDR, the iridium-192 source may need to be replaced more frequently.

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The shipments for the new and returned HDR sources occur only between the HDR vendor and their customer licensee who uses the vendor's HDR model.

In addition, the vendor arranges for a service engineer to perform the source exchange at the customer licensee's location.

This service engineer also prepares the old decayed iridium-192 source for return shipment.

The vendor is required currently by 10 CFR 30.41 to verify that their customer has a license which authorizes the receipt of an HDR source for medical use in the vendor's HDR model.

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Requiring NSTS tracking of HDR irridium-192 sources provides no improvement and source accountability or security. But, it would impose significant regulatory burden.

NRC staff estimates that there are approximately 1,100 HDR licensees and about three-quarters of these licensees have no Category 1 or Category 2 sources.

This means that NSTS tracking would be totally new to most HDR licensees.

The additional cost to the HDR vendor for NSTS tracking and for meeting the other regulatory changes NRC staff is evaluating, will be passed on to the customer licensee.

Plus, the licensee will have their own NSTS reporting cost or other security requirements and all will have unnecessary additional regulatory compliance responsibilities imposed upon them.

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An HDR licensee only possesses one to two sources per HDR unit at any given time. And the HDR vendor maintains source tracking information for its customer licensee and is actively involved in each of these source exchanges.

The HDR vendor would question a customer's license document which indicated more HDR units than the number installed or planned for installation by the HDR vendor.

What benefit would be gained by NSTS tracking of HDR sources?

The regulatory burden imposed by the changes being considered would negatively impact cancer patients' access to HDR radiation therapy.

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The HDR vendors estimate that a little more than a 1,000 of the HDR licensees are routinely replacing their iridium-192 sources or have them actively in use.

With an NSTS transaction submitted by the vendor and by the customer licensee for each source transfer, there would be more than 8,000 additional transactions a year entered into the NSTS.

There's more than 8,000 of these transactions because some licensees possess more than one HDR unit and some high use HDRs may need more frequent source exchange.

At the NRC January 31st, 2017 public meeting on this topic, it was mentioned that only 30 to 40 percent of licensees do online NSTS reporting for Category 2 and Category 1 sources.

With the proposed addition of Category 3 source tracking being done by many more new NSTS users, will there be enough NSTS support staff to input the increased reporting information in a timely manner?

And, what is the benefit in requiring license verification before every HDR source transfer when the transfers are limited to two licensees who maintain an active business relationship?

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Are the license verification system and the whole NRC web-based licensing system ready to support the addition of Category 3 source

regulatory and process changes being considered?

Based on my review of Agreement State comments submitted for NRC's request for comment on the topic, I wonder if all Agreement States will be able to fully participate in the NRC web-based licensing system?

With the addition of NSTS reporting for Category 3 sources, will it negatively impact Agreement State resources? And, will this cause delay in replacing HDR iridium-192 sources?

And, I ask, with the addition of NSTS reporting for Category 3 sources actually dilute the system's effectiveness for Category 1 and 2 source accountability?

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The International Atomic Energy Agency has defined Category 3 as those sources, if not safely managed or securely protected, could cause permanent injury to a person who handled them or were otherwise in contact with them for some hours.

It could possibly, although it is unlikely, be fatal to be close to this amount of unshielded radioactive material for a period of days to weeks.

The existing controls and reporting requirements in NRC regulations already provide robust accountability and security for the IAEA defined security risks posed by Category 3 sources.

The Category 3 Source Security and Accountability Working Group has been directed to perform a vulnerability assessment to identify changes in the threat environment since 2009 that argue in favor or against enhanced security measures for the protection of Category 3 sources and for the expansion to NSTS reporting to include Category 3 sources.

As part of the vulnerability assessment, the working group should evaluate the impact of including Category 3 sources on maintaining the enhanced security measures already in place for Category 1 and 2.

Will inclusion of Category 3 sources overwhelm programs and potentially diminish Category 1 and 2 source security?

I believe there are no safety or security benefits for including HDR Category 3 sources in the NSTS tracking or in enhanced security measures.

And, the changes being considered are not warranted when compared to the costs and the impacts the changes would have on the NRC, on Agreement States, on HDR vendors and their licensees and on patients and their physicians seeking effective cancer therapy options.

I, again, thank you for the opportunity to speak with you today, and I'll turn it over to Dr. John Suh.

DR. SUH: Thank you.

Thank you for giving me the opportunity to talk about medical event reporting for all modalities except permanent implant brachytherapy.

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I'd like to thank the various Subcommittee Members and also thank the NRC staff, especially Dr. Katie Tapp who helped with this report.

Next slide?

The Subcommittee which was formed in October of 2015 was charged with the -- to propose the appropriate criteria for medical event reporting for events other than permanent impact brachytherapy.

Permanent implant brachytherapy medical event has been

addressed previously by the ACMUI and is before the Commission as part of the Part 35 rulemaking.

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In terms of the rationale over the past 15 years, medical event reporting has not changed significantly. Given advances in nuclear medicine imaging and radiation oncology, the current definition may not be sufficient for authorized users and regulators.

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To give some perspective in terms of statistics and in terms of the number of medical events in the United States annually, it is estimated that of the -- there's 15 million diagnostic and 150,000 therapeutic procedures utilizing radioactive materials annually.

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If you look at the number of medical events that have been reported from fiscal year 2013 to fiscal year 2015, you can see that approximately 50 medical events are reported.

So, considering the number of diagnostic and therapeutic procedures performed each year annually in the United States, this number is very small.

So, any change in terms of the definition of medical event reporting would need to balance regulations versus the practice of medicine.

And also, it's important to note that medical event reporting does not equate patient harm.

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So, does the -- does this -- the number of medical events

reported, does this accurately reflect the true number of cases if the current definition may be ambiguous?

Furthermore, the current process which is perceived by some as being punitive and also engenders a sense of urgency given the requirement that the report be reported the next calendar day, and the written report given within 15 days and also the referring physician be notified within the next day lead to the desired goal of transparency, education, and adoption of best practices which will help promote safety culture?

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In terms of other guiding principles, the Subcommittee believed that the medical event reporting should allow for identification of a medical event and provide a forum to discuss how to avoid and/or reduce the likelihood of such an event.

In addition to definitions of medical event reporting need to be broad, simple, and consistent so reports are easily applicable by authorized users, evaluable by regulators, and process focused on order to eliminate any ambiguity.

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The Subcommittee believes that any proposed change should not be overly prescriptive and must not encroach on the practice of medicine.

And, whenever possible, the focus of medical event reporting should be on education and improvement rather than punitive action to foster a just culture of quality and safety.

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In terms of medical event criteria which need to be covered if

there was a change in medical event definition, it would be quite broad including high dose rate brachytherapy, Gamma Knife radiosurgery, low does rate temporary implants, various interoperative modalities and an array of radiation delivery from 2D -- 2 dimensional treatment delivery to very sophisticated stereotactic body radiotherapy, or SBRT, and also selective internal radiation therapies using yttrium-90.

The Subcommittee felt that the creation of subsections would not be beneficial and would not be in accordance to keeping the definition broad, simple, and consistent and also not practical.

If one evaluates the current definition of 35.3045, there are some clear medical event reporting, wrong drug, wrong route of administration, wrong patient, wrong mode, leaking sources, and dose variation of radiopharmaceuticals of 20 percent. That's very clear in terms of medical event reporting.

Perhaps some definitions which are less clear or ambiguous is particularly in the radiation oncology world is whether or not the current definitions of total dose delivered differs from prescribed dose by 20 percent or more and single fraction dose delivered differs from prescribed dose by 50 percent or more with the caveat that, in current radiation oncology practices, we prescribe to a volume rather than to a point.

But, as I'll discuss in the next slide, we felt that this definition should not be changed.

In addition, the intervention of a patient or human subject in which the administration of a byproduct material, irradiation from byproduct materials results or will result in unintentional permanent functional damage to

an organ or physiologic system as is termed by a physician is currently being evaluated by the ACMUI Committee.

The current definition of Part 35.2 states that treatment site means the anatomical definition of the tissue intended to receive a radiation dose as prescribed in the written directive.

And, since the written directive gives the authorized users a great deal of flexibility, this may be a potential source of ambiguity as treatment site can have different meanings to an authorized user.

One of the discussion within the Subcommittee is whether or not this definition of treatment site should be changed to a target volume or a target site.

We know through varies task groups and as well as other reports, that the definition of how an authorized user defines a target volume or a target site can vary from individual to individual.

In fact, it may actually also vary from an institution even with the same two practitioners.

So, as a result, the group felt that this should not be changed.

And, furthermore, there have been recent reports suggesting that the standardization and consistency of what constitutes a target is difficult to achieve.

So, the recommendations from the Subcommittee are that the use of permanent definition for permanent implant brachytherapy as proposed to the Commission as part of 10 CFR Part 35 rulemaking be adopted, continue to use the current 10 CFR Part 35.3045 definition for medical event reporting for all modalities except for permanent implant brachytherapy.

ACMUI is actively discussing patient intervention at this time.

We encourage major societies to issue a white paper or papers to develop consensus of what should be incorporated into a written directive from various diagnostic and therapeutic modalities.

We believe that the benefit of a white paper would help with inspection and regulations by promoting standardization and identification of medical events.

It would help assist licensees to determine if a medical event has occurred and assist institutions to develop standard operating procedures to prevent future medical events.

It is important that we continue to increase awareness and education, to promote best practices so that patients receive safe and effective treatment and diagnostic procedures from radiation.

Thank you.

CHAIRMAN SVINICKI: Thank you each for this presentations. We will begin the question and answer period with the questions of Commissioner Burns.

COMMISSIONER BURNS: Thank you, Chairman, and I want to thank members of the committee for appearing before you today and giving us an overview of the various activities.

This is an important committee in terms of its advisory function to the Commission, and it has a long history, almost 60 years, going back to the late 1950s under our predecessor agency, the Atomic Energy Commission, so I think it is -- it's in a very important function, an advisory -- an advisory function that it carries out for us, particularly as we look at the interface between radiation

safety, both from an occupational standpoint and a patient standpoint, but also assuring that the benefits -- this is one of those areas where the benefits of using therapeutic and diagnostic treatments using radioactive materials has benefits to patients, so it's important that we sort of -- you know, we look at the things from the various points of view, and that is one of the things I think this committee does a good job helping us do.

I acknowledge, as Dr. Alderson has mentioned, you have some vacancies. I appreciate your -- your recognition of Frank Costello, who I mentioned at I think a meeting we had last month or in the last two months was someone I had worked with as a young attorney here at the NRC when he was -- in terms of the Materials program, so yes, I think we all miss Frank and what he has contributed, both to your committee and -- and to this community over the years.

And so hopefully we will work on that. I take it, and my understanding is from the staff that some of the issues is the security clearance process, which even for those of us who are here and have worked -- I can remember going through a number of times, even though I had had one for 25 years or something like that, even the -- some of the upgrades or the renewals take -- take some time, but hopefully, we will sort of work through -- work through those issues.

And I think you have all touched on a number of issues that are important. I have a few questions. Maybe we will try to explore in greater depth some of them, but certainly, the -- the issue on -- on training is one that -- that has really come to the fore I think in the last year. You know, we are dealing with the issues, and really, this is another issue that in a way, you know,

particularly post-9/11 attacks, the question on source security and -- and, again, getting the right -- right balance.

I know I had the opportunity to visit Inova Fairfax Hospital last year, and, you know, spoke to me about, you know, in terms of security measures, both for the Gamma Knife, for the blood irradiators, and things like that, and again, the issue of balancing security versus balancing, you know, the need for patient access and the ability to use these things in treatments is an important one.

And then the medical events I know is -- as many know, I did a long career in that. That issue of medical event reporting has been one over the years, and, you know, I started in the Agency, we were calling misadministrations before we moved to medical terminology, but medical events, but I think Dr. Suh, you -- you touched on some important issues about, you know, clarity of reporting, purpose of reporting, and consistency of reporting, and so I think your advice to the committee on that can -- can go a long way.

Let me ask a few questions. I will start with Dr. Palestro in terms of the work that is being done in the training and experience, and I think -- I think you touched on -- talked about -- or touched on potentially two approaches. Right now, you could argue we have in the regulation, lack of better term, I will call it prescriptive approach on the 700 hours, although I guess for -- for I-131, it's the 80-hour requirement, but you talked about -- I think you described it as sort of more like a master component approach, or -- and I would call it perhaps a performance -- maybe not so much a performance-based approach, but a way of looking at what makes sense in terms of the types of treatments or the types of material that are being used.

Right -- you know, as the regulations say right now, it has, you know, identified -- you know, identified numbers. Have you all thought -- I mean, maybe very early on, and I don't mean to put you on the spot, but thought about what it might look like if there were a more variable type approach to some of the training requirements? Because obviously, we have a specific requirement in the regulation now, and, you know, it sounds like the committee thinking about is -- might be the possibility that there might be differences, but of course, one of the -- the issues you have, this is where sort of the -- the practicalities meet the regulatory process, is how would you either prescribe those or provide the flexibility? And I don't know whether the committee has thought about that at all yet. It may be premature.

DR. PALESTRO: We have looked at it briefly, but we're not far enough along to make any sort of definitive comments. One of the concerns that we have is understanding the rationale or the potential rationale for limited approval, limited use, if you will: how many limited use situations should be available?

COMMISSIONER BURNS: Yes.

DR. PALESTRO: In other words, now we have one or two categories, but do we then go and divide it into three or four or five or ten? That becomes unmanageable for everyone, so we don't have a definite answer at the present --

COMMISSIONER BURNS: Yes --

DR. PALESTRO: -- time.

COMMISSIONER BURNS: -- okay. Because in some ways, it almost becomes the exceptions swallow the rule --

DR. PALESTRO: Exactly.

COMMISSIONER BURNS: -- if you will, so I can understand that. All right, I appreciate that, and I appreciate the continued work that the subcommittee will -- will do on --

DR. PALESTRO: Thank you.

COMMISSIONER BURNS: -- will do on that. Ms. Weil, you touched on this issue as well. I might just give you the opportunity, there are other particular issues on your mind in terms of you're working on with respect -- as in effect the patients' rights advocate on the committee that are sort of at the forefront of your mind right now?

MS. WEIL: I would like to offer some support to Dr. Langhorst's position on the Category 3 sources for HDR. It will undoubtedly impact patient access to -- to a curative process. It is just going to be very cumbersome for -- for institutions to -- to comply with -- with new regulatory requirements, and they will probably simply decide not to offer this therapy.

COMMISSIONER BURNS: Yes, okay. And Dr. Langhorst, one of the things, and -- and, you know, the Commission is doing a lot in this area, you know, Commissioner Baran offered a proposal that the Commission endorsed in terms of our sort of holistic looking at some of the source security -- source security issues.

One of the things, and I think this came up in the meeting we had with the Organization of Agreement States and CRCPD, you know, that was the same meeting I was mentioning that we sort of acknowledged Frank's service, but one -- one thing I thought I heard, and I am not -- I stand to be corrected, was that a lot of the burden might be with the National Source Tracking

System, that web-based licensing might not be such a heavy lift. But, you know, I don't know if you have any perspective on that, or what the interaction at all you have had with the -- with Agreement States or the CRCPD on these kinds of issues?

DR. LANGHORST: Well, the web-based licensing system I think is an admirable thing to have, and I would love as a licensee to be able to plug into that --

COMMISSIONER BURNS: Yes.

DR. LANGHORST: -- because that would help me be able to identify currently who I am allowed to transfer --

COMMISSIONER BURNS: Yes.

DR. LANGHORST: -- radioactive material to.

COMMISSIONER BURNS: Yes.

DR. LANGHORST: My understanding is that the -- and I am getting way beyond my scope of understanding -- that the database and the systems being used aren't necessarily compatible with those being in place in certain Agreement States, and so, you know, there has to be --

COMMISSIONER BURNS: Okay.

DR. LANGHORST: -- a workaround to share that licensing information and so on. But what the web-based licensing system offers is a one place to go to find that information, which is extremely valuable to the -- to the source community, the manufacturers, and -- and device manufacturers. But Agreement States, I know some of them may not have much of anything other than to fax you or scan a copy of the license for you to put in that database.

COMMISSIONER BURNS: Yes, okay. Now I think this is an

issue we will continue to -- well, we will be working through, you know, obviously, in our -- need to be -- well, with the obligation we have in terms of the periodic review that came out of the Energy Policy Act, as I recall, as well as some of the outcomes from the GAO stings, although again, I think you make an interesting point that -- forgive me, because I forget all the acronyms --

DR. LANGHORST: That's okay.

COMMISSIONER BURNS: -- in terms of --

DR. LANGHORST: HDR?

COMMISSIONER BURNS: -- in the HDR, thank you, in terms of what you actually provide, I mean, what the manufacturer -- in effect that transactional event between the manufacturer and the end user in terms of the -- you know, the limitations of number of sources, what that relationship is, is perhaps very different than some of what we are seeing in the scenarios that -- used in the various -- in the couple stings that were done by GAO.

DR. LANGHORST: And that is -- it comes to that. You can't have a one-size-fits-all, necessarily. You -- you --

COMMISSIONER BURNS: Yes.

DR. LANGHORST: -- need to be able to consider different scenarios, different environments of which these transactions are happening --

COMMISSIONER BURNS: Yes.

DR. LANGHORST: -- and -- and the point of -- there is existing security and accountability requirements that we must meet, and we're doing that successfully.

COMMISSIONER BURNS: Okay. Thanks very much. My time is up, Chairman. Thank you.

CHAIRMAN SVINICKI: Well, thank you all for the presentations, again. As I prepare for this routine meeting, I take the time to reacquaint myself with the credentials and experience of the members of the committee, and I am always struck and impressed by the willingness to serve of such capable and candidly very busy people who this is not their principal job.

I share the reflection of Commissioner Burns, which is that this is a unique element of our regulatory responsibility is the medical uses of radiological materials, and it is something that Ms. Weil has very eloquently stated the fundamental truth we seek, which is to find regulation that is adequately protective while not unnecessarily restrictive.

On the one hand, I would like to think that I would reach a state of comforting myself that, given how dynamic the medical field is, that we have achieved that sweet spot of not suppressing the development of new modalities and new things that could be so beneficial to the lives of Americans, and again, whether or not we are practitioners in the field of nuclear medicine, all of us are at one point or another patients, and so it just feels very direct and personal to seek that.

And I say I wish I could become entirely confident that we -- we are balancing that at the perfect balance point, but I think it is good to be a little bit uncertain of that because what it causes us to do is to continually reevaluate where we are. It is interesting, in a social setting recently, in a friend of friend kind of environment, I walked up to make small talk. It turned out I was introducing myself to an anesthesiologist and a surgeon, so it was a very intellectual gathering, I guess, but they asked me, you know, who I was and what I did, and they didn't know the Nuclear Regulatory Commission well, but they

knew, of course, nuclear medicine.

And ironically, the anesthesiologist, I said, you know, it's an interesting area of regulation for us because we are to address the radiological qualities and properties of the use of these materials, but we're not to interfere with the practice of medicine, and she turned to me, the anesthesiologist, and she goes that part, I am familiar with. You are not supposed to be interfering with the practice of medicine.

(Laughter.)

CHAIRMAN SVINICKI: So she knew that much about NRC's framework for these things. But so in seeking this, as Commissioner Burns has noted, this committee, the role that they play, and I know there is the uniqueness that they are an advisory committee to the NRC staff because of the essential need we have to have practitioners and current practitioners be involved in this advisory committee. I think if we had people whose knowledge was ten years old and they were long-retired, that would not be sufficient for our regulatory needs, so it is not a committee advising the Commission, but as is evident by this type of meeting, it is something that we take in as members of the Commission, and I think it gives us a kind of enhanced confidence as we address the various regulatory measures that we are hearing from people who are dealing directly with patients, who are day-to-day practitioners in these areas.

It is interesting though on that not interfering with the practice of medicine, I wonder sometimes in general are we getting it more right or more wrong? I am sure over the course of time, new things are coming to the fore, and we may or may not be doing a terribly good job of that. Is that something that the advisory committee has some sense of, so that if there was something

so essentially problematic about the framework, not maybe because it was problematic when first promulgated, but maybe given the emergence of new types of treatments or something, it is becoming very problematic? Do you feel that the structure and form of the ACMUI would allow you to have the right committee composition with the right expertise to become aware so that you could bring that to the Agency's attention? Do you think it is structured properly to do that?

DR. ALDERSON: I will take the first shot at that, and I invite my colleagues to contribute. I think it is structured appropriately. In fact, I think that even in today's meeting, you know, we have brought forth some issues that we are concerned about, talked about whether they -- what sort of changes would be required, guidance, rulemaking, et cetera, et cetera. The staff has freely discussed those issues with us, and we're trying to make progress on them. So we are not reticent to bring the problems to the fore.

So I think the structure as it is now and our ability to call other people as our own consultants, not actually during a meeting, but, you know, between meetings creates a good potential for us to be able to continue to do this. Does anyone else wish to comment on that?

CHAIRMAN SVINICKI: Okay. Well, thank you for that feedback, and I know we do look -- I am certain that on some frequency, we're looking at kind of the charter and the structure and the composition of the committee, and there are -- I think over the course of this very long history that Commissioner Burns talked about, there have been changes in the types of expertise that are solicited for as the membership turns over.

I would also note on the fact that there are many administrative

elements to serving on an advisory committee. I am not suggesting that the various disclosures and background checks are in any way unnecessary, but I -- I hope that that isn't the -- it isn't, by the current composition of the committee, to my mind, there is no evidence that it is suppressing the willingness of very capable individuals to serve. Nonetheless, those things taking a long time, I would note for anyone wondering, you know, what kind of people are we putting on this committee, that there's, you know, issues that things are taking a long time, I would say, as Commissioner Burns said, that is in no way evidence of there being any issue. It is simply that there is sometimes a backlog on some of the security paperwork.

And the irony here is that the more complex it is, it gets, you know, pushed off to the side of the desk, and then it's like, well, I can meet my timeliness metrics on these security checks by doing ten easy ones instead of resolving -- it's a very unfortunate thing, and I am not excusing it, but I would hope for the successful resolution for the members where there is paperwork outstanding.

And on the -- Dr. Langhorst, I appreciate your presentation. I have served long enough on this Commission that there are very few issues of true new impression for me, so I do have a voting history on the possible expansion of the NSTS, and particularly on the -- the issue of Category 3 sources. Nonetheless, we have an evaluation underway, and I will receive that evaluation with an open mind. I will complement it against the Commission's consistent monitoring of the threat environment in the United States, and, to a certain degree, globally, because what exists in the world can end up on your doorstep. So I think those two prongs are very important to be considered.

I -- as challenging as the national security environment is, I think I don't -- I don't see as much of a dynamic step change there. I think that in order to make a security change, it should be rooted in some fundamental view that the threat has -- has evolved or modified itself in some way, so that is why I think that those two things are a companion.

I would just note as well that we have had the Congress looking at this issue. There have been GAO studies of it. And then, as a result of that, there have occasionally been public policy discussions in the Congress about legislating these matters, which would in some form really take it out of the NRC's hands.

I am aware that the medical professions impacted by those changes have made their voices heard, and I don't say this to encourage advocacy from one side against another. I encourage all those who have a view, when the Congress takes something up, to make their voices heard about it. But I think that the security concerns are more instinctively understandable than some of the implications for access, the cost of the delivery of medicine and things. I think it is essential that the practitioners come forward and, again, as busy people, make certain that those implications are understood, not only -- so I appreciate that folks have commented in our processes, but I think that there is always the chance that policymakers in legislative bodies might take something up as well, and so it is important for all citizens who have a view on that to participate in that.

And I think on the medical event reporting, I -- I continue -- I appreciate Dr. Suh very much. The thoughtful recommendation to, you know, you looked at maybe splitting it out a little bit more and ultimately made a

recommendation to report all the modalities except for the brachytherapy under the current definition, so I still do appreciate that you led with the fact that medical event reporting does not correlate necessarily to patient harm, and I think that there are implications, even though we have moved away from misadministrations or other perhaps even more pejorative terms, medical events sounds neutral. Unless it's your medical event with a patient, it does not sound terribly -- and if it's your loved one, it doesn't sound terribly neutral to you, so appreciate the continued look at that, and again, just thank you all for your willingness to serve.

And it is just, again, as I am in my tenth year of service on this Commission, the existence of this committee is something that I can reside a lot of confidence in and lean into, so thank you very much for your service. Thank you. Commissioner Baran?

COMMISSIONER BARAN: Well, let me just start where the Chairman left off, which is thanking you all for your service on the committee. We really appreciate it. I know it's helpful to the staff, and when we get the opportunity to pick your brain, too, it is very helpful to us.

Dr. Langhorst, you talked about the HDR units used to treat different types of cancer, and you mentioned that there are about 1100 HDR licensees and that the sources for the units are replaced every one to three months, so it sounds like there are a lot of routine source transfers between the vendor and the licensees. Is it just one HDR vendor, or are there a number of vendors?

DR. LANGHORST: Currently, there are two vendors.

COMMISSIONER BARAN: Two vendors. And do you have a

sense of how many of the HDR source transfers involve repeat customers who are well-known to those two vendors?

DR. LANGHORST: Well, I would consider most of them are.

COMMISSIONER BARAN: Okay.

DR. LANGHORST: And the HDR vendor would be installing their HDR unit without the source before they would ever send the source.

COMMISSIONER BARAN: Okay. So your sense is that a vast majority of these folks are repeat people. They sold the unit to them, and then every month, every two months, every three months, there's one or more source transfers with the same person on the other end every time, that is --

DR. LANGHORST: Correct.

COMMISSIONER BARAN: -- your sense of how it --

DR. LANGHORST: Yes.

COMMISSIONER BARAN: -- usually works? As you mentioned, one option that staff is assessing is including Category 3 sources in the National Source Tracking System. Another potential option is to require vendors to verify Category 3 licenses prior to a transfer through the License Verification System, or directly with a licensing authority, whether it is NRC or the Agreement State. The license verification approach could be structured to apply to all Category 3 transfers, or it could be tailored to an appropriate subset of transfers.

In the context of HDRs, what would you think about requiring license verification for only new or unknown customers wanting to purchase a Category 3 source?

DR. LANGHORST: Well, currently, the HDR vendors have to

verify the license to -- in order to install an HDR unit, so there has to be a license that is approved and -- before they ever even bring in the HDR unit.

COMMISSIONER BARAN: Okay. So if there are two vendors, and let's say, you know, a particular facility purchased the unit from Vendor A, and then for whatever reason, can you go to Vendor B at some later point for your sources?

DR. LANGHORST: Only if you have that Vendor B's unit --

COMMISSIONER BARAN: Okay.

DR. LANGHORST: -- so that sources are not interchangeable between the vendors.

COMMISSIONER BARAN: Is there any mechanism by which the units themselves would transfer from one licensee to another?

DR. LANGHORST: No.

COMMISSIONER BARAN: So it sounds like what you're saying, in this particular --

DR. LANGHORST: I --

COMMISSIONER BARAN: -- category, maybe 100 percent of the people are going to be known to the vendor on an ongoing basis?

DR. LANGHORST: Yes.

COMMISSIONER BARAN: Okay.

DR. LANGHORST: I would correct in that if you have a licensee who then changes ownership --

COMMISSIONER BARAN: Yes.

DR. LANGHORST: -- you have to be mindful of that the new license covers that.

COMMISSIONER BARAN: Okay.

DR. LANGHORST: So that could be one sense where you have to be sure that if there is a change in ownership, that the -- either the license remains in existence, or that the new license covers that. But that would be one of the business relationships that the HDR vendor would have with that customer in order to make sure that they are still licensed for that.

COMMISSIONER BARAN: Okay. Well, that is helpful context. Thank you.

I wanted to also ask about training and experience requirements. Dr. Palestro, I was looking at the subcommittee's September status report, and it looks like from this, you identified -- the subcommittee identified at least six of the regulatory provisions to review, at least initially. And you mentioned you started with 190, and there's 290, 390, 392, 394, 396. And it sounds like you are -- you are -- you have started with 190 and plan to work your way down the list. Is that --

DR. PALESTRO: That is correct.

COMMISSIONER BARAN: -- the plan? And do you have a sense of how long it will take to review each of those items on the list, each of the provisions?

DR. PALESTRO: No. To be honest with you, I really don't.

COMMISSIONER BARAN: Okay.

DR. PALESTRO: 190 was a very narrow scope, and it went very simply and smoothly. 200 is a broader scope. It is going to take longer to review, and when we get into the 300 series, I think it is going to be even more complicated.

The -- the rationale behind starting out slowly is to try to debug our plan, our template, our criteria, and so forth.

COMMISSIONER BARAN: Yes.

DR. PALESTRO: So I don't want to try to -- to put a -- a timeline on it.

COMMISSIONER BARAN: Okay.

DR. PALESTRO: I would hope that by this time next year, we certainly will have completed 200, and perhaps started the 300 series.

COMMISSIONER BARAN: Okay. And is your work on the 200 series already underway?

DR. PALESTRO: No, not at this --

COMMISSIONER BARAN: All right.

DR. PALESTRO: -- point.

COMMISSIONER BARAN: It seems like most of the stakeholder interest has been focused on the alpha and beta emitters, which I believe are addressed by the sixth provision on the list. Are you hearing a significant amount of stakeholder interest or concern on the -- on the first five provisions, on the other provisions?

DR. PALESTRO: The answer is no.

COMMISSIONER BARAN: Okay.

DR. PALESTRO: And the stakeholder interest on the sixth provision, the committee had come to the conclusion that there was -- was no reason at the time to change the training and experience requirements because we couldn't demonstrate convincingly that there were issues with patient access, so the stakeholder input in that has decreased a bit.

COMMISSIONER BARAN: I completely understand the rationale for trying to test out your approach, and starting with the kind of most straightforward case and then progressing. Speaking for myself only, though, I think there would be some value of getting to the alpha and beta emitter piece sooner rather than later. If we're looking at a year before we start the 300 series, and then this is fourth on the list in the 300 series, I worry that the -- the area -- areas that people are most interested in and focused on are kind of years into the future. Is it workable to move up, you know, the sixth item on this list for earlier review by the subcommittee?

DR. PALESTRO: I think the answer is a qualified yes, and then if we get through the 200 series perhaps more quickly than I would anticipate, or at least with few or no issues that develop, we can then accelerate our course, but I cannot answer that definitively at this point.

COMMISSIONER BARAN: Okay.

DR. PALESTRO: And my concern, I appreciate the -- the interest in that and -- and the importance of addressing it, I want to make sure that we address it correctly.

COMMISSIONER BARAN: Yes, absolutely.

DR. PALESTRO: You know, radiation, unfortunately, in our society, the word "radiation" is anathema, and I want to make sure that not only is there patient access, but that we have appropriate radiation safety, so it's kind of a balancing act that we have to do.

COMMISSIONER BARAN: In terms of the analysis you are performing for each particular provision, in my mind, the most valuable analysis is one that would take a fresh look, start at the beginning, and ask the

fundamental question what are the right T&E requirements for that particular class? What are the competencies and training experience that would ensure safety for that particular class? Is that the approach you all are taking, that you're kind of starting with a blank sheet of paper and asking, okay, what is -- what is the right -- what are the right requirements for this area?

DR. PALESTRO: Yes.

COMMISSIONER BARAN: Okay. Good, great. Well, I am glad to hear that.

(Laughter.)

COMMISSIONER BARAN: That is -- from my point of view that is the perfect answer.

My sense is that it would be very difficult to determine whether a given T&E requirement is unnecessarily limiting the number of authorized users, and therefore unnecessarily limiting patient access to a particular treatment. You know, if a particular radiopharmaceutical is not being used much, or as much as it used to be, or isn't accelerating at a certain pace, you know, maybe it's there are not enough authorized users, maybe it is practitioners think there are superior technologies, or -- or they are more familiar with other technologies, or this technology is particularly costly.

I mean, it could be any number of factors, presumably, and I am not sure sorting through that particular causation analysis is really going to be that fruitful. But what is your sense of that?

DR. PALESTRO: The answer is we're grappling with that, and I think you are absolutely correct, and all we can really do is base -- in terms of patient access, is base our conclusions on inference. If there are no issues

raised about patient access, then we will conclude, or we conclude that patient access is not an issue that needs to be addressed. I have no other way -- I don't have any other -- other idea of how to approach it.

COMMISSIONER BARAN: Yes.

DR. PALESTRO: You know, there are not data of any sort. We can look at medical safety -- or medical events, radiation safety events, and there are logs of data on that, but in terms of patient access, it is almost anecdotal.

COMMISSIONER BARAN: Yes. Well, the overall effort, it is -- you know, there is really, at some point, you get to a judgment call on this, right? There is no formula that's going to spit out an answer for the right number of competencies or hours or whatever the metric is going to be.

Ms. Weil, do you have any thoughts on this? I know you were talking about this in your presentation. Anything based on this conversation you wanted to share?

MS. WEIL: Well, in terms of trying to assess whether there are limitations for patients who are trying to access a particular therapy, I think it is important that we reach out to those disease-specific patient advocacy organizations, like the Lymphoma Research Foundation and the Leukemia/Lymphoma Society, to ascertain what they have heard, because those are the folks who are likely to hear from this particular constituency about any problems that -- that might occur.

And -- and we need to -- you know, and that is why I am privileged to be a member of this subcommittee, because that is my constituency, and I will continue to try to get any information I can about this

particular problem.

COMMISSIONER BARAN: Well, I really appreciate the subcommittee's work in this area. I think it makes sense for NRC as an agency, as a regulator, to take a fresh look at our current T&E requirements to see if they need to be updated or tailored for certain classes of radiopharmaceuticals, and ACMUI's insights are very helpful in that effort, so I would encourage you to think through, you know, the prioritization of your work there and -- and where you think your work would be most helpful to the staff and to the Agency overall. And thank you.

CHAIRMAN SVINICKI: Did you have any --

COMMISSIONER BARAN: No.

CHAIRMAN SVINICKI: -- additional questions?

COMMISSIONER BARAN: Thank you.

CHAIRMAN SVINICKI: Okay. Well, thank you all again. As I've noted, I derive such value from these discussions. And thank you for your continued work. I would just note before I adjourn that I think we are doing a group photo, so for the members of the committee and my colleagues, please don't run out of the room. Thank you, and we are adjourned.

(Whereupon, the meeting went off the record at 11:21 a.m.)