

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

PROCEEDINGS

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

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

3 Next slide, please?

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

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

10 Next slide, please?

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

14 Next slide, please?

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

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

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

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

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

1 Committee.

2 Next slide, please?

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

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

11 Next slide, please?

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

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

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

19 Next slide, please?

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

24 And, progress and improving ACMUI internal and external
25 communications.

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

5 Next slide, please?

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

10 Next slide, please?

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

15 Next slide, please?

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

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

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

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

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

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

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

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

12 Next slide, please?

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

17 The next presentation will be by Dr. Palestro.

18 DR. PALESTRO: Thank you, Dr. Alderson.

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

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

24 Next slide, please?

25 The charge of this Committee was to periodically review training

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

3 Next slide, please?

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

8 Next slide, please?

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

12 Next slide, please?

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

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

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

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

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

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

1 factor that might trigger an accelerated review.

2 Next slide, please?

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

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

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

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

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

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

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

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

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

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

1 Next slide, please?

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

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

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

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

15 A word about competency -- next slide, please?

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

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

21 Next slide, please?

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

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

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

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

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

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

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

22 Next slide, please?

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

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

1 do current proposed regulations limit patient access to procedures?

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

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

7 Next slide, please?

8 The Subcommittee recognizes the keen interest in 10 CFR
9 35.300. However, we also recognize that the charge of the Subcommittee --
10 with the responsibilities that the Subcommittee has been charged with are quite
11 extensive, complicated and require a slow, methodical approach.

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

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

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

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

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

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

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

5 Next slide, please?

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

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

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

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

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

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

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

24 Next slide?

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

1 Weil, Patient Rights Advocate.

2 MS. WEIL: Thank you, Dr. Palestro.

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

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

9 Next slide, please?

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

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

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

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

18 Next slide, please?

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

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

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

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

3 Next slide, please?

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

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

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

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

16 Will pharmaceutical research and development be
17 discouraged?

18 Will existing treatment options be withdrawn for lack of
19 profitability?

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

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

25 These new delivery systems may be amenable to more nimble

1 or less restrictive regulation.

2 Next slide, please?

3 So, here are two examples of the extremes.

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

7 We have iodine-131 which requires 800 hours -- 80, I'm sorry,
8 80 hours. Is that too little?

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

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

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

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

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

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

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

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

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

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

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

20 Again, this needs to be evaluated by the Subcommittee.

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

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

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

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

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

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

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

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

17 Next slide, please?

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

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

25 Next slide, please?

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

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

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

9 Next slide, please?

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

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

15 Next slide, please?

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

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

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

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

1 Next slide, please?

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

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

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

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

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

16 Next slide, please?

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

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

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

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

4 Next slide, please?

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

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

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

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

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

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

23 Next slide, please?

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

1 regulatory and process changes being considered?

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

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

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

11 Next slide, please?

12 The International Atomic Energy Agency has defined Category
13 3 as those sources, if not safely managed or securely protected, could cause
14 permanent injury to a person who handled them or were otherwise in contact
15 with them for some hours.

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

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

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

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

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

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

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

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

15 DR. SUH: Thank you.

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

18 Next slide?

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

21 Next slide?

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

25 Permanent implant brachytherapy medical event has been

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

3 Next slide?

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

8 Next slide?

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

13 Next slide?

14 If you look at the number of medical events that have been
15 reported from fiscal year 2013 to fiscal year 2015, you can see that approximately
16 50 medical events are reported.

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

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

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

24 Next slide?

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

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

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

9 Next slide?

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

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

18 Next slide, please?

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

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

24 Next slide?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 ACMUI is actively discussing patient intervention at this time.

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

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

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

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

14 Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

17 COMMISSIONER BURNS: Yes.

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

22 COMMISSIONER BURNS: Yes --

23 DR. PALESTRO: -- time.

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

1 DR. PALESTRO: Exactly.

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

5 DR. PALESTRO: Thank you.

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

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

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

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

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

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

8 COMMISSIONER BURNS: Yes.

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

11 COMMISSIONER BURNS: Yes.

12 DR. LANGHORST: -- radioactive material to.

13 COMMISSIONER BURNS: Yes.

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

18 COMMISSIONER BURNS: Okay.

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

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

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

6 DR. LANGHORST: That's okay.

7 COMMISSIONER BURNS: -- in terms of --

8 DR. LANGHORST: HDR?

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

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

17 COMMISSIONER BURNS: Yes.

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

20 COMMISSIONER BURNS: Yes.

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

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

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

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

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

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

1 knew, of course, nuclear medicine.

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

8 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 DR. LANGHORST: Currently, there are two vendors.

25 COMMISSIONER BARAN: Two vendors. And do you have a

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

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

4 COMMISSIONER BARAN: Okay.

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

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

11 DR. LANGHORST: Correct.

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

13 DR. LANGHORST: Yes.

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

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

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

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

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

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

8 COMMISSIONER BARAN: Okay.

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

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

13 DR. LANGHORST: No.

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

16 DR. LANGHORST: I --

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

19 DR. LANGHORST: Yes.

20 COMMISSIONER BARAN: Okay.

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

23 COMMISSIONER BARAN: Yes.

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

1 COMMISSIONER BARAN: Okay.

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

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

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

16 DR. PALESTRO: That is correct.

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

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

21 COMMISSIONER BARAN: Okay.

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

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

3 COMMISSIONER BARAN: Yes.

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

6 COMMISSIONER BARAN: Okay.

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

9 COMMISSIONER BARAN: Okay. And is your work on the
10 200 series already underway?

11 DR. PALESTRO: No, not at this --

12 COMMISSIONER BARAN: All right.

13 DR. PALESTRO: -- point.

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

19 DR. PALESTRO: The answer is no.

20 COMMISSIONER BARAN: Okay.

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

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

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

14 COMMISSIONER BARAN: Okay.

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

18 COMMISSIONER BARAN: Yes, absolutely.

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

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

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

6 DR. PALESTRO: Yes.

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

9 (Laughter.)

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

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

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

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

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

4 COMMISSIONER BARAN: Yes.

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

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

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

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

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

1 particular problem.

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

10 CHAIRMAN SVINICKI: Did you have any --

11 COMMISSIONER BARAN: No.

12 CHAIRMAN SVINICKI: -- additional questions?

13 COMMISSIONER BARAN: Thank you.

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

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