

UNITED STATES

NUCLEAR REGULATORY COMMISSION

+ + + + +

PUBLIC MEETING WITH THE ADVISORY COMMITTEE

ON THE MEDICAL USES OF ISOTOPES (ACMUI)

+ + + + +

THURSDAY,

MARCH 8, 2018

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

Chairman Svinicki and Commissioner Baran 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.

KRISTINE L. SVINICKI, Chairman

JEFF BARAN, Commissioner

ALSO PRESENT:

ANNETTE VIETTI-COOK, Secretary of the Commission

MARGARET DOANE, General Counsel

ACMUI MEMBERS:

PHILIP ALDERSON, M.D., Chair

PAT ZANZONICO, Ph.D., Vice Chair

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

CHRISTOPHER PALESTRO, M.D., Nuclear Medicine
Physician

LAURA WEIL, Patients' Rights Advocate

P R O C E E D I N G S

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

10:02 a.m.

CHAIRMAN SVINICKI: (presiding) Good morning, everyone.

I will be very precise in my terminology this morning. We meet now -- Commissioner Baran and I are conducting a public meeting this morning with the Advisory Committee on the Medical Uses of Isotopes.

Commissioner Burns sends his apologies. Due to a prior commitment, he could not attend today's Commission meeting with the ACMUI. The Commissioner will be informed of today's discussions upon his return to the office. I will just note that I know he sincerely regretted the scheduling of this meeting, but was not able to -- he had made this prior commitment and he wanted to honor that. So, again, I know he will take great interest in this discussion when he returns to the office.

Again, Commissioner Baran and I will hear views of our Advisory Committee on the Medical Uses of Isotopes on medically-related topics of regulatory interest. This is always a meeting where I take a lot on. The reason that the Advisory Committee on Medical Uses of Isotopes exists that we do have this regulatory jurisdiction over the medical uses. And yet, we are not squarely a medical-related regulator. So, this

1 Advisory Committee plays a very important role in
2 providing perspectives and insights to the NRC staff
3 in this meeting. In these public meetings that they
4 conduct with the Commission, we get to hear directly
5 and benefit from the expertise that you all provide.

6 Before we turn it over to the Committee
7 members, I would ask if Commissioner Baran has any
8 comments to make.

9 Okay. Hearing none, I will turn it over
10 to the current ACMUI Chair, Dr. Philip Alderson, and
11 if you would begin. And then, if you would like to
12 hand off to each other, or you can hand it back to me,
13 and I'll hand it off. It is a public meeting, so it
14 could be maybe a little less formal, but whatever works.

15 And thank you again for being here today.

16 DR. ALDERSON: Thank you, Chairman
17 Svinicki. It's our pleasure and honor to be here today,
18 and Commissioner Baran, thank you for being here.

19 It's my role here to give you an overview
20 of what we're going to discuss in the next few minutes.

21 So, we will review, as we traditionally do, the ACMUI
22 purpose and the membership, and then, the topics that
23 we'll be discussing with you and some areas of future
24 interest.

25 So, the ACMUI exists to advise the NRC staff
26 and you, of course, as our Commissioners, on policy

1 on medical uses of radionuclides and to provide
2 technical assistance and to serve as your consultants.

3 This involves a number of membership positions, and
4 they are listed on a third of the slides. They include
5 a health care administrator, a nuclear medicine
6 physician, two radiation oncologists, a nuclear
7 cardiologist, a diagnostic radiologist, two medical
8 physicists, a nuclear pharmacist, a radiation safety
9 officer, a patients' rights advocate, an agreement
10 state representative, and a representative of the FDA.

11 If you're looking at the materials in front
12 of you, those positions that are followed by an asterisk
13 are people who have currently been appointed, but are
14 not fully yet approved to vote on the Committee.

15 In the next slide we'll review some of the
16 topics that the ACMUI has addressed in the past year.

17 We have spent a fair amount of time -- and you will
18 hear a report on a moment -- about training and
19 experience requirements. Now in the last year we began
20 looking at 35.100 uses. That's unsealed byproduct
21 material for uptake, dilution, excretion studies, for
22 which a written directive is not required. And the
23 plan was to move methodically sort of up the numerical
24 rank through the various categories. As it turns out,
25 as you'll hear in a moment, we've now moved forward
26 to 35.300, and you'll hear more report about that in

1 a minute.

2 We also have been very interested in
3 medical event reporting for all modalities except that
4 of permanent implant brachytherapy. We've tried to
5 clarify for your use, for ours, that of the Congress,
6 what patient intervention really means, what does
7 constitute patient intervention. Because if a patient
8 intervenes, we don't have a medical event by definition.
9 So, we've tried to clarify that a bit.

10 And we've also looked at the impact of
11 medical event reporting on patient safety culture.
12 We would like to see, we would encourage a positive
13 culture that rewards near misses, rewards people for
14 finding things that need to be corrected and correcting
15 them. It is not punitive in nature. And you will,
16 again, hear more about that in one of our follow-up
17 reports.

18 We've also had an extensive look at
19 guidelines for nursing mothers to whom diagnostic or
20 therapeutic radiopharmaceuticals are administered.
21 The issue there being that, if those pharmaceuticals
22 are onboard, they can radiate the young child in two
23 ways, just from emanating from the other and, also,
24 from concentrating in and being part of the milk. So,
25 you'll hear a good report on that particular issue.

26 Other topics: potential changes to the

1 NRC's Patient Release Program. This has been a topic
2 for years and years as we continue to try to adjust
3 the release criteria to current technology and
4 approaches, and make it as safe and effective as
5 possible for the patient and for the loved ones of the
6 patient with whom they might come into contact.

7 We've also looked at the physical presence
8 requirements for an authorized user when the Leksell
9 Gamma Knife Icon, which is a new version of that machine,
10 is used. And we have suggested potential changes that
11 could make that a more efficient process.

12 We also have looked at, and hope to have
13 made some progress, in improving the communications
14 of the ACMUI, communications in various directions,
15 communications just among ourselves; between the ACMUI
16 and the staff, your staff, who work directly with us;
17 between the ACMUI and you, the Commissioners.

18 And so, we hope to get the user community
19 much more aware of the sorts of things we're doing to
20 facilitate safety and efficiency and to hear
21 person-to-person their comments. So, in that regard,
22 a number of our people now are attending at and speaking
23 at particular sessions in major national meetings of
24 our constituents and getting a lot of good interaction
25 and feedback.

26 We've also had continuing discussions, as

1 I said a moment ago, of the training and experience
2 requirements, and the current focus is on 35.300 uses,
3 about which you'll hear from Dr. Palestro.

4 Yes, we, indeed, have reviewed medical
5 event issues, including the patient safety culture.
6 We also have looked at Regulatory Guide 8.39, Release
7 of Patients Administered Radioactive Materials, and
8 looked at how to make that more efficient and more
9 broadly-based. 8.39 tends to focus quite much on
10 iodine-131, but there are a lot of other things coming
11 along that need to be considered. So, the Committee
12 has worked hard to try to broaden that perspective and,
13 as I said earlier, ways to enhance communications with
14 many different groups.

15 We currently have these issues and a number
16 of others under discussion. And as new issues arise,
17 including emerging technologies, we'll address those
18 and provide advice on aspects relevant to safe handling
19 of radionuclides.

20 Now that concludes my overview report, and
21 I will now pass the baton to Dr. Palestro.

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

23 My name is Chris Palestro, and I am the
24 ACMUI nuclear medicine physician representative. I'm
25 also the Chair of ACMUI Subcommittee on Training and
26 Experience Requirements for All Modalities. Over the

1 next few minutes, I would like to update you on some
2 of the work that the Subcommittee has done regarding
3 training and experience.

4 May I have the next slide, please?

5 This Subcommittee on Training and
6 Experience was established in 2016, and we are charged
7 with the periodic review of the training and experience
8 requirements currently in effect for all modalities,
9 as well as to make recommendations for changes as
10 needed.

11 Next slide, please.

12 So, the Subcommittee is responsible for
13 reviewing the training and experience requirements
14 currently in effect for the uses of unsealed byproduct
15 materials, 10 CFR 35.100, 200, 300, and 1000, as well
16 as the sealed byproduct materials, 10 CFR 35.400, 500,
17 600, and 1000.

18 Next slide, please.

19 In order to accomplish our tasks, the
20 Subcommittee developed a comprehensive review
21 template, and it was developed to ensure that there
22 would be a standardized review process; that we could
23 have meaningful comparisons of reviews over time, and
24 finally, that decisions about changes in training and
25 experience requirements would be based on data.

26 Next slide, please.

1 The Subcommittee planned to begin their
2 initial reviews with 10 CFR 35.100, followed by 35.200,
3 300, et cetera. However, because of ongoing patient
4 access concerns, the Subcommittee has been directed
5 to prioritize its review of the training and experience
6 requirements for the use of unsealed byproduct material
7 for which a written directive is required,
8 10 CFR 35.390.

9 Next slide, please.

10 The Subcommittee has identified some
11 significant developments. First, on January 26th of
12 this year, the United States Food and Drug
13 Administration approved lutetium-177 dotatate for
14 treatment of somatostatin receptor-positive
15 gastroenteropancreatic neuroendocrine tumors,
16 including tumors of the foregut, midgut, and hindgut.
17 And this approval is distinctly different from
18 previous approvals of other unsealed sources in that
19 it is a very broad indication, meaning that it has the
20 potential to be used in a much larger number of patients
21 than previously-approved agents.

22 In addition to that, these tumors, which
23 were once thought to be relatively uncommon, are now
24 recognized as the second most common tumor of the GI
25 tract. So, there potentially will be a very high demand
26 for lutetium-177 dotatate.

1 Along with that, the Subcommittee has
2 identified the fact that there is a waning number of
3 nuclear medicine physicians in the United States.
4 There were fewer than 50 first-time candidates who sat
5 for the 2016 American Board of Nuclear Medicine
6 certification examination, and this is in contrast to
7 the 80 to 100 candidates that had sat for this
8 examination in previous years.

9 A review of the Accreditation Council for
10 Graduate Medical Education database shows that a decade
11 ago in academic year 2007-2008 there was 62 nuclear
12 medicine residency programs with 157 residents. In
13 the current academic year, 2017-2018, there are 41
14 nuclear medicine residency programs with 75 residents.

15 So, over the course of a decade, the number of nuclear
16 medicine residents has decreased by slightly more than
17 50 percent.

18 Now, although there is a much smaller
19 number, if you look at the data -- I'm sorry, in the
20 next slide of nuclear radiologists -- it also appears
21 to be trending downward. If you look at 2013, '14,
22 '15, there were 13, 11, 10; 2016-2017, only 2 and 5
23 individuals, respectively, sat for the American Board
24 of Radiology Nuclear Radiology Certificate of Added
25 Qualifications Examination.

26 And to put this into perspective, if we

1 were to look at data for nuclear medicine and for the
2 American Board of Radiology, Therapeutic Radiology,
3 approximately 250 graduates. There was approximately
4 a total of 250 graduates from both of these programs
5 on a yearly basis, all of whom would be qualified, once
6 they passed their Board certification exam, to be
7 Authorized Users. A decrease from that 250 of 40 to
8 45 individuals coming just from nuclear medicine
9 represents a drop of somewhere between 12 and 15 percent
10 of new Authorized Users entering the field, and that
11 is not an insignificant decrease, in the Subcommittee's
12 opinion. So, there certainly are emerging concerns.

13 Next slide, please.

14 Previous discussions and presentations
15 that we've held over the past two-and-a-half or three
16 years focused on whether or not there was a sufficient
17 versus an insufficient number of Authorized Users at
18 the present time for administration of an infrequently
19 used therapeutic radiopharmaceutical, Zevalin. No
20 consideration really was given - it was a very focused
21 review -- no consideration was given to future numbers
22 of Authorized Users, nor to new agents that were under
23 development or about to be approved. The Food and Drug
24 Administration approval of the new CFR Part 35.390 drug
25 lutetium-177 dotatate with a potential for a high volume
26 suggests that reevaluation of the situation is in order.

1 Next slide, please.

2 In considering the development of an
3 alternate pathway, we clearly need to address, to the
4 extent that we can, future needs. And it's also, I
5 think, worthwhile to point out that over the course
6 of the past few years the discussions have focused on
7 a sufficient or an insufficient number of AUs. There's
8 never been a suggestion raised that perhaps there was
9 a surplus of AUs. So, I don't think that is an item
10 of concern, that we have a surplus. That certainly
11 is not an issue.

12 And then, finally, could a decrease in the
13 number of Authorized Users and an increase in procedures
14 in the 35.390 category affect patient access as new
15 agents in this class of radiopharmaceuticals become
16 available?

17 Next slide, please.

18 And with the Commissioners' permission,
19 I would like to restate the conclusion, not that it's
20 time to reconsider developing an alternate pathway,
21 but, rather, the time has come to develop an alternate
22 Authorized User pathway for 10 CFR 35.390.

23 Thank you, and I will turn the microphone
24 over to Dr. Dilsizian.

25 MR. ZANZONICO: I am not Dr. Dilsizian.
26 I am Dr. Zanzonico, and I am actually the departing

1 nuclear medicine physicist and Vice Chair of the ACMUI.

2 And I will be addressing the ACMUI comments on the
3 staff's recommendations for revisions to the Patient
4 Release Program.

5 Next slide, please.

6 The Subcommittee members were Dr. Sue
7 Langhorst, the immediate past radiation safety officer
8 member of the ACMUI; Dr. Palestro, whom you just heard
9 from; Ms. Laura Weil, the patient rights advocate
10 members, and myself.

11 Next slide, please.

12 The Subcommittee charge was to review and
13 provide recommendations on the Draft SECY paper
14 entitled, "Staff Recommendations for Revision of the
15 Patient Release Program". And as you know, the patient
16 release issue has been a persisting and at times
17 contentious one for the ACMUI and the NRC in general.

18 And so, this is an update, so to speak, on that issue.

19 Next slide, please.

20 In terms of background, the current
21 dose-based patient release rule, 10 CFR 35.75,
22 replaced the longstanding activity-based rule, the
23 so-called 30-millicurie rule, which was the basis of
24 patient release following radionuclide therapy for many
25 years. More specifically, the current dose-based rule
26 allows a licensee to release a patient if the total

1 effective dose equivalent, or TEDE, to any individual
2 from exposure to that patient is not likely to exceed
3 5 millicieverts, or .5 millirem.

4 Next slide, please.

5 In June of 2011, the staff was directed,
6 the NRC staff was directed to evaluate whether there
7 are gaps in the available data regarding doses received
8 by members of the public from released radionuclide
9 therapy patients and, if such gaps were found, to
10 provide a recommendation on whether and how such data
11 could be accrued to fill in those gaps.

12 Next slide.

13 In a SECY paper from 2012 entitled, "Data
14 Collection Regarding Patient Release," gaps were, in
15 fact, identified related specifically to internal doses
16 to members of the public and, also, internal and
17 external doses to members of the public from patients
18 released to locations other than their primary
19 residence, their homes. And that is released to
20 locations such as hotels and nursing homes.

21 Next slide, please.

22 So, the documents which the Subcommittee
23 reviewed were the subsequently prepared Draft SECY
24 paper and two support documents, a licensee survey
25 entitled, "Assessment of Where Patients Reside
26 Immediately Following their Release Report" and a

1 literature survey plus a compilation of model
2 calculations entitled, "Patient Release Following
3 Radioiodine Therapy, A Review of the Technical
4 Literature, Dose Calculations, and Recommendations".

5 Next slide, please.

6 So, among the findings and comments of our
7 Subcommittee was that the literature review was
8 thorough and the model calculations sound. The model
9 calculations were based on Monte Carlo simulations.
10 And if you have a background in reactor technology,
11 you're certainly aware of Monte Carlo simulations and
12 recognize it as the gold standard for these sorts of
13 calculations.

14 We subsequently found -- and I think this
15 is perhaps the most important conclusion we came
16 to -- that the current dose base, absorbed dose base,
17 approach to assessing patient releasability was
18 validated as more protective of public safety than the
19 prior activity-based approach. And we often cite the
20 example where hyperthyroid or Graves disease patients
21 treated with as little as 10 millicuries of I-131 iodide
22 actually deliver a higher dose to individuals around
23 them than thyroid cancer patients treated with an order
24 of magnitude or more higher activity because of the
25 difference in the pharmacokinetics in those two patient
26 classes.

1 So, we, therefore, concluded and reiterate
2 our conclusion that the current 5-millicievert, or
3 500-millirem, projected dose limit should remain in
4 effect as a per-event limit and is appropriate for all
5 potentially exposed cohorts, including pregnant women
6 and children. And I should emphasize that the National
7 Council on Radiation Protection and Measurement, NCRP,
8 endorses that position as well.

9 Next slide, please.

10 A second set of conclusions is that the
11 assumption in regulatory guidance that the internal
12 dose contribution is negligible has been validated
13 rather emphatically. There actually is a large
14 peer-reviewed scientific literature evaluating
15 internal or possible internal contamination of family
16 members and others in close contact with the patient
17 receiving radioiodine, for example, radioiodine
18 therapy immediately following their therapy and
19 release. And among these data are thyroid radioiodine
20 measurements of relatives, including children, of such
21 patients, and that's a very sensitive bioassay of
22 internal contamination because the thyroid
23 concentrates iodine so avidly. And from those data
24 and others, as I say, it has been validated that there
25 is, in fact, negligible internal contamination.

26 Other assumptions and methods in the

1 pertinent regulatory guidance, Appendix U of
2 NUREG-1556, as well as Reg Guide 8.39, if anything,
3 are excessively conservative. And we again point to
4 NCRP Peer Report No. 155 entitled, "Management of
5 Radionuclide Therapy Patients" for what we feel are
6 more realistic and more real-life-relevant sorts of
7 assumptions, although I have to make a disclaimer.
8 I was a coauthor of that report. So, it's near and
9 dear to my heart.

10 Importantly, it was found that a patient
11 staying at a hotel or a location other than their primary
12 residence immediately following radionuclide therapy
13 is not a common practice -- and that was based on the
14 licensee survey that was performed -- and is unlikely
15 to result in doses to workers and others exceeding even
16 1 millicievert, or 100 millirem, and that's consistent
17 with prior analyses and reports of the ACMUI.

18 Next slide, please.

19 Certainly, instructions, written
20 instructions, should be provided to the patient well
21 in advance of a planned therapy, so that the patient
22 can make plans consistent with radiation safety
23 precautions recommended following such therapy, but
24 we stopped short of recommending a specific time
25 interval since we could envision clinical scenarios
26 where that might interfere with timely administration

1 of a needed medical therapy. And I again point out
2 that in NCRP Report No. 155 there is a model set of
3 radiation safety precautions that can easily be
4 personalized to individual patients.

5 We also recommended that the NRC should
6 consider updating Appendix U and NUREG-1556 which deals
7 with patient release and post-release precautions to
8 reference Regulatory Guide 8.39 rather than eliminating
9 8.39, since that latter document is so familiar and
10 so widely used by the user community.

11 So, next slide, please.

12 To wrap up, the findings and
13 recommendations in the Draft SECY paper and support
14 documents really, we feel, validate not only the
15 existing dose-based release criteria rule, but also
16 the ACMUI's report, patient release report, in 2010.

17 And has been alluded to, the Patient Release Program
18 should be applicable to all radionuclides. It should
19 not be radio-iodine-specific, especially as we
20 anticipate in the near-term additional promising
21 treatments for cancer and other diseases using
22 systemically-administered radionuclides. And this
23 program should be flexible, not overly conservative,
24 not overly restrictive, so as not to encumber the
25 development and clinical implementation of new medical
26 procedures.

1 And with that, I conclude and now turn the
2 microphone over to Dr. Vasken Dilsizian.

3 DR. DILSIZIAN: Thank you very much. It's
4 a pleasure to be presenting the top of medical event
5 reporting and impact on medical licensee patient safety
6 culture, which represents really a summary of reports
7 from several Subcommittee members addressing this
8 topic.

9 Medical event reporting -- next slide,
10 please -- has not really changed significantly over
11 many years, and the annual number of reports is really
12 extremely low considering that an estimate 15 million
13 diagnostic and 150,000 therapeutic procedures are
14 performed annually.

15 Next slide, please.

16 So, given that the medical event rates are
17 extremely low, the question is, does it accurately
18 reflect the true number of cases? And given the
19 perception of a medical event being potentially
20 punitive, are centers reluctant to report medical
21 events? Such is the question that's being posed to
22 us.

23 And next slide, please.

24 Medical event versus medical error. Even
25 though a medical event is not necessarily a violation,
26 however, failure to report it is a violation, and

1 reporting such medical events by a physician may be
2 perceived negatively in most medical centers. And
3 particularly when the physician has to also communicate
4 that error or event with their patient and referring
5 physicians, there is a perception that this is really
6 a serious medical error.

7 And so, what is the problem that we are
8 trying to solve, therefore? Can we identify potential
9 ways that improve the effectiveness of the medical event
10 self-reporting to support a culture of safety? And
11 can we suggest ways that we can share these medical
12 event reports and lessons learned, if you will, from
13 the medical community to promote safety?

14 Next slide, please.

15 So, if we look at this list -- oh, next
16 slide, please -- reporting of medical events, what we're
17 trying to say is that it should be educational rather
18 than potentially punitive. And the whole goal of
19 medical event reporting should actually track a
20 specific event or trends, identify the problem, report
21 it to the medical community, recommend corrective
22 action with feedback loop for constructive improvement,
23 and learn from these mistakes.

24 And next slide, please.

25 So, based on these concepts, the guiding
26 principles, therefore, should be that, ideally, the

1 NRC should enhance patient safety culture while
2 maintaining its regulatory authority to protect
3 patients during medical use of byproduct materials,
4 and the focus on medical event reporting should be,
5 therefore, on learning and how to avoid or reduce the
6 likelihood of such events in the future, rather than
7 punitive-appearing action. And I will expand on that.

8 Next slide, please.

9 For example, medical events rarely cause
10 patient harm, but why is a notification required so
11 quickly. That is, no later than the next calendar day
12 after discovery of the medical event. And, of course,
13 soon after this notification, NRC inspection generally
14 takes place, looking for violations as a cause of the
15 medical event, within five days of the reporting.

16 So, next slide.

17 If we think about safety culture in
18 general, and the NRC representing nuclear safety
19 culture, which actually impacts patient occupational
20 and public safety culture, there are other patient
21 safety culture organizations such as the CMS-approved
22 Joint Commission or the patient safety organization
23 like the HHS.

24 And the next slide, please.

25 And we try to compare and see how those
26 organizations treat patient safety issues versus the

1 NRC. One major difference would become the patient
2 or individual -- not the patient -- the individual
3 licensee identity. So, on the left-hand side, the NRC
4 reporting information includes licensee identity,
5 which is also on the NRC website. And unfortunately,
6 it remains there, even if the event later is determined
7 by the NRC not to be a radical event. On the other
8 hand, accrediting or patient safety organizations
9 reporting tends to be anonymous to those outside the
10 hospital, the patient, or patient advocate.

11 Next slide, please.

12 Regarding information sharing, NRC
13 approaches it by, besides posting the event report on
14 the NRC website, the NRC also posts the inspection
15 reports, and those are the violations and licensee
16 responses. And this is important because, if similar
17 events occur, the NRC will issue a regulatory summary
18 documenting and alerting licensees or may initiate
19 rulemaking to prevent future events. On the other
20 hand, the accrediting or patient safety organizations
21 tend to provide databases to track events, provide
22 education or tips on tools, best practices to prevent
23 errors, and general patient safety initiatives to
24 improve safety culture.

25 Next slide, please.

26 So, what possible things we can recommend

1 to the NRC that may make sense, but not really change
2 the current reporting system? One question is, are
3 all medical events unnecessarily high-impact events?

4 Can we grade them, if you will, based on high versus
5 low impacts? And, accordingly, if the impact is high,
6 there would be no change in the form of current
7 reporting. There would be timely notification of the
8 NRC within 24 hours with a reactive inspection within
9 five days.

10 On the other hand -- again, we haven't
11 decided this what is considered low versus high
12 impact -- if the ACMUI along with the staff comes up
13 with some type of a criteria that would define what
14 a low-impact event would be, that would not require
15 immediate notification. They would be notifying the
16 NRC, but not within 24 hours, if you will, allowing,
17 therefore -- next slide -- the low-impacts will, then,
18 undergo some self-evaluation, the recommendation of
19 corrective action, which should be reported to the NRC
20 at a later date, through either NRC or NRC-approved
21 patient safety organizations.

22 Ideally, only high-impact events should
23 be made public. Low-impact events should be perhaps
24 anonymous to licensee information location and be used
25 as educational purposes for corrective action and,
26 therefore, encourage more reporting rather than

1 discourage reporting because it appears very punitive
2 in nature.

3 Next slide.

4 So, as we were discussing this, the NRC
5 staff suggested that the ACMUI could explore a program
6 like the reactor oversight process and the way in which
7 the NRC and the reactor community has developed and
8 tested this change in the regulatory oversight, for
9 possible methods of implementing NRC medical event
10 oversight improvements using current Part 35 reporting
11 regulations.

12 Next slide, please.

13 So, for example, a short-term
14 recommendation would be for the NRC to develop and test
15 a pilot program, like done with the reactor oversight
16 process, to allow a medical use licensee to evaluate
17 medical events. Perhaps with or without an approved
18 patient safety organization program, the NRC itself
19 can develop a program to also look at the low-event
20 rates and reporting.

21 The next slide, please.

22 The licensee will report medical events,
23 per current requirements. NRC, however, will not post
24 events on its website or will make posting anonymous.

25 Those are the low events. It will continue,
26 obviously, reporting the high events. And hopefully,

1 with these low-event cases as defined will not come
2 down to inspection except for the high-impact medical
3 event cases.

4 Next slide, please.

5 So, a licensee, therefore, will develop
6 a written report⁶ of low-impact medical events soon
7 after the event occurs to review either immediately,
8 sometime later on, or before the next NRC inspection.

9 NRC will develop temporary inspection procedures for
10 reporting reviews and to evaluate enforcement manual
11 changes for medical events to support a test program.

12 The number of participants and the length of time will
13 be determined, if this is agreeable, and the medical
14 events, obviously, will be reported to ACMUI for
15 evaluation during this testing pilot period.

16 Next slide.

17 After the pilot test period is completed,
18 the NRC should consider opening the program to all NRC
19 medical use licensees who request approval of their
20 patient safety program as well as to the agreement
21 states who request to implement the program with their
22 medical licensees.

23 Thank you very much for your attention.
24 This is the end of my presentation, and I would like
25 to introduce Ms. Laura Weil, who is going to be talking
26 about patients' right advocacy perspectives.

1 MS. WEIL: Thank you. Thank you for the
2 opportunity to present some patient advocacy
3 perspectives today.

4 I'd like to clarify that these are my
5 thoughts and do not necessarily represent a consensus
6 of the ACMUI as a whole.

7 So, I'll start with the training and
8 experience requirements. I was a member of that
9 Subcommittee as well. And given the realities of this
10 Subcommittee -- it's just four members -- with an
11 inevitably rotating membership, it makes sense for us
12 to solicit, and perhaps rely on, training and experience
13 recommendations from professional societies and
14 physician organizations. But one should be aware that
15 there's a potential for a subtle conflict of interest
16 and the potential for the impact of bias on these
17 recommendations.

18 Medicine in the United States is a
19 business. And certain stakeholder groups like
20 healthcare facilities and specialty physicians,
21 individual medical practices, all have an economic
22 interest in capturing advantageous patient groups, as
23 defined perhaps by age, geography, insured status,
24 sometimes disease.

25 Next slide, please.

26 This economic pressure can lead to turf

1 issues, as various stakeholder groups vie for business
2 in order to survive financially. One might conceivably
3 argue that these pressures could increase conscious
4 or unconscious biases that might influence the
5 recommendations for training and experience by
6 physician groups and professional societies, although
7 certainly with an overt and honest goal of maximizing
8 safety and quality of care, but with the accompanying
9 effect of preserving exclusivity.

10 Relaxing the 700-hour training and
11 experience requirement would enable clinicians outside
12 the traditional specialties to offer treatments and
13 reap financial rewards that are currently a proprietary
14 practice area that happens to come with exclusive access
15 to the resultant revenues. This is not to say that
16 members of these professional associations would behave
17 in an unprofessional or unethical manner, but simply
18 that the possibility of bias does exist.

19 While the original request to develop a
20 new alternate pathway for 35.390 drugs was related to
21 one particular drug whose use is reported to be minimal
22 for various reasons, new drugs represent a much larger
23 potential market and the ability to benefit many
24 patients. This, coupled with the reported waning of
25 nuclear medicine physicians in training, makes
26 compelling argument for considering the question of

1 a potentially more accessible, yet still safe,
2 alternate pathway, while another element of concern
3 is the very real potential for decreased investment
4 in research and development of innovative
5 radiopharmaceuticals if patient access is unduly or
6 unreasonably limited and the market for new and
7 potential drugs is curtailed due to decreasing numbers
8 of Authorized Users.

9 The pharmaceutical industry is almost
10 exclusively in the for-profit sector, and no company
11 is going to invest resources in development of drugs
12 that patients can't get to. Contributing to that
13 concern is the concentration of existing Authorized
14 Users in major medical centers and not in geographic
15 areas with only smaller community health facilities
16 or narrow geographically-restrictive insurance
17 networks. This effectively makes some therapies
18 inaccessible to patients who may be financially or
19 logistically unable to seek care in major centers where
20 traditionally-trained Authorized Users tend to
21 concentrate.

22 Next slide, please.

23 So, what we need to think about perhaps
24 is how well has the 80-hour alternate pathway in 35.394
25 worked for patients receiving iodine-131. Does the
26 significantly curtailed training and experience

1 requirement have an impact on the issues surrounding
2 patient release? Are all physicians administering
3 iodine-131, especially in the non-hospital setting,
4 adequately prepared and aware of radionuclide safety
5 issues?

6 So, I would like to move on -- next slide,
7 please -- if I may, to this related question and talk
8 about the SECY paper regarding patient release that
9 was recently released. And I would like to focus on
10 one aspect of the paper's research and recommendations,
11 which is the instructions that iodine-131 patients
12 receive, and I would like to read some relevant quotes
13 from the SECY paper.

14 Next slide, please. Oh, that's it.

15 "The data indicates that the spread of
16 contamination from patient to other persons can be
17 minimized by following instructions."

18 Next slide, please.

19 "Family members of patients receiving the
20 highest doses of iodine-131 administrations often
21 receive some of the lowest doses. This points to the
22 importance of behavior patterns and following ALARA
23 guidance and instructions provided by the licensee."

24 Next slide, please.

25 "For cancer patients, all transportation
26 exposure scenarios indicate that transportation

1 situations pose a radiation concern for members of the
2 public. And the SECY paper recommends that the
3 licensee's assessment of the patient's likely behavior
4 after release is required and necessary."

5 Next slide, please.

6 "The decision to release the patient should
7 be reviewed before starting treatment to determine the
8 conditions under which the patient is expected to be
9 released and whether the living arrangements, modes
10 of transportation, and staying at a hotel are such that
11 releasing the patient is unlikely to result in doses
12 over 5 millicievert."

13 So, those are all direct quotes from the
14 SECY paper. And it concludes that "The dominant factor
15 determining both internal and -- next slide,
16 please -- external doses to members of the public from
17 exposure to a patient that's been administered
18 iodine-131 is the behavior of the patient after
19 release."

20 Next slide, please.

21 The ACMUI Subcommittee on Patient Release
22 presented in the fall of 2017, and discussed here today,
23 recommended, and I quote, "Written and oral
24 instructions must be provided to the patient far enough
25 in advance of treatment without compromising patient
26 care to ensure that the patient has sufficient time

1 to determine whether or not he or she can actually comply
2 with the instructions and make whatever arrangements
3 may be necessary for compliance."

4 It's clear from The Federal Register
5 comments on the proposed changes to the patient release
6 rule and my anecdotal discussions with patients over
7 the years that there's uneven provision of clear,
8 timely, language-appropriate, and consistent
9 instructions to patients. And while major medical
10 centers of excellence and well-respected healthcare
11 facilities may have the resources to assure that this
12 aspect of care is performed well, patients who receive
13 care in non-hospital settings or patients who are handed
14 off to remote facilities for their radioactive iodine
15 may have less consistent access to timely and
16 appropriate instructions.

17 Next slide, please.

18 One thing the discussion has not adequately
19 addressed is the fact that the 1997 patient release
20 rule effectively allowed insurance and third-party
21 payers to refuse to reimburse for hospitalization after
22 iodine-131 therapy. And as a result, financial
23 responsibility for hospitalization in those rare
24 instances when it is necessary is left to the patient
25 or to the hospital or the healthcare facility to absorb
26 as unreimbursed care.

1 Next slide, please.

2 In addition to appropriate dose or activity
3 limits that are now considered for patient release,
4 clear and formal regulatory language for assessing
5 behavior or logistical parameters should be developed
6 to justify patient release or to justify
7 insurance-covered hospitalization, if that's required
8 to keep radiation exposure to caregivers and the public
9 ALARA.

10 Next slide.

11 It's been argued that the timing of
12 provision of these release instructions, when and how
13 to assess the likelihood of patient adherence, and when
14 to require hospitalization or delayed release is a
15 clinical and practice-of-medicine issue. I contend
16 it's a public health issue and well within the purview
17 of NRC regulation.

18 Next slide, please.

19 So, I'd like to move on to talk about safety
20 culture and the ACMUI recommendations regarding patient
21 safety organizations. There are really two basic
22 reporting paradigms. One is the identified required
23 reporting, and the other is de-identified voluntary
24 reporting. And these are really mutually-exclusive
25 paradigms. One could view these as variations of the
26 carrot-and-stick concept.

1 Slide, please.

2 The de-identified paradigm is voluntary
3 and it is seen by the medical community as non-punitive.

4 The goal is to proactively order the community detail
5 of problematic systems issues and/or events in order
6 to facilitate preemptive corrective actions based on
7 the possibility of similar occurrences in similar
8 situations. There are major strikes to this paradigm,
9 its non-punitive image. There's no downside to
10 reporting, and the goal is global education. The
11 weakness is its voluntariness. It's not clear what
12 percentage of incidents are actually reported nor how
13 often the information about events and near-misses is
14 actually accessed and used for program improvement at
15 other facilities. There's the absence of a stick here,
16 but not everyone is taking advantage of the carrot.

17 The identified required reporting paradigm
18 is seen as extremely punitive and, thus, facilities
19 are very reluctant to disclose events. This leads to
20 a culture of hiding and underreporting that's really
21 counterproductive to a process of proactive assessment
22 and preemptive correction. Healthcare facilities and
23 individual clinicians who are identified with medical
24 events or errors risk financial losses resulting from
25 lost patient volume and the related revenue or
26 disadvantaged reimbursement negotiations with

1 third-party payers. There's clearly a stick here, but
2 there's no carrot at all.

3 Next slide, please.

4 The ACMUI proposes that NRC pilot a limited
5 trial to test the effectiveness of a sort of hybrid
6 program, an anonymous, but required reporting paradigm
7 utilizing recognized patient safety organizations in
8 lieu of the existing NRC approach. Here we have the
9 stick, required reporting, coupled with a carrot,
10 anonymity, and the opportunity to participate in a
11 proactive process. And while such a trial might not
12 be easily implementable at this time, it would be
13 advantageous to try to incorporate some of the benefits
14 of de-identified reporting where possible in the NRC
15 process.

16 Thank you.

17 CHAIRMAN SVINICKI: I take it that's -- I
18 don't just take it -- that is the concluding
19 presentation of the panel. And I want to thank each
20 of the presenters again, but the Committee members as
21 a whole. I realize that the work that you have
22 presented was contributed to by many members of the
23 Committee. So, thank you all for your work.

24 By my notes, we would have Commissioner
25 Baran begin the question period, if you're ready.
26 Thank you.

1 COMMISSIONER BARAN: Sure. Thanks.

2 Well, let me echo that thanks. We really
3 appreciate your thoughts and all the work you put in
4 on this.

5 Let's start with training and experience.

6 Dr. Palestro, during our last Commission meeting
7 together, we had a good discussion about the current
8 training and experience requirements for Authorized
9 Users. And I appreciate that the Subcommittee has
10 prioritized its review of the appropriateness of the
11 requirements for alpha and beta emitters. Can you
12 update us on this effort and give us a sense of the
13 Subcommittee's latest thinking? How far along are you
14 on that?

15 DR. PALESTRO: In response to your
16 question, we are aware that the staff has to provide
17 you with an update at the end of August. So, it's our
18 intention to work closely with the staff over the next
19 several months to prepare, certainly, a preliminary
20 outline of what that sort of alternative pathway would
21 be.

22 COMMISSIONER BARAN: Okay. And you
23 talked about FDA's approval of lutetium-177 for the
24 treatment of certain neuroendocrine tumors and the
25 Subcommittee's expectation that there could be a high
26 demand for that beta emitter. It sounds like the

1 Subcommittee is now concerned that there may not be
2 enough Authorized Users to meet this demand, and that's
3 a pretty big change from the discussion we were having
4 last year. What is -- and maybe it is too
5 preliminary -- but let me just ask, what's your current
6 thinking on how we should address this potential
7 shortage of Authorized Users? Are you contemplating
8 a change to the 700-hour training and experience
9 requirements, and how does that relate to the review
10 you all are doing that's alpha and beta emitters?

11 DR. PALESTRO: The answer is not changing
12 the 700 hours because that pathway includes not only
13 the 390, but also the 100 and 200 categories, but,
14 rather, creating a very specific, very focused
15 alternate pathway limited to the use of unsealed sources
16 in the 35.390 category.

17 COMMISSIONER BARAN: Okay. So, this is
18 more of a kind of class of
19 radiopharmaceutical-specific-type approach that
20 you're contemplating?

21 DR. PALESTRO: That's correct.

22 COMMISSIONER BARAN: Okay. Well, I look
23 forward to hearing what you all come up with there,
24 and I appreciate your work.

25 Is there anything you wanted to share on
26 that? It sounds like you're still a little bit at the

1 beginning of that process.

2 DR. PALESTRO: We are at the beginning,
3 but I think that there are three components to this.

4 One is the development of the curriculum, the
5 educational program. Two, we have to define how
6 competency will be determined. And, three,
7 determining competency at one point in time is no longer
8 sufficient. There has to be a method of ensuring that
9 there is maintenance of competency over time, very much
10 paralleling what goes on in the medical field today.

11 COMMISSIONER BARAN: Okay. Thanks.

12 I also want to ask about medical event
13 reporting. In 2017, there were 43 medical events
14 reported. There were 50 in 2016 and 57 in 2015. So,
15 as Dr. Dilsizian pointed out, that's a pretty low number
16 compared to the millions of procedures performed each
17 year. And it's good that that number is low, as long
18 as we're getting good, complete reporting.

19 I heard the concern expressed that NRC's
20 reporting requirements are viewed as punitive and may
21 encourage Authorized Users to hide medical events.
22 Do you think there is widespread noncompliance with
23 our medical event reporting requirements?

24 DR. DILSIZIAN: Shall I take that? Well,
25 to answer the last question, we won't know that. I
26 don't think we can guess that.

1 But we do know that in other models of
2 patient safety culture, when you allow residents, for
3 example, to report that their hours are longer than
4 what agency generally requires, when you have a safety
5 culture, you do see more events being reported. But
6 we don't know whether that applies to us directly.

7 I just want to address a couple of points,
8 if I may. One is that, while we realize that the event
9 rates are low relative to the number of procedures that
10 are being performed, however, I think we should not
11 accept no change; that the NRC should actually see a
12 decline over time. If you look at the number of years,
13 it's always been in that range. But we should actually
14 see a decline, and, hopefully, the goal should be zero.

15 And so, where is the educational part of this, so we
16 can just be very happy with these numbers? But I think
17 we should have a higher goal. And any patient who is
18 being inappropriately treated, it should be that there
19 should be some teaching point that should be present.

20 That would be one of the recommendations we would like
21 to recommend.

22 COMMISSIONER BARAN: I definitely agree
23 with that as a basic goal. I guess the question is
24 how we get there. You know, one way is to actually
25 have a situation in which medical events are occurring,
26 and another way is to define a certain number of medical

1 events away, so that the number goes down. And I think
2 the former is a much better way to get to zero.

3 As I understand it, the Committee is
4 suggesting that NRC pilot a change, and the idea is
5 that licensees wouldn't report medical events to NRC
6 right away, like they do now. NRC would no longer post
7 the event reports on our website for the public to see.

8 And if we did post them, we redact the licensee's name
9 to keep that information from the public. And then,
10 NRC would only conduct a reactive inspection if someone
11 died or was permanently harmed or needed to be treated
12 as a result of the medical event. Is that a fair summary
13 of the proposal?

14 DR. DILSIZIAN: Well, again, I will just
15 take a more moderate view of that, in that there are,
16 for example -- I mean, I will give one example. When
17 you take a patient post-thyroid-surgery, and if there
18 is an isolated node, the medically-indicated
19 therapeutic range is between 100 millicuries and 150.

20 So, if you have a prescribed dose of 120 and the
21 individual gets 145, on the regulatory says that's above
22 20 percent, that should be reported as a major event.

23 From the medical perspective, that's the therapeutic
24 range of treatment. So, the patient actually got the
25 proper treatment. From the regulatory perspective,
26 that's a major mishap.

1 Now I'm not saying it shouldn't be it is
2 a mishap; that it should be researched as to why is
3 it that nobody paid attention to 20 percent; why did
4 they miss it? That's fair. But does it require the
5 high impact of immediate inspection, reporting? And
6 that's where we're trying to balance it. We're trying
7 to balance what is an error that's acceptable medically
8 versus clearly unacceptable and the patient did not
9 get the proper treatment as medically indicated.

10 COMMISSIONER BARAN: Well, I take your
11 point and I understand the point you're making there.

12 And I like to think of myself as an open-minded person.

13 And I say this with great fondness and respect. But
14 this struck me as a really terrible idea, what you are
15 proposing here.

16 The notion of the reactor oversight process
17 being kind of a model for this was discussed, but this
18 is not at all how the reactor oversight process works,
19 how you're describing this. We don't require a
20 radiological event to kill or injure someone before
21 conducting an inspection. All of our inspection
22 reports are online unless they include sensitive
23 security information. Non-emergency reactor events
24 are reported within one hour or four hours or eight
25 hours, depending on the situation. So, elements of
26 what you're proposing are like the opposite of what

1 we do in the reactor oversight process.

2 As I understand this, under the proposed
3 approach, NRC wouldn't even conduct a reactive
4 inspection if you had a series of over- or
5 underexposures at a facility as long as no one ended
6 up either with no fatalities or serious injuries, or
7 something that required immediate treatment.

8 So, I said a lot there, and I want to give
9 you all a chance to respond to that. Obviously, I'm
10 pretty skeptical about this as a pilot even. I don't
11 see how the benefits would accrue to the public of this
12 type of approach. But let me give you a chance to answer
13 whether I'm missing something here or you think I'm
14 being unfair or you think I'm mischaracterizing what
15 is being proposed.

16 DR. DILSIZIAN: No. No, I think you're
17 being fair. I think that the Committee is not ready
18 to tell you what is a low impact at this time. I think
19 to characterize it that we're not going to report
20 anything except for if someone dies --

21 COMMISSIONER BARAN: Right.

22 DR. DILSIZIAN: -- I think is the extreme
23 view. That's not what we are proposing.

24 We are saying there are gradations of
25 impacts, and that perhaps, for encouraging people to
26 report without the consequences of this being a major

1 event, if it wasn't, we should have an alternate way
2 of reporting. We haven't defined that yet. And as
3 you know, there's Y-90, there's I-131. There's all
4 these different procedures.

5 If it's agreeable, obviously, you have to
6 be given the charge to go into it. If not, then we
7 can maintain it the way it is. We are simply trying
8 to address what hasn't changed for many years. Maybe
9 it's a good thing. Maybe nothing needs to be changed.
10 But we were asked to address that issue.

11 COMMISSIONER BARAN: Okay. All right.
12 Well, we're not voting on anything today. You could
13 mark me down for a "don't pursue it".

14 (Laughter.)

15 But I appreciate your response, and please
16 take my comments the way they are intended, which is
17 just having the respectful discussion about this as
18 an idea, it was not an idea that struck me as a good
19 one. But maybe others have different views. So, thank
20 you.

21 CHAIRMAN SVINICKI: Well, thank you, and
22 let's hear from someone right now who has a different
23 view.

24 (Laughter.)

25 This is the way --

26 COMMISSIONER BARAN: Is the way it's

1 supposed to work.

2 CHAIRMAN SVINICKI: -- it's supposed to
3 work, and we talk about this before Congress and others.

4 We compliment them on their wisdom of having a
5 Commission structure on these difficult issues. It's
6 the same reason why we have a committee structure, so
7 that you all can provide your views. There can be this
8 kind of give-and-take. And I actually appreciate very
9 much my colleague's very candid reaction, and these
10 kind of patient house issues are something that aren't
11 entirely familiar terrain for 90 percent of what we
12 do here. So, I struggle with some of the same things.

13 On this particular issue, I might be struggling with
14 a different subset of issues.

15 But let me begin again by thanking you all
16 for the work that you do, which is very, very valuable
17 to me in getting my arms around these issues. And a
18 lot of the things we regulate, all the consequences
19 fall so squarely within our own regulatory
20 jurisdiction. This one I think is more complicated
21 because it has a connection to the practice of medicine,
22 to health care. And, therefore, we try to make good
23 decisions and have consequences that are predictable
24 and not have consequences to patient health that fall
25 so far outside what we expected. So, your input is
26 very helpful to us in trying to predict what that range

1 is.

2 I did want to just comment on the overview
3 slide about the composition of individuals on the
4 Committee, the vacancies, and the little asterisk to
5 say that security clearances are pending. I just want
6 to clarify for anyone listening that that is a system
7 wide issue. It has, to my knowledge, zero to do with
8 the very wonderful individuals that we are attempting
9 to push through that process. It's becoming somewhat
10 chronic and there's a lot of delay in that system.
11 So, I appreciate the patience of individuals on the
12 Committee with the long timeframes that that can take.

13 And so, again, we need the expertise. So, please don't
14 give up in frustration. It's not unique to the
15 particular individuals, and I just wanted to clarify
16 that.

17 I appreciate, also, that you've looked at
18 communications issues and how it is that you can be
19 most effective in engaging both the Commission, the
20 NRC staff, and your broader community of practitioners
21 to try to bring a diversity of views back to our
22 deliberations. The uniqueness about the ACMUI is that
23 you are, many of you, I think, to a person, current
24 practitioners of the areas of expertise. I would
25 contrast this with some other government advisory
26 committees where, if individuals are actively involved,

1 they're not supposed to be giving advice because of
2 conflict of interest. It is one of the reasons why
3 the ACMUI engages with the NRC staff and is not an
4 advisory committee to the Commission directly. But
5 I view that as the benefit of your advice is that you
6 are current practitioners and these are rather dynamic
7 areas, but it does, as a result, lead to things, I think,
8 as Ms. Weil pointed out very eloquently, is there a
9 tension of interest there? Is there kind of a push
10 and pull, conflict of interest, and other things? So,
11 we take that in and balance that upon receipt of the
12 advice.

13 And the patient access concerns is
14 something that I have focused on. This is the first
15 time in the years I've served here that ACMUI has
16 reported, again to my memory, on these trends of lower
17 numbers of -- both lower numbers of residency programs
18 and lower number of practitioners going into some of
19 the specialties. Is there any broader contributors
20 to that that we're just not aware of, as the Nuclear
21 Regulatory Commission? Is it a particularly
22 non-lucrative field or something like that? I mean,
23 what do you, if you had to at least hypothesize some
24 contributors to those declining numbers, what do you
25 think they are?

26 MR. ZANZONICO: I think there are numerous

1 factors involved. I would say -- and again, this is
2 my own personal opinion -- that regulatory issues are
3 at the very bottom, the least significant of all of
4 those factors. I think probably one of the most
5 important contributing factors has to do with
6 economics. If you look at the average hospital across
7 the country, there simply isn't a sufficient enough
8 volume of nuclear medicine procedures to justify the
9 presence of a full-time nuclear physician. And I think
10 that's the biggest issue.

11 For example, there are six people,
12 including myself, in my Division of Nuclear Medicine,
13 but we also are responsible for 12 sites, including
14 nine hospitals and three outpatient facilities. And
15 I would say that, if you look at the numbers in terms
16 of how they're measured today, that's a sufficient
17 volume to support the six of us.

18 CHAIRMAN SVINICKI: And that gets to the
19 heart a little bit of why I asked the question about
20 the broader contributors. Because although regulatory
21 issues may not be a contributor to the decline, they
22 may be a very fruitful way to address and try to offset
23 the effect of the decline. So, I took your
24 recommendations about areas to evaluate and look at
25 in that spirit, meaning not that regulatory burdens
26 contributed to the decline, but should we look at the

1 regulatory framework to provide some offsetting effect
2 in terms of patient access? And I take the Committee's
3 recommendations in that spirit and think that that's
4 worth us taking onboard and thinking about.

5 On the patient release, I also have served
6 on the Commission long enough to know that this is
7 something that I think we're circling again to and
8 reevaluating, and I think there's benefit in that, of
9 course, because things change over the course of time.

10 But, Dr. Zanzonico, your slide 9 with the
11 conclusion that a patient staying at a hotel following
12 radionuclide therapy is not a widespread practice,
13 there are, of course -- and the Committee is well aware
14 of this -- constituencies that disagree with that very,
15 very violently. So, what I think is helpful, and that
16 the Committee has taken a look or once again taken a
17 look, at a survey of licensees' understandings of where
18 patients are going upon their release. Of course, that
19 is as good as the licensees' awareness of and the
20 patient's willingness to be forthcoming with their
21 practitioner about where it is they are going.

22 But, again, it has been, I won't say
23 frustrating, but I've had no great ideas on how we could
24 resolve the kind of belief set of constituencies that
25 this is a widespread thing. And yet, when we go and
26 look at it systematically, or the Committee looks at

1 it, we're not finding that. So, I don't know if there
2 is a disconnect there and what it is, but I appreciate
3 that that constituency is very, very well-motivated
4 on this point. And so, I appreciate that they certainly
5 know why they observe this. And our ability to bring
6 that into alignment is just something that I'm short
7 on ideas of how to do that, I think. I appreciate the
8 Committee having looked at it and looked at the licensee
9 survey and, then, of course, the NRC staff will evaluate
10 that as well. So, that's just a little bit of
11 commentary.

12 I just wanted to point out that we don't
13 have that constituency here on the Committee, so they're
14 not presenting anything today. But I want them to know
15 that the Commission is well aware that there's a
16 different view out there about that. How to resolve
17 it, I'm not sure, but I think we can just stay open
18 and keep taking in the data as we find it.

19 So, let me turn to medical event reporting.

20 In my time here, I've even had votes that are publicly
21 available where I have been forthcoming about how I
22 struggle with knowing that medical event reporting -- a
23 medical event does not necessarily indicate any kind
24 of adverse health outcome or even a probability of or
25 even a low probability. It is a very binary thing.

26 And so, when I read about the comparisons

1 to the reactor oversight process, maybe I came at it
2 more simply. At first, I had to think about it for
3 a minute, but, then, my thought was the reactor
4 oversight process has a graduated set of escalations
5 of things. And I took your comparison to be more about
6 that than necessarily kind of a consequence-based.
7 But the medical event reporting is, once you hit the
8 threshold, it's completely divorced from the
9 probability of an adverse outcome and, as we've heard
10 today, can even be the appropriate therapeutic range.

11 And so, I am not a medical practitioner.

12 I've been a patient and I have loved ones that have
13 had cancers that have some of the therapies that you
14 all talk about. And I try to stay current on just what
15 any average person should know about health care.
16 There is increasing research, although I don't purport
17 to be an expert on it, on the health effects of chronic
18 low-grade stress. So, when we add to the stress of
19 a patient who is receiving these therapies, may have
20 compromised immune system, may have other things, the
21 chronic low-grade stress of being told that there was
22 a medical event in their treatment, I can't imagine
23 that that's a positive health outcome for that patient
24 or their loved ones. And I've spoken to this in votes
25 that I've filed, of how I struggle with this. It sounds
26 like you can just tell people this doesn't mean

1 anything; don't be upset, until it's your loved one
2 or you're the patient, and I think you feel it very,
3 very keenly.

4 So, I looked at the pilot proposal, and
5 I can acknowledge this much today: it is the
6 Committee's creative kind of thought process of how
7 could you take a carrot, take a stick, to use Ms. Weil's
8 terminology, but how could you foster an environment
9 where at least the likelihood of covering up something
10 or not reporting it, or being in noncompliance with
11 the regulations, was significantly diminished? And
12 therefore, that could do two things. You would learn
13 a lot more and, second of all, you might create that
14 learning culture that you could get back to those
15 practitioners.

16 But I did join this Commission early in
17 the time when there was national controversy over a
18 practitioner at the Veterans Administration and a large
19 number of administrations. So, I know the deep concern
20 that that can cause. So, I'm not ready, and we're not
21 voting today on anything. And I don't know, but I think
22 the notion of setting some thresholds and having
23 different processes, again, parallel to the ROP, having
24 a graduated set of regulatory responses, is perhaps
25 worth thinking about.

26 And I confess this is my view because I've

1 struggled with this over the years of just the trigger
2 is so absolute on these medical events. And when I
3 follow this later and see, you know, a year later, two
4 years later, did we ever have a report of an adverse
5 health outcome, I don't -- if I've seen any, they're
6 so few that I can't really even remember them, and the
7 onslaught of the ones where there was no adverse health
8 outcome.

9 So, I have -- as I tend to do at these,
10 because I find this all so very
11 thought-provoking -- I've said a lot. Is there anyone
12 who would just quickly -- I'm a little over my time -- but
13 maybe, Ms. Weil, would you like -- I've referred to
14 your presentation. Is there anything that you would
15 like to add? I'm fascinated by your work, and really
16 you've presented a number of times. Thank you. You
17 struggle, I think, with the most philosophical aspects.

18 So, they are both the most interesting to me, but also
19 the toughest.

20 With that, does my colleague have anything
21 further?

22 COMMISSIONER BARAN: Can I just two
23 minutes? I'm curious on patient release. From the
24 presentation, it sounded like the Subcommittee's view
25 was -- and maybe the whole Committee's view was -- yes,
26 instructions should be provided well in advance, so

1 that people can make the appropriate plans, but trying
2 to specify that in any kind of prescriptive way in a
3 regulation isn't a good idea. I got the sense that
4 you had a different view on that. Do you have, is there
5 a particular requirement there that you have in mind
6 that you see would be workable? Or is it more -- let
7 me just stop the question there.

8 MS. WEIL: Well, you know, the requirement
9 is that patients be treated as individuals and their
10 individual situations be considered in planning for
11 release. And the provision of instructions needs to
12 be individualized as well, when that happens. If
13 you're a nursing mom, then you need to know well ahead
14 of time that you need to stop nursing many weeks, months,
15 before iodine is administered. You need to plan for
16 that. If you have little kids at home and one bathroom,
17 you need time to plan.

18 The thing we struggled with is that these
19 recommendations are not iodine-specific. So, any
20 particular time provision that we recommended would
21 perhaps impact problematically on the ability of
22 clinicians to administer other radionuclides that
23 perhaps have more urgency. There isn't a great deal
24 of urgency in providing iodine for thyroid cancer
25 patients. You can wait. But, you know, there are
26 other situations where it might not be beneficial to

1 wait, and that's very hard to balance.

2 COMMISSIONER BARAN: Is that something you
3 think can be balanced well in the guidance? Is updating
4 the guidance the best way to go here, from your point
5 of view, or --

6 MR. ZANZONICO: Well, first, I would like
7 to reinforce what Ms. Weil said. There was unanimity
8 on the part of the Subcommittee and the Committee as
9 a whole that instructions can, and certainly should
10 be, provided well in advance of the treatment.

11 I would think there is also unanimity that,
12 certainly, there shouldn't be a prescriptive timeframe
13 written into regulation. That would just be too
14 ironclad, I think. And conceivably, as new
15 radionuclide therapies are introduced -- we heard about
16 lutetium-177 dotatate, and so forth -- you know,
17 additional ones on the way, that putting a number into
18 regulation could be an impediment to therapies and
19 appropriate medical care in some instances.

20 Conceivably, it could be incorporated into
21 guidance. A concern always with guidance is that it's
22 viewed, appropriately so, as best practice and, in turn,
23 has a constraining effect on actual practice. And as
24 Ms. Weil said, that is what we struggled with, to convey
25 to practitioners and licensees that they really should
26 and must provide instructions, written, oral, and so

1 forth, as far in advance of treatment as possible, but
2 at the same time not constraining treatment in instances
3 where there may be some urgency.

4 And it certainly should not be in
5 regulation, in guidance. That would be preferable to
6 regulation, but, again, that imposes some constraints,
7 some limitation, as well, we think, on practitioners.

8 So, it's a difficult issue to address, and I would
9 stop short of even personally recommending it in
10 guidance.

11 COMMISSIONER BARAN: Ms. Weil I think said
12 that your sense from over the years, and the folks you've
13 talked to, is that there's kind of a wide spectrum of
14 practices in this regard. Some people are doing it
15 exactly the right way and some not so much, and people
16 have less time to really get prepared.

17 I mean, as a Subcommittee or Committee,
18 is there some sense about, well, how do you meaningfully
19 address that kind of breadth of practice in the area,
20 so that you have more people providing more time for
21 folks to make the appropriate plans? So, regulations
22 on one end of the spectrum, it sounds like that you
23 don't think that's a good idea. I could see the
24 argument there. Guidance is kind of moving this
25 direction. I guess presentations at medical
26 conferences or something, maybe it's further down.

1 Do you have a sense of what's -- I know
2 it's tricky, but how do you strike the balance on that,
3 so you have an improved practice in this area without
4 doing something that's going to constrain?

5 MR. ZANZONICO: Well, I think even without
6 specifying some numerical timeframe --

7 COMMISSIONER BARAN: Yes.

8 MR. ZANZONICO: -- by specifying very
9 emphatically that there is a need, a requirement, for
10 providing written and oral instructions well in advance
11 of the treatment, I think that would impact prospective
12 users as well. Because I think, as Ms. Weil has said
13 at times, and unfortunately, as we know, sometimes
14 patients who are about to receive some radionuclide
15 therapy, immediately prior to the administration of
16 the therapy are told for the first time that there are
17 some applicable instructions. I mean, that's
18 unacceptable.

19 So, including even in guidance and even
20 regulation, but without a specific numerical timeframe,
21 that instructions must be provided in advance, and as
22 far in advance as practical of the treatment, would
23 have an impact as well.

24 Also, in terms of variability of
25 instruction, we certainly know that's the case as well.

26 That's why I referenced the model procedure and NCRP

1 Report No. 155, which really addresses not only the
2 issue of releasability of patients, but of post-release
3 precautions, and so forth.

4 So, I think regulation and/or guidance can
5 make an impact on that without the necessity of
6 specifying a specific time interval.

7 COMMISSIONER BARAN: Okay. Thank you.
8 Thanks.

9 CHAIRMAN SVINICKI: All right. Again,
10 thank you all for your presentations today.

11 And Commissioner Baran and I will now
12 conclude our public meeting.

13 Thank you very much.

14 (Whereupon, at 11:20 a.m., the meeting was
15 adjourned.)

16

17

18

19

20

21

22

23

24

25

26