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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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MEETING

+ + + + +

THURSDAY,

APRIL 27, 2017

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The meeting was convened in room T2-B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., Philip Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

PAT B. ZANZONICO, Ph.D., Vice Chairman

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

RONALD D. ENNIS, M.D., Radiation Oncologist

SUSAN M. LANGHORST, Ph.D., Radiation Safety
Officer

DARLENE F. METTER, M.D., Diagnostic Radiologist

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

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

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JOHN H. SUH, M.D., Radiation Oncologist

LAURA M. WEIL, Patients' Rights Advocate

NON-VOTING: ZOUBIR OUHIB

NON-VOTING: RICHARD GREEN

NRC STAFF PRESENT:

DANIEL COLLINS, Director, Division of Material
Safety, State, Tribal and Rulemaking Programs

JOSEPH NICK, Acting Deputy Director, Division of
Material Safety, State, Tribal and Rulemaking
Programs (MSTR)

DOUGLAS BOLLOCK, ACMUI Designated Federal
Officer

MICHELLE SMETHERS, ACMUI Alternate Designated
Federal Officer and ACMUI Coordinator

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

MICHAEL FULLER, NMSS/MSTR/MSEB

VINCENT HOLAHAN, Ph.D., NMSS/MSTR

SOPHIE HOLIDAY, NMSS/MSTR/MSEB

ESTHER HOUSEMAN, OGC/GCLR/RMR

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

MANUEL JIMENEZ, NRR/DRA/ARCB

MINH-THUY NGUYEN, RES/DSA/RPB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

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

TORRE TAYLOR, NMSS/MSTR/RPMB

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JOHN THORP, OIG/AIGA

MEMBERS OF THE PUBLIC PRESENT:

BETTE BLANKENSHIP, American Association of
Physicists in Medicine (AAPM)

MICHAEL CALLAHAN, CCMSC Corp

CAITLIN KUBLER, Society of Nuclear Medicine and
Molecular Imaging (SNMMI)

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

JOSEPHINE PICCONE, Independent

CINDY TOMLINSON, American Society for Radiation
Oncology

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P R O C E E D I N G S

8:00 a.m.

1
2
3 CHAIRMAN ALDERSON: Good morning. I
4 would like to call us to order. We started on time.
5 This is the second day of the meeting of the ACMUI. The
6 first item on the agenda for this morning is medical
7 event reporting for all modalities, other than
8 permanent implant brachytherapy and John Suh will
9 present this report.

10 DR. SUH: Thank you, Dr. Alderson. So,
11 I'm going to be presenting Medical Event Reporting for
12 All Modalities Except Permanent Implant Brachytherapy.

13 Next slide, please. I would like to thank
14 the various subcommittee members who are listed here on
15 this slide. Also, I would like to thank Dr. Katie Tapp
16 for her assistance as well and other NRC staff. Next
17 slide.

18 So the subcommittee charge, which was
19 formed in October 2015, was to propose the appropriate
20 criteria for medical event reporting for events other
21 than permanent implant brachytherapy. Permanent
22 implant brachytherapy medical events were addressed
23 previously by the ACMUI. Next slide.

24 So the rationale is that over the past 15
25 years, medical event reporting has not changed

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1 significantly and given the advances in imaging,
2 nuclear medicine, radiation oncology, the current
3 definition may not be sufficient for authorized users
4 and regulators and may result in ambiguity. Next
5 slide.

6 To give some statistics in terms of number
7 of medical events annually, the annual number of events
8 is extremely low, considering that an estimated 15
9 million diagnostic and 150,000 therapeutic procedures
10 utilizing radioactive materials or byproducts and
11 performed annually in the United States. Next slide.

12 So to give some perspective in terms of
13 number of medical events from fiscal year 2013 to fiscal
14 year 2015, you can see that the number of medical events
15 in each of the subcategories has remained very low and
16 approximately 40 to 50 per year.

17 So in terms of number of medical events,
18 does this accurately reflect the true number of cases
19 if the current definition may be ambiguous? And does
20 the current process, which is perceived by some to be
21 punitive, and also causes some urgency, given the fact
22 that the notification has to occur within 24 hours, a
23 written report has to be done within 15 days, and there
24 is this perception of possible harm being done to the
25 patient, does this lead to the desired goal of

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1 transparency, education, and adoption of best
2 practices?

3 In terms of some of the guiding principles
4 of the subcommittee, the medical event reporting should
5 allow for identification of a medical event and provide
6 a forum to discuss how to avoid and/or reduce the
7 likelihood of such an event.

8 In addition, the definitions of medical
9 event need to be broad, simple, and consistent, so that
10 reports are easily applicable by the authorized user,
11 evaluable by regulators, and process-focused in order
12 to eliminate any ambiguity.

13 In addition, the subcommittee believes
14 that any proposed change should not be overly
15 prescriptive and must not encroach on the practice of
16 medicine.

17 Furthermore, the focus of medical event
18 reporting should be focused on education and
19 improvement, rather than punitive action. And this is
20 really to foster a just culture of quality and safety.
21 And the fact that there are 7,000 medical licensees
22 between the NRC Agreement States, this is very
23 important.

24 In terms of medical event criteria, there
25 are a number of modalities that would need to be covered

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1 if there is any change towards medical event reporting,
2 ranging from high-dose brachytherapy, Gamma Knife
3 radiosurgery, the use of low dose rate temporary
4 implants, interoperative modalities, various radiation
5 oncology modalities ranging from two dimensional
6 therapy all the way to very sophisticated,
7 high-precision stereotactic procedures, and also
8 selective internal radiation therapy or yttrium-90.

9 And so one of the considerations was
10 whether or not the consideration of subsections would
11 be appropriate. In keeping with the principle keeping
12 things broad, simple, and consistent, we felt that this
13 is not pragmatic.

14 If one looks at the current definition of
15 35.3045, there are clear medical event reporting such
16 as wrong dose, wrong route of administration, wrong
17 patient, wrong mode, leaking sealed source, and total
18 radiopharmaceutical dose that deviates greater than 20
19 percent.

20 If one looks particularly at radiation
21 oncology, one may question whether or not the current
22 definition may cause ambiguity because we prescribe to
23 a volume rather than to a point. And if you look at two
24 of the definitions, total dose to the treatment site
25 differs from prescribed dose by 20 percent or more; or

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1 single fraction dose to treatment sites differs from
2 prescribed dose by 50 percent or more, one could
3 question whether or not this should be changed, given
4 some of the spatial shift that can occur when treating
5 high doses of high precision radiation. I will discuss
6 in the next slide why the committee felt that we should
7 not be having a modification to this definition.

8 In addition, intervention by patient or
9 human subject in which the administration of byproduct
10 material or radiation from a byproduct material results
11 or will result in unintended permanent functional
12 damage to an organ or a physiological system as
13 determined by a physician is further being discussed by
14 the ACMUI.

15 If one looks at the definition of 35.2, the
16 current definition of treatment site means the
17 anatomical definition of the tissue intended to receive
18 a radiation dose, as written in the written directive.

19 Since the written directive gives the
20 authorized user a great deal of flexibility, this may
21 be a potential source of ambiguity as treatment site can
22 have different meanings among authorized uses.

23 We had a discussion of whether or not this
24 should -- the treatment site should be changed to
25 treatment volume or target site but, given the variation

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1 in terms of how one may define target volume or target
2 site, despite reports from various organizations such
3 as the ICRU, the feeling was that treatment site was
4 sufficient.

5 Furthermore, if you looked at further
6 reports from task groups such as the AAPM,
7 standardization and consistency of target nomenclature
8 is actually not easily achieved.

9 So the recommendations are that the new
10 definitions for permanent implant brachytherapy be
11 utilized; continue the use of current 10 C.F.R. Part
12 35.3045 for definition of medical event reporting for
13 all modalities except permanent implant brachytherapy.
14 The ACMUI is discussing patient intervention at this
15 time.

16 We encourage major societies to issue a
17 white paper to develop consensus on what should be
18 incorporated into a written directive for various
19 diagnostic and therapeutic modalities. We believe
20 that the benefit of a white paper would help with
21 inspection and regulation by promoting standardization
22 for identifying medical events, would assist licensees
23 to determine if a medical event has occurred, and would
24 assist institutions to develop standard operating
25 procedures to prevent future medical events.

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1 We hope that a white paper would increase
2 awareness and education, and instill best practices in
3 various organizations, and create the culture of safety
4 where the best and most effective therapies are
5 available for patients.

6 Thank you.

7 CHAIRMAN ALDERSON: Thank you, Dr. Suh.
8 So this report is now open for discussion from the ACMUI.
9 Comments, questions? Dr. Zanzonico.

10 DR. ZANZONICO: This is just a minor point
11 but in the current definition there is a reference to
12 permanent damage. I am wondering if something less
13 permanent like long-term damage might be more
14 appropriate. And what I am specifically thinking of is
15 an instance where there may be unintended high-dose
16 irradiation of the gonads. And for example even in
17 I-131 treated patients with hundreds of millicuries,
18 reproductive function is impaired for one to two years
19 but it does recover but I mean that could be a
20 consequence of a medical event.

21 For example, if a patient was supposed to
22 get a tracer dose and got a therapy dose instead of
23 I-131, I was wondering if there is some value in
24 replacing the word permanent with long-term to try and
25 capture those possible events.

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1 DR. SUH: I mean that is a consideration.
2 In my mind, the word permanent would make the medical
3 event a more serious consequence and, as a result, the
4 use of the word permanent is something we should still
5 consider in the definition.

6 DR. ZANZONICO: Yes, I mean I'm kind of
7 ambivalent about it in the sense that when you use a term
8 like long-term, what is long-term? Permanent is pretty
9 absolute and pretty clear but you introduce some
10 ambiguity with a term like long-term. So that was just
11 a question.

12 CHAIRMAN ALDERSON: Dr. Ennis would like
13 to comment.

14 DR. ENNIS: So I mean that term is only in
15 the patient intervention aspect of the definition,
16 which is kind of under consideration elsewhere. The
17 regular parts of the definition don't, at this point,
18 incorporate anything having to do with permanent
19 damage.

20 DR. ZANZONICO: Yes, I'm ambivalent.

21 CHAIRMAN ALDERSON: Yes, Sue -- Dr.
22 Langhorst.

23 DR. LANGHORST: Well one thing that has
24 always bothered me about written directives is written
25 directives, while some people may consider them

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1 prescriptions, written directives are designed for
2 regulatory control or regulatory review.

3 A radiation oncologist wants to be as
4 precise and exact in how they want this treatment to be
5 done on this patient. A medical physicist wants to get
6 it just perfect but we know we can't reach perfection,
7 especially in the human body. And so what a
8 prescription is and what a written directive is don't
9 meet up. Written directive you want to have it be
10 somewhat loose so that you can meet the regulatory
11 requirement but it doesn't meet the prescriptive part
12 of what that physician wants to ideally do. And that's
13 always the frustration I've had in looking at these two
14 things that just don't mesh up.

15 Sorry, I just had that opinion.

16 CHAIRMAN ALDERSON: Dr. Suh, would you
17 like to respond to that opinion before we go to Dr.
18 Ouhib?

19 DR. SUH: Sure. So I agree that the
20 written directive is a catchall versus a prescription,
21 which you want to be as precise as possible. You know
22 that being said, from the subcommittee our thoughts were
23 we should consider having the societies give some
24 direction in terms of what should constitute a proper
25 written directive, to perhaps become a little more

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1 prescriptive but, at the same time, not impacting on the
2 art of medicine because, again, in terms of how in
3 certain department, for instance, one radiation
4 oncologist may have a certain way of writing the written
5 directive versus another physician. So I think it is
6 very important to offer that platitude.

7 That being said, it is also important that
8 there is some guidance and some standardization in terms
9 of how that is done to try to minimize safety -- to
10 maximize safety and minimize errors from occurring.

11 DR. LANGHORST: But I don't think the
12 written directive is there for safety. It is there to
13 show your regulatory compliance. Your prescription is
14 what you're trying to do to maximize the benefit of
15 treatment and minimize the other potential risk to the
16 patient.

17 I just think that there is a difference
18 there and we have to recognize that a written directive
19 is not a catch-all. A written directive is to show to
20 the regulators that you've administered this
21 radioactive material in accordance with the physician's
22 directive.

23 CHAIRMAN ALDERSON: Thank you, Dr.
24 Langhorst.

25 Dr. Ouhib.

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1 MR. OUHIB: I fully understand where Susan
2 is coming from; however, I can tell you based on our
3 experience the written directive and prescription are
4 merging. There has been a paradigm shift, actually,
5 and when you look at even at say the APAC's
6 accreditation, ASTRO, for instance, there are
7 expectation but it is not from the regulatory. It is
8 from the practice guideline what is expected. And for
9 the brachytherapy team, for instance, we have sort of
10 shifted away from the word prescription. They said we
11 need the written directives here. But the written
12 directives help the whole team understand what is
13 supposed to be done, how, what is needed, and so on and
14 so forth. That has really changed the mentality that
15 my gosh, where have we been. This is really good
16 information in the written directives and we need to
17 continue doing this.

18 So I think we are seeing a shift and people
19 are moving away from prescription and talking about
20 written directives because they see the benefit of such
21 a thing.

22 DR. LANGHORST: I understand that. But
23 are the regulators, do they understand what all you're
24 putting in there? I mean a written directive is just
25 that for the regulated compliance to review that.

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1 I agree you guys are going to hey, this is
2 how we should do this. This is best for the patient and
3 so on. Are you getting too descriptive in what that is
4 so that anything outside that an inspector could say
5 well you didn't do it in accordance with what was written
6 here?

7 I mean that is the difficulty I see, that
8 you want to go for the ideal, the best you can get, and
9 make sure everybody understands it. And I guess it is
10 how you define written directive. And I understand
11 where you're coming from but I think there is confusion
12 as to what -- how people use a written directive and how
13 they define this stuff.

14 So I applaud the efforts and the suggestion
15 of white paper that describes some of these more -- what
16 were you saying -- to make it more consistent among
17 practitioners but it shouldn't be too prescriptive.

18 CHAIRMAN ALDERSON: Dr. Ennis would like
19 to comment again.

20 DR. ENNIS: So I think that was a really
21 good insight into the tension that we were really
22 struggling with because I think you are right, they are
23 conceptually slightly different but we are using one
24 thing to do both.

25 So are you suggesting then that we should

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1 think about having two separate things, a written
2 directive and a prescription? That's not how things
3 happen in practice and that will certainly be a
4 challenge. Otherwise, there is always going to be this
5 inherent tension.

6 DR. LANGHORST: No, I'm not suggesting
7 that but I'm just -- I want to recognize that there is
8 different purpose and the regulatory purpose is just to
9 say did you do it in accordance with what the physician
10 directed. And so do you make that a little more not so
11 descriptive so that you don't have trouble meeting the
12 compliance aspect? But then how do you make sure your
13 team knows exactly what you want done? And so that is
14 the conflict that I see and I don't have a good solution
15 for it.

16 CHAIRMAN ALDERSON: Are there further
17 comments about this issue or this report? Yes, Laura.

18 MS. WEIL: Just I was astounded at the
19 numbers you quoted the number of procedures and the
20 number of medical events. And I just have to point out
21 that you're talking about a rate of .0003 percent of
22 medical events per -- which is astoundingly low. It is
23 astounding. And that we spend so much time on the
24 concept of medical events and medical event reporting
25 and it is such a teeny-weeny number.

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1 CHAIRMAN ALDERSON: Dr. Langhorst.

2 DR. LANGHORST: I wanted to ask you, Dr.
3 Suh, about kind of along the lines that Ms. Weil is
4 discussing. How does this expectation of a physician
5 compare to other medical practices? I mean is there
6 anything out there that has such strict reporting
7 requirements? Are these too much? Are they just
8 right? Are they way overboard? I mean I think this is
9 what surprises a lot of physicians that try to come into
10 this type of practice of all the responsibilities, all
11 the regulatory responsibilities that they personally
12 are responsible for. Thank you.

13 DR. SUH: So there is no question that, in
14 terms of the safe and effective delivery of radiation,
15 there is a great deal of scrutiny and there is a very
16 high bar. So the expectation is that there is extremely
17 high performance. We want to do what is safe for the
18 patient, make sure we protect the public, et cetera. So
19 I think the bar has been set very, very high.

20 So if you look at other medical specialties
21 where we know errors can occur in terms of wrong site
22 surgery, wrong drug delivery, et cetera, it is not under
23 the same scrutiny.

24 That being said, my personal opinion is
25 that we should continue to strive to provide the safest

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1 most effective therapy possible for all patients. And
2 if one looks at medical event reporting, I would say
3 probably about ten percent of the reports that we see
4 annually could have been easily avoided by doing a
5 universal time out -- patient name, birth date, site
6 delivery.

7 So I think we still have a ways to go in
8 terms of getting that number even lower. So even though
9 the percentage is very low, as Ms. Weil pointed out is
10 .0003 percent, which is terrific --

11 MS. WEIL: Three zeros.

12 DR. SUH: -- it is something that we should
13 continue to strive to look for it.

14 And also in terms of the definition of --
15 and I completely agree with Mr. Ouhib -- in terms of the
16 written directive and where the prescription is going,
17 I do see that it is becoming more and more aligned to
18 how that is now. Whether or not that is the intention,
19 I think it is the right thing to do because at the end
20 of the day, as you mentioned, there are some differences
21 in how one radiation oncologist may prescribe in
22 volumes, if you look at where the tumor is, not just
23 where the tumor is but what I may consider areas at risk
24 or what the planning should be. There is going to be
25 some variation. In fact even some protocols among the

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1 national experts there is differences. If you go to
2 meetings, there are classic slides where you show once
3 you draw up what you think is the volume and there can
4 be quite a bit of variation among 15 experts.

5 So I think there needs to be some latitude
6 but, at the same time, there is no question that certain
7 medical events, such as delivering the drug to the wrong
8 patient, wrong site, giving excessively high doses of
9 radiation, those are clear medical events and I think
10 we still need to have that very high level of performance
11 from authorized users.

12 CHAIRMAN ALDERSON: Yes, Mike Fuller.

13 MR. FULLER: Thank you, Dr. Alderson.
14 Yes, this is Mike Fuller. I will just offer one
15 perspective sort of from the regulator's point of view
16 is that while we also see this divergence -- I mean I'm
17 sorry convergence, if you will, of the written directive
18 and the prescription, it was kind of, I don't want to
19 say by design, but when this -- and Donna-Beth lived
20 through this more than I did -- but back in the day when
21 this all first got started, the expectation was that
22 things would be written. So the key word there was
23 written. And that was the problem that needed to be
24 solved at the time was that there was a lot of
25 instructions being given to allied professional staff

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1 from the physician that were not written down. So that
2 was really the big problem that was needing to be solved.

3 One of the things, though, that we tend to
4 focus on from a regulatory perspective and the way that
5 we believe that we have been able to avoid impacting the
6 art of medicine, as Dr. Suh mentioned, is with the
7 tolerance. And I think most folks would agree that when
8 we have medical events reported to us, those are the
9 events where a tolerance which would not be acceptable,
10 I wouldn't think, to any radiation oncologist or
11 physician has been exceeded by quite a bit. So when we
12 say plus or minus 20 percent, that tolerance is such that
13 I think everyone agrees is unacceptable.

14 So those are the two things I would just
15 offer as a perspective from the regulator's point of
16 view is that the key being on things being written down
17 and the key -- and also a recognition that the
18 tolerances, in other words when written directives are
19 required to be reported, they have gone, the actual
20 administered dose or dosage is such that it is, I think
21 most reasonable people would agree that it has been
22 exceeded by too much.

23 And then, of course, the other criteria
24 about which something is reported I think everyone would
25 agree, too, is wrong patient, wrong radionuclide, and

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1 so forth and so on.

2 And so I just offer that as a perspective
3 and so that when the written directive and the
4 prescription it seems like through the process seems to
5 be converging, you could actually have a procedure that
6 didn't exactly meet the expectations of the authorized
7 user but it still wouldn't be a medical event. It may
8 be a lot of those that were not reported and shouldn't
9 be.

10 So, I just offer that.

11 DR. LANGHORST: I would say yes, we agree
12 that those types of situations are not wanted and you
13 want to evaluate those and correct whatever caused that
14 circumstance but should it be the NRC imposing that or
15 should it be the physician, the organization they are
16 working under and evaluating on a general patient safety
17 situation?

18 CHAIRMAN ALDERSON: Yes, Dr. Ouhib.

19 MR. OUHIB: Just to go back to what Dr.
20 Langhorst had said regarding the written directives and
21 all that, to the best of my knowledge, the regulators
22 have certain expectation what should be in the written
23 directives. There are certain items that they expect
24 to see there. And if those are there, that's good
25 enough.

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1 It is also up to the institution to perhaps
2 add whatever they feel is appropriate or needed in terms
3 of putting in the written directives that you want to
4 do ultrasound prior to do your APPI case and make sure
5 that the rad onc is notified and all that. That is up
6 to the institution to add there but they are not held
7 by the regulators that did you do the ultra sound. That
8 is not part of their job, basically. That's
9 institution. But the regulators are looking for okay,
10 what isotope are you using? What is your dose
11 prescription? What is the, and so on and so forth.

12 So I think, personally, I don't mind having more
13 items in the written directives because probably they
14 would only help patient safety and patient care. But
15 in the same token, as long as we are meeting what the
16 regulators are expecting, that's fine.

17 CHAIRMAN ALDERSON: Are there any more
18 comments about this report?

19 Well, thank you Dr. Suh, that was a very
20 interesting discussion and I certainly encourage you to
21 pursue the white paper idea and this idea of actually
22 using time out and other certain procedures as a part
23 of these therapies.

24 Thank you very much.

25 DR. LANGHORST: Is there a written report

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1 for this? Yes, so we have to approve the written
2 report.

3 DR. SUH: There is a written report. It
4 should be in your handouts.

5 DR. LANGHORST: Yes.

6 CHAIRMAN ALDERSON: Is there a motion?

7 DR. ENNIS: So moved.

8 CHAIRMAN ALDERSON: There is a motion. Is
9 there a second?

10 DR. ZANZONICO: There is.

11 CHAIRMAN ALDERSON: Is there discussion?

12 All in favor?

13 (Chorus of aye.)

14 CHAIRMAN ALDERSON: It's unanimous. It
15 is approved.

16 All right, the next --

17 DR. PALESTRO: Regarding the written
18 reports, yes, Training and Experience had a written
19 report yesterday.

20 CHAIRMAN ALDERSON: Ah, that we did not
21 approve.

22 DR. PALESTRO: We did not --

23 CHAIRMAN ALDERSON: -- formally approve.

24 All right. I'm sure that you've all read it and are
25 familiar with it.

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1 Is there a motion that someone would like
2 to make?

3 DR. METTER: So moved.

4 CHAIRMAN ALDERSON: There is a motion --

5 MS. WEIL: Second.

6 CHAIRMAN ALDERSON: -- and a second to
7 approve. Is there further discussion?

8 All in favor, please raise your hand. Oh,
9 that's right, they can't prove it. Right.

10 Very good. It's unanimous. It is
11 approved.

12 All right, we're ready for the next report
13 and ahead of schedule right now. This is the Patient
14 Intervention Subcommittee report. Dr. Dilsizian.

15 DR. DILSIZIAN: Thank you very much.

16 This is a topic that ACMUI has addressed in
17 the past and we were charged to clarify Issue II
18 recommendation from our prior 2015 recommendation.
19 And this is to determine whether the NRC staff can
20 actually implement our Issue II recommendation. So our
21 subcommittee members listed here met again on a
22 conference call and we discussed the issue.

23 And just to kind of review what the
24 background is of the issue, patient intervention means
25 actions by the patient or human research subject,

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1 whether intentional or unintentional, such as
2 dislodging or removing treatment devices or prematurely
3 terminating the administration.

4 The 2002 Final Rule states that a licensee
5 shall report any event resulting from intervention of
6 a patient or human research subject in which the
7 administration of byproduct material or radiation from
8 byproduct material results or will result in unintended
9 permanent functional damage to an organ or a
10 physiological system, as determined by a physician.

11 The 2014 proposed rule made no changes
12 regarding patient action. However, the question was
13 brought up what about unintentional treatment outcome
14 not related directly to the patient action. And what
15 we meant by that was that patients could have anomalies,
16 anatomical or physiological, that tend to not follow the
17 directions that you wanted to do as your planned goal.
18 And does that constitute, therefore, a patient
19 intervention. Again, this would be a passive rather
20 than an active patient intervention, if you will.

21 And so our committee discussed this in 2015
22 and we made recommendations. However, Mike Fuller very
23 nicely, in the last presentation, said what is the
24 problem that we are trying to solve because he felt that
25 this issue was actually addressed. And the way the two

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1 points that he made was that Mr. Costello's presentation
2 in March of 2015 was concerning particularly about Y-90
3 microspheres specific to the issue as well you can have
4 the patient's artery contracts and so that when you are
5 administering the spheres, it can actually go
6 retrograde into the GI artery and then you have got a
7 gastric ulcer and symptoms related to that or you can
8 have lung shunt fraction that was calculated
9 predetermined but then by the time you treat the patient
10 things might have changed and, therefore, the shunt will
11 have been larger and then the outcome will have been not
12 as predicted.

13 And so Mike's point was well we addressed
14 this in February 12, 2016 revision, where we put an
15 exception made for shunting when shunting was evaluated
16 prior to the treatment in the course of the
17 manufacturer's procedures and also exception was made
18 for emergent patient conditions that might prevent the
19 administration according to the written directive.

20 And so the 2015 Issue II recommendation we
21 are talking about relates to all treatments and not
22 limited to Y-90 treatments. And so the point that we
23 were trying to make there was that an unintentional
24 treatment outcome due to anatomical or physiological
25 anomaly and/or some imaging uncertainty falls into the

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1 category of the art of medical practice, providing that,
2 obviously, the standards of medical practice are met by
3 the physician.

4 And so we thought about this long and we
5 came to the conclusion that even if we were to report
6 these treatment outcomes, they are unpredictable and
7 unavoidable because it is really patient specific. It
8 can't be generalized to the global patient population.
9 It will not help to prevent such events in the future
10 and, therefore, cannot be regulated. And if not
11 regulated, we didn't think it should be reported. That
12 was the thought process.

13 So Mike said well what is the problem that
14 we are trying to solve? Well, again, we revisited this
15 and this seems to keep coming back to us. And well it
16 is an event. What we just described would have been a
17 medical event but it is not a violation because it is
18 a passive patient-specific event. However, if we don't
19 report such medical events, it is considered a
20 violation. So it is a very delicate balance here.

21 And so we said well, what's wrong with
22 reporting medical events? Why not just report it?
23 Well, if you do, there are perceived negatively in the
24 medical centers that there was actually error, even
25 though it is a passive medical event.

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1 So, that's the issue that we have been
2 trying to struggle with -- events versus medical errors.
3 And again, in our minds, a medical error would be what
4 we've heard a number of times where there is a
5 misadministration or the wrong grade of pharmaceutical,
6 the wrong patient, time out was not done, clear
7 violation of procedure where the wrong thing was
8 performed.

9 On the other hand, if you we're talking
10 about some unintentional treatment outcome that is due
11 to some anatomical or physiological anomaly, that is
12 really an event and we don't think that that should be
13 really reported because that would be perceived as if
14 it's a medical error and that has all these consequences
15 in the medical centers.

16 That is the balance that we've been
17 struggling with. And so what is the solution? Well,
18 I mean I don't know if we are going to redefine events
19 and errors, that is something we are going to have to
20 discuss as a group but one thing we would recommend is
21 that we can learn from these events, if you will. And
22 I think the best way to report events is in a registry,
23 where you track these things, say how often it is
24 happening. Where is the trend? Is it more often over
25 time? Identifying the problem, reporting it to the

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1 medical community, corrective action. There is a
2 feedback loop, constructive improvement, learn from the
3 mistakes. This would be less punitive and it would be
4 seen more as an educational protocol, rather than be
5 perceived that the physicians are doing something wrong
6 within their institution.

7 So that is the conclusion is that in
8 summary, our recommendation was not limited to Y-90.
9 We are trying to think about generally speaking. And
10 we are trying to, again, differentiate between events
11 and errors, which is a very fine topic and maybe we can
12 re-discuss this as a group.

13 CHAIRMAN ALDERSON: Thank you, Dr.
14 Dilsizian.

15 Are there comments, questions? Yes, Dr.
16 Zanzonico.

17 DR. ZANZONICO: So I think it was a very
18 reasonable presentation and this distinction between
19 medical events and undesired outcomes is an important
20 one. But I really question the value of a registry. As
21 valuable as the information may be in a certain context,
22 you know my perception is that practitioners don't read
23 the regulatory literature. And it is requiring more
24 reporting, requirements on behalf of practitioners and
25 hospitals. I mean practitioners read their

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1 literature, the peer review journals. They go to their
2 respective meetings and they read their society
3 guidelines but my perception is they don't read the
4 regulatory literature for improvements, or advances, or
5 whatever in medical practice.

6 So I'm thinking that the additional time
7 and effort and so forth for maintaining a registry, as
8 valuable as it might be in a certain context, does it
9 really justify in the regulatory context? That's just
10 a comment.

11 CHAIRMAN ALDERSON: Dr. Ennis.

12 DR. ENNIS: I think what we're saying is
13 what is now defined as a medical event, as patient
14 intervention, should instead, so it's not creating a new
15 regulatory thing, it is just changing the way the
16 regulatory process should go, but instead of that being
17 a medical event should, instead, go into some kind of
18 registry.

19 So we're not creating a new burden. We are
20 proposing, the subcommittee is proposing that that
21 definition of medical event as patient intervention
22 when it's passive not be a medical event but be called
23 something else, medical error or whatever, and go into
24 a registry as opposed to the regular medical event
25 process.

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1 DR. ZANZONICO: So what I'm thinking is
2 most of what are being called medical events should be
3 eliminated altogether as a reportable item. Other than
4 correctable mistakes, wrong dose, wrong patient, wrong
5 mode of administration, et cetera, et cetera, anything
6 that even borders on patient intervention, anatomic
7 anomaly, some unforeseeable change in patient condition
8 between a pretreatment evaluation and the actual
9 treatment, I think any such thing should be eliminated
10 altogether as a reportable event and that would
11 eliminate the need for the registry. And all that
12 should remain as reportable events or however
13 everything else is characterized are correctable
14 mistakes. And to me that is the intention of the
15 medical event, to allow practitioners who commit the
16 mistake and otherwise to avoid those mistakes in the
17 future. But anything bordering on patient
18 intervention I just think is outside regulatory purview
19 and should be eliminated as a reportable item.

20 CHAIRMAN ALDERSON: Mr. Ouhib.

21 MR. OUHIB: Yes, I'm not sure about I would
22 agree with that. I guess the decision we based, are we
23 learning anything from those events that are being
24 reported. And if we are learning something, then they
25 should be reported in a sense. However, I'm hearing an

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1 issue of perception. How is that perceived by the
2 community, by the institution itself, by colleagues, by
3 whatever? Is there a possibility of having something
4 unintentional event, medical event? So, therefore,
5 then now it falls in a completely different category,
6 per se, but I think there is still a benefit in learning
7 exactly what happened.

8 I would be interested that when someone is
9 doing a new modality, all of a sudden there was something
10 that was unexpected and never happened but all of a
11 sudden we are seeing it. And then all of a sudden
12 somebody says well, guess what, yes, it happened to me,
13 too.

14 Just a thought.

15 CHAIRMAN ALDERSON: Dr. Langhorst.

16 DR. LANGHORST: The question is not
17 whether you report it or not. The question is whether
18 you have to report it in the regulatory space versus
19 whether you report it in a practice of medicine space
20 where you can do process improvement for patient safety.

21 So, it's not that you don't report it, you
22 don't share it. Is there a different mechanism than it
23 be in the NRC Agreement State regulatory space?

24 MR. OUHIB: Yes, I would have to agree,
25 assuming that with the majority of people participating

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1 in a PSO, you know so that way that information is
2 available to all users or the majority of the users.
3 That would be great. But if it is reported to a small
4 group or I'm not sure where, now is that information only
5 available to a certain number of people or is that
6 available to all users?

7 DR. LANGHORST: Well, we have been
8 discussing over several years how NRC information and
9 Agreement State information isn't publicly available
10 either. So the reporting that is happening in the
11 regulatory space isn't getting out there for process
12 improvement purposes.

13 CHAIRMAN ALDERSON: Mr. Ouhib, you just
14 used an acronym. I would like you just to explain it.
15 PSO?

16 MR. OUHIB: Yes, Patient Safety
17 Organizations.

18 CHAIRMAN ALDERSON: Thank you.

19 MR. OUHIB: And that's where people are
20 basically reporting their events.

21 CHAIRMAN ALDERSON: Right, thank you.

22 Other comments or questions? I have a
23 question.

24 DR. ZANZONICO: Can I just --

25 CHAIRMAN ALDERSON: Yes.

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1 DR. ZANZONICO: Yes, I just want to say Sue
2 said it much more eloquently than I did but that was my
3 point, that not that these events should not be
4 reported. They absolutely should. The question is
5 where do you get the most bang for your buck reporting
6 and to me it's not the regulatory literature. You know
7 I'm sorry to disappoint the NRC but practitioners don't
8 pour over the regulatory literature. They read their
9 respective peer review journals. They go to their
10 meetings and so forth. And that's where you get the
11 most value out of report and the dissemination of this
12 sort of information.

13 DR. DILSIZIAN: And I agree with you. I
14 think that where I would go is case reports. I mean that
15 is where -- I mean we don't look at the regulatory
16 information. We look for it at the journal and there
17 is an interesting case report that an event occurred,
18 that is where I learn things.

19 And I think I am with you to leave this in
20 a medical journal arena, medical community arena,
21 rather than regulatory.

22 CHAIRMAN ALDERSON: If I can clear my
23 throat, there is a question that I would like to ask that
24 falls into the area of the improved communications that
25 we're trying to develop.

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1 In this particular case the question has to
2 do -- we are, in this report, and we are discussing
3 changing a definition that exists. And so the question
4 I have is with respect to the NRC what would be required
5 to actually do that. I mean we are having a theoretical
6 discussion as if we could just say snap our fingers and
7 that would be gone. But what would actually be required
8 to change what exists now to the sorts of things that
9 have been recommended?

10 MR. BOLLOCK: Right. And I think it's
11 important that, Mike and I we have had discussions on
12 this, the regulatory perspective I think obviously I
13 think is key in the discussion on this topic.

14 But to answer your first question, to
15 change our definition as is and what is required, in
16 order to change that, that is a rule change.

17 CHAIRMAN ALDERSON: That's a rule change.

18 MR. BOLLOCK: Right. However, now the
19 regulatory perspective on a medical event and then our
20 requirements. So under our rules if it reaches it in
21 the criteria of 35.3045, it has to be reported.

22 And one of the things that can be reported
23 as to perspective is if you know it, the cause is patient
24 intervention, that can be part of the report. And then
25 everything that follows after that is that, in itself,

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1 at that point the institution that has reported it has
2 met their regulatory requirement.

3 We understand this discussion has been
4 going on for years. We understand the real world.
5 When a report comes out, we have inspectors and the
6 States have inspectors that like to go out and inspect.
7 And it's not that they like to do it, there is a very
8 -- you know how our process works as regulators, we can't
9 be at every institution, at every licensee at all times.
10 It is not like it is with the power plants; we have
11 resident inspectors.

12 So there is periodic inspections to kind of
13 spot check to ensure the people follow regulations and
14 that the use of byproduct materials is done safely in
15 our view. I mean that is just -- that is the best way
16 we can do it with the resources we have available. And
17 unfortunately, when an event comes in, these are rare,
18 that means inspectors go out to look. It is just enough
19 of a reason for our inspectors, the State inspectors to
20 go out and look at the -- and inspect and look through
21 and make sure the regulations are all met.

22 So from that point on -- I mean we
23 understand that, in itself, can cause heartache and
24 headache for the licensees. But that is our
25 regulations. That is our job. That is our role. We

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1 have, federal government has the authority to do all of
2 these things. And you know we as a regulator, that is
3 what we do.

4 CHAIRMAN ALDERSON: So that is not a
5 surprising answer but I think it does put into context
6 the kind of discussions we're having and it leads to a
7 corollary question.

8 So if our esteemed colleague, Frank, were
9 still with us, it was he more than any other who used
10 to say put it in guidance space. So could you in fact
11 take some suggestions like this and put them into
12 guidance language?

13 MR. BOLLOCK: So that's -- and I hate to
14 push it back. How we currently have it without any
15 change to regulations, it would still be required to
16 report as a medical event. If you do know that, if you
17 think the cause is patient intervention, that could be
18 in the report and that helps the licensees. They have
19 their reasons for it and, at that point, that is what
20 it is.

21 Guidance or kind of questioning the
22 recommendations asking for some other kind of
23 reporting, if you are getting us involved in that, it
24 is not any different than what is happening now.

25 If it is a database of information that we

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1 are controlling, that is information that, again, our
2 inspectors have to say okay, something has happened
3 here. We spot check or we appear to see and then kind
4 of spot checks based on any other information we have.
5 Here's something that happened, we are going to go out
6 and observe resources.

7 CHAIRMAN ALDERSON: Mike Fuller would like
8 to comment and I know two other people --

9 MR. BOLLOCK: Yes, and I know Mike is very
10 -- yes.

11 MR. FULLER: So Doug is right but I would
12 like to kind of bring this back to some of the earlier
13 discussions about perception.

14 We hear a lot and have for many, many years
15 from the medical community and I think absolutely
16 justified that when we go into a -- we call them reactive
17 inspections. When we do a reactive inspection because
18 of a medical event has been reported, that that is viewed
19 as punitive, even though that is not our perspective.
20 Our perspective is, again, our stated purpose for why
21 medical events have to be reported and so that we
22 understand them and then we can well, first of all, find
23 out what was the root cause. And if it turns out to be
24 the root cause is the weakness in the program, then you
25 don't have compliance with a different rule, which is

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1 that you must have policies and procedures in place to
2 ensure that these don't happen.

3 Now, that's not 100 percent of the time
4 because quite often, and I don't know what the
5 percentages are but it is very high, we go and do a
6 reactive inspection. We look at everything. We look
7 at the circumstances, and we see that there was no
8 violation. So in our way of thinking, again, back to
9 perspectives, there was nothing punitive about that.
10 But I also really, really understand that from the
11 medical community's perspective and certainly that
12 authorized user, that entire process was punitive.

13 So that's, I think, where the tension is and
14 where the rub is.

15 Now to answer your question specifically,
16 Dr. Alderson, does it take rulemaking, I believe that
17 it does and it could be done in one of two ways. We could
18 redefine the term patient intervention. That's one
19 place we could do it. Or we could just go to the medical
20 event reporting criteria and add a category that say
21 would exclude these sorts of thing in some general way.

22 So I think it is a foregone conclusion it
23 would require rulemaking and we can't issue guidance in
24 that sense. Now, the way we have worked around this in
25 some of the more emerging technologies is recognizing

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1 that for a particular technology that might not be
2 mature, there are certain things -- and this is what we
3 do with yttrium-90, as everyone knows, is we recognize
4 that these things are common occurrences to the shunting
5 and the arterial spasms, so on and so on. So we said
6 we don't want every one of those reported; there is not
7 a value in that.

8 So I think if we just stay focused on what
9 is the purpose for reporting medical events and what is
10 the value to everyone -- one of the things Dr. Langhorst
11 said, you know our NMED is not public and that is
12 absolutely true. But our job is to, even though the
13 rate of these reports is very, very low, our job is to
14 examine these, analyze these, look for trends, or look
15 for something that is so important that shouldn't
16 happen. We want to make sure it doesn't happen in other
17 places. So we will issue, and we have many, many times,
18 issued what we call generic communications, information
19 notices and things like that and that's how we get the
20 word out.

21 But you are absolutely right, it is not
22 every single time; we don't provide that feedback. So,
23 anyway --

24 CHAIRMAN ALDERSON: Thank you.

25 We have hands raised by Dr. Palestro and Ms.

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1 Weil. Dr. Palestro.

2 DR. PALESTRO: Yes, I have a couple of
3 comments. Number one, while the regulatory literature
4 may not be as widely perused by practicing physicians
5 as the medical literature, you know there is really
6 nothing that precludes an individual from not only
7 reporting it directly with the authorities but they are
8 publishing it as well. They are not mutually
9 exclusive.

10 So to me, that's not a valid argument for
11 eliminating or changing a definition of medical events.

12 With respect to the concept that a medical
13 event is viewed as punitive, talking about yttrium-90,
14 for example, even assuming that this is patient
15 intervention, the end result can be a severe
16 complication, as we all know, and that's going to come
17 to the institutional authorities, regardless of what
18 it's called. And any sort of review, investigation is
19 going to be perceived by the AU and everybody involved
20 is punitive.

21 So, again, I'm not sure that changing the
22 definition necessarily makes it any less of a quote,
23 unquote punitive approach. In one case it is viewed as
24 punitive by the regulatory or because it is coming from
25 regulatory. In the other case, it is viewed as punitive

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1 because it is coming from the institutional
2 authorities, risk management and so forth.

3 CHAIRMAN ALDERSON: Ms. Weil.

4 MS. WEIL: I wonder if NRC can do a better
5 job of communicating with healthcare institutions about
6 the purpose of the investigation that follows these
7 kinds of medical events. And framing it explicitly in
8 this punitive language or somehow diffusing this
9 perception that it is necessarily punitive. Perhaps
10 the outcome of the investigation will be such that it
11 is punitive because an actual error was made, as opposed
12 to just an inadvertent result of passive patient
13 intervention.

14 CHAIRMAN ALDERSON: Let's get a view, Mr.
15 Bullock.

16 MR. BOLLOCK: Yes, and Mike can add to this
17 or correct it but when our inspectors go to the sites,
18 there is an entrance brief based on the purpose of why
19 they are there and that is when those discussions would
20 occur. And then there is an exit with the appropriate
21 licensee staff and what the inspectors have found and
22 any prospective findings if there are potential
23 violations, things like that. So those discussions do
24 happen. It is in our process for the entrance and exits
25 when they do arrive for that type of discussion.

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1 Now, the depth of that discussion, I mean
2 we do train our inspectors and we have expectations that
3 they are clear on inspection on who they are talking to,
4 why they are there, and they would be able to answer
5 those questions or give that -- they will explain that.
6 That is an expectation. The inspectors are trained.
7 They are trained well. That's feedback. We can
8 continue to encourage that with our inspectors and the
9 State's. We can absolutely do that.

10 And I think Donna-Beth, Dr. Howe may be able
11 to add.

12 CHAIRMAN ALDERSON: Dr. Howe.

13 DR. HOWE: This question came up a number
14 of years ago and Sue is right, the NMED is not publicly
15 available but the events that are reported to the NRC
16 are publicly available on a daily basis. And you have
17 to monitor every day.

18 And so one of the things we did was the
19 medical community said not all medical events create
20 harm for the patients. So we have a disclaimer now on
21 those events that are reported every day in NRC's event
22 reporting system available on the web that says a
23 medical event does not necessarily mean harm to the
24 patient but could mean an issue at the institution for
25 its radiation safety program. So we have put a

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1 disclaimer to essentially make sure people don't
2 immediately assume that there is harm to the patient.

3 The other thing one has to understand is
4 that our medical event reporting criteria will catch
5 things that cause harm to the patient but our threshold
6 is low and our threshold is low so we catch these
7 precursor events. But as you see from our report, we
8 have millions, hundreds of thousands of medical
9 procedures every year. We have 50 medical events. It
10 is very low and I think that is a message that this
11 community is doing well to keep it low.

12 CHAIRMAN ALDERSON: There were other
13 people who wished to comment. Is that still true? Dr.
14 Ennis.

15 DR. ENNIS: So this is kind of leading into
16 what we are going to report later on today about safety
17 culture. I'm kind of wondering whether we should just
18 -- my comments are more aligned with that. So maybe
19 I'll just wait for that discussion.

20 CHAIRMAN ALDERSON: Very good. Mr.
21 Ouhib.

22 MR. OUHIB: And that is exactly where I was
23 going, too. But I might mention and what Mr. Fuller
24 just mentioned here, those are items that they are
25 really opening opportunities to actually try to change

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1 that perception of being punitive and all that. So you
2 recognize there is an issue. Let's jump on this and
3 come up with something that is going to be embraced by
4 the medical community but also, in the same token, it
5 is an opportunity for NRC and regulators to actually try
6 to change perhaps that image, how it is being perceived
7 and how and so on and so forth.

8 So I think let's grab these opportunities.

9 CHAIRMAN ALDERSON: Right. So we do have
10 a chance this afternoon that Dr. Langhorst will lead a
11 discussion with the title Medical Event Report and
12 Impact on Safety Culture.

13 So I would suggest that if we have comments
14 about that aspect, which is virtually what we're talking
15 about anyway, maybe we should save them until this
16 afternoon.

17 Dr. Langhorst.

18 DR. LANGHORST: One of the things in
19 medical event report and I agree with Dr. Howe that the
20 bar is set very low to find these precursor events but
21 what is frustrating is that the time line is so fast and
22 this goes back to Dr. Suh's presentation.

23 You have 24 hours -- well, next calendar
24 day, excuse me not 24 hours, that you have to report.
25 Now is that when the event occurs and then you have to

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1 report or do you have time to evaluate whether this was
2 a medical event or not or do you have to do that within
3 that calendar day?

4 And then there's a 15-day written report.
5 And part of that 15 days is when your inspector is coming
6 in and you're spending time making sure they are seeing
7 all the regulatory portion and they're looking only at
8 NRC Agreement State regulations. They don't consider
9 anything -- they do but I mean the regulatory aspect,
10 they are focused on this aspect. They are not focused
11 on the total patient safety.

12 So that's the more frustrating thing of if
13 this isn't that emergent, I mean it could be, but if it
14 isn't that emergent, you don't have time to even put
15 together you evaluation and that's what's frustrating.
16 And you have to complete your written report within 15
17 days. So maybe that's where there could be some change
18 in that it doesn't have to be a reporting that it's that
19 quick or that it's evaluated. And then once you have
20 decided it is a medical or found it's a medical event,
21 you report it.

22 The other thing, and I just wanted to
23 clarify with you, I mean you have patient intervention
24 and it says then it's not a medical event, the licensee
25 doesn't have to report that. If the NRC then later

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1 comes back and says no, we think it's a medical event
2 because you didn't prove it was patient intervention,
3 then that's when you get the violation.

4 So that's another kind of confusing thing
5 because there is very easy patient intervention you can
6 show but then with the unintentional that you are
7 talking about, I mean how do you even identify that?

8 But if everything else went right, that's
9 what happened. So, thank you very much.

10 CHAIRMAN ALDERSON: Thank you. So we will
11 have an opportunity to pursue this further this
12 afternoon.

13 Are there any other comments this morning?
14 This is a written report, too, so we will, I think, have
15 to approve this written report, which is very much, as
16 Dr. Dilsizian gave his verbal report to us. Is there
17 a motion to that effect?

18 DR. ZANZONICO: I just wanted -- just from
19 the regulatory point of view, in Dr. Dilsizian's
20 presentation and in the subcommittee report, they were
21 suggesting the creation of this sort of registry. I
22 mean is that -- would not that also require rulemaking
23 because it is something different than what appears in
24 the regulations themselves?

25 MR. BOLLOCK: And actually, if you were

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1 going to approve the report, we would need -- if it is
2 -- I don't know if it is clear who is to create this
3 registry and then what the expectation -- is it to
4 replace medical events? Well then it would have to
5 replace 35.3045, which would take rulemaking.

6 If it is something that the community is
7 controlling and a recommendation that you all reach out,
8 that is some kind of clarification that we need from your
9 report if we are going to be able to take action on that.

10 CHAIRMAN ALDERSON: Okay.

11 MR. BOLLOCK: So that is some clarity that
12 we would need for us to do that.

13 DR. DILSIZIAN: I can address that. I
14 think our sense was this being a medical community
15 issue, not a regulatory issue. As we clearly stated
16 that we can't regulate something that occurs
17 occasionally and you meet in some patients. I would
18 assume that this registry would not be under the
19 auspices of NRC regulatory.

20 CHAIRMAN ALDERSON: Are you suggesting
21 that the report needs to be amended to state that fact?

22 MR. BOLLOCK: Just clarification. And I
23 was looking at the report. I just want to make sure that
24 I'm on it with the report.

25 Right.

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1 MR. FULLER: If you could just put it on the
2 screen the recommendation slide, I think that --

3 MR. BOLLOCK: Yes, and I'm looking at --

4 MR. FULLER: Just to clarify that
5 recommendation.

6 MR. BOLLOCK: Right.

7 DR. DILSIZIAN: Yes, we put it in
8 quotation, as you can see the registry.

9 MR. BOLLOCK: Right. Yes.

10 DR. DILSIZIAN: That's why we were just
11 suggesting something like a registry.

12 MR. BOLLOCK: Right, exactly. I have the
13 written report, the draft report in front of me.

14 So it says establish a registry of
15 unintended -- it goes through just like the slide. So
16 it is unclear who would develop the registry. If it is
17 us, what are the other -- yes, if we were to develop this
18 in replacing of our current reporting, replace the
19 current reporting is rulemaking. If it is creating a
20 registry and there is some differences to it, it is work
21 that we have to do, we would need more guidance of what
22 the expectations from the community would want in that.
23 And we would also have to consider resources to create
24 this registry.

25 So, that needs some clarification.

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1 CHAIRMAN ALDERSON: So Dr. Dilsizian, did
2 you just not say that your intention was for this to be
3 in the medical community, rather than the NRC?

4 DR. DILSIZIAN: Yes, correct. That would
5 be my recommendation.

6 Second, I think I agree that one thing would
7 be that not to report at all because the reporting
8 itself, if it brings in the NRC and regulators in and
9 it appears that there has been a major medical error is
10 what we're trying to prevent.

11 This slide is meant to simply say that we
12 can track and trend, if you would like, to make sure that
13 this is not a common occurrence. And it may be there
14 is an underlying problem that can be corrective action.
15 But I think in general, our feeling is that this is a
16 part of medicine. These things happen. We don't have
17 any explanation necessarily. It is a specific unique
18 problem to a patient. We can determine how often these
19 happen, track it, or we could simply say leave it to the
20 medical community and leave it at that.

21 CHAIRMAN ALDERSON: I believe that the
22 NRC's concern is the written report that we're about to
23 vote on and that it may not say that.

24 So for example, if the report said up there,
25 and I will use the slide as a reference point, it began

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1 after the title with "the medical community will create
2 a registry" and then it said the same exact thing, that
3 would be clear to the Agency about what -- that it was
4 not responsible for doing any of this.

5 MR. BOLLOCK: And then what is the
6 intention? If there is more to that, if that registry
7 -- if the intention of the registry is to replace. We
8 just want to make sure that we fully understand what the
9 committee is recommending for us to view.

10 MR. OUHIB: Isn't that what item four is,
11 reporting to the medical community?

12 DR. DILSIZIAN: Well that can happen
13 through the regulatory system or through outside
14 organizations.

15 CHAIRMAN ALDERSON: Right, it could happen
16 through the medical community, right.

17 Yes, Laura?

18 MS. WEIL: And some of these registries
19 already exist, which should also perhaps be explicitly
20 stated. It is not a matter of just creating them but
21 rather utilizing existing resources.

22 MR. BOLLOCK: Yes and the direct report is
23 one of the examples given.

24 CHAIRMAN ALDERSON: Dr. Ennis?

25 DR. ENNIS: Well, are we saying A) we think

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1 the rule should be changed so that patient intervention
2 that is passive is clearly not reportable? That's a
3 rule change if we were recommending A.

4 And then B) are we actually mandating that
5 people report it in some type of registry? I mean is
6 that our opinion? And then what is the implication of
7 our having an opinion or NRC having an opinion that the
8 medical community must? I mean they can't really do
9 that.

10 So like how do -- I'm not sure how we say
11 or are we just giving a report that will go out into ether
12 space saying we think there should be a registry but our
13 real point is rulemaking to make it not an event?

14 DR. DILSIZIAN: I think it is the latter
15 that we more or less said, that it should not be reported
16 to the NRC and that if the medical community would like
17 to know, the trending tracking is to be done in the
18 existing registries, rather than part of the NRC. That
19 was my sense of the group. Do you guys agree?

20 DR. ENNIS: I think so. But so that means
21 we are talking rulemaking to change patient
22 intervention to make it more clear about the passive
23 part. So that's a big deal. That's rulemaking.

24 And then, too, the other recommendation is
25 not a mandate from any regulatory, just the advice of

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1 the ACMUI to the medical community.

2 CHAIRMAN ALDERSON: So I think that the
3 written report should be amended to clarify these issues
4 and that probably, and perhaps you can get that done
5 today and actually work with the NRC on that so that the
6 Agency and the committee are okay with what's written
7 and it provides some kind of avenue for going forward
8 with some sort of productive action, whoever's
9 responsibility that might be.

10 MR. BOLLOCK: Yes and my staff, we don't
11 want to directly tell you what to do. We just want to
12 make sure we understand what your recommendation is so
13 that we can take appropriate action and get back to you.

14 CHAIRMAN ALDERSON: Right. So we will not
15 vote on the written report at this particular time. We
16 will wait until an amendment is offered.

17 DR. ENNIS: Question to NRC. If we were to
18 theoretically do rulemaking, is it such a possibility
19 that the rule would mandate registry in some way? Is
20 that, in theory, something that can be done?

21 MR. BOLLOCK: Yes, and Dr. Tapp may be able
22 to answer.

23 CHAIRMAN ALDERSON: Dr. Tapp.

24 DR. TAPP: This is something that I've been
25 thinking about because I have been point of contact on

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1 the report that Dr. Langhorst is going to talk about
2 later about the safety culture impact in medical event
3 reporting.

4 It is possible for us to do something, and
5 this rulemaking in past years of consideration of
6 stakeholder comments. But for us to consider
7 recommending that people report to a national standard
8 registry and it is not possible for everyone, we could
9 do almost an alternative pathway.

10 So I mean you do have options. It will be
11 possible for us to do that, if that was your
12 recommendation and going through the whole rulemaking
13 process if you find that to be the best option.

14 CHAIRMAN ALDERSON: Well this is something
15 you will have to consider as you consider the amendment
16 to the written report.

17 MR. BOLLOCK: Right if it opens up to
18 rulemaking, as Dr. Tapp just pointed out, there are all
19 sorts of options. There are things we could do.

20 CHAIRMAN ALDERSON: Yes, Mike?

21 MR. FULLER: And one comment about
22 rulemaking in general. I know because we have just come
23 through this decades-long rulemaking recently and still
24 are not across the finish line or the goal line or
25 whatever, that being said, I would not -- I would --

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1 rulemaking is important. It is, by definition and by
2 national policy and so forth, it is a very deliberative
3 process and it takes some time. However, if you believe
4 that the rules need to be changed, then we need to
5 consider changing the rules. That's what we rely upon
6 this body for.

7 And so while we're all I guess a little
8 gun-shy right now when it comes to rulemaking, I don't
9 want folks to just think that we should do everything
10 else to avoid that because it is the main tool that we
11 have to get things right.

12 So if this take rulemaking and that's what
13 you want to recommend, then the staff will be prepared
14 to accept that recommendation and do what we need to do.

15 CHAIRMAN ALDERSON: Well I think this has
16 been a very productive discussion. I would like to
17 curtail this discussion now. I'm going to hand this
18 back to Dr. Dilsizian and the committee to consider
19 amended language which could come today. And if it
20 doesn't come, it doesn't have to come today. If it
21 doesn't, then I would continue this particular issue and
22 have it on the agenda for the fall meeting, at which time
23 you would have an amended recommendation.

24 Thank you very much.

25 DR. LANGHORST: Or we could do a short

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1 teleconference on it before then.

2 CHAIRMAN ALDERSON: You still could do
3 that, too, absolutely, yes, in the interim.

4 Very good. Thank you very much.

5 Now, we find ourselves ahead on time. And
6 what I would like to suggest, but this is just open to
7 discussion, I would like to suggest just taking a brief
8 break, let's say until 20 after, eight to ten minutes,
9 and then reconvening for the ACMUI to once again just
10 kind of run through what we are going to do at the report
11 to the Commission because that's what we'll do at 10:00.

12 MS. SMETHERS: So we'll just want to head
13 over there, though at 9:30.

14 CHAIRMAN ALDERSON: Sorry?

15 MS. SMETHERS: We'll want to head over to
16 the room around 9:30.

17 CHAIRMAN ALDERSON: At 9:30, well so you
18 don't really have very much time at all, then, you're
19 saying.

20 Well I would still suggest let's take a
21 ten-minute break and we will reconvene and decide how
22 to handle ourselves from there. Thanks very much.

23 (Whereupon, the above-entitled matter
24 went off the record at 9:11 a.m. and resumed at 1:01
25 p.m.)

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1 CHAIRMAN ALDERSON: Welcome to the
2 afternoon session. We are going to hear a report from
3 Ms. Taylor of the NRC on the Part 35 rulemaking status.

4 MS. TAYLOR: Good afternoon. I'm with the
5 NMSS Office in the branch that does the rulemaking and
6 the report may be [INAUDIBLE].

7 I'm generally, I'm going to do a very brief
8 background, on the status. I will put the contacts up
9 again for people. It's been a while since we've met.
10 And then, of course, if anyone has questions.

11 So remember we had a final rule and we gave
12 it to the Commission back in June. There is the number
13 up on the slide, SEC-16-0080. It is a public document
14 and the accession number is there. I'll read it to
15 anyone that can't see it and want to write it down,
16 ML16123A342. That paper does include ACMUI's
17 recommendation, the report on that draft final rule in
18 full and then we have our response in there, too, for
19 anyone on the phone or in the audience that didn't know
20 that from before.

21 The status, it is still under Commission
22 review. We are waiting on an SRM. And once we get
23 that, we will do the final package preparation following
24 whatever direction they give us and it will have the
25 final review and approval on the paperwork reduction

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1 requirements under OMB.

2 And then we hope to be able to publish it.
3 That time period is roughly, once it gets to OMB, we are
4 roughly in the 90-day range but we hear they are a little
5 bit behind, but they could be ahead by the time it gets
6 there.

7 Just a reminder that the effective date is
8 going to be 180 days from the date of publication and
9 the Agreement States will have three years from the
10 effective date. They typically do from the date of
11 publication as well but, in this case, we're giving them
12 a little more time.

13 There are the contacts again, Mike Fuller
14 and Doug for the technical questions and myself on the
15 rulemaking process. And sorry I can't give you more
16 information.

17 Do you have a question, Mike?

18 MR. FULLER: No.

19 MS. TAYLOR: Oh.

20 MR. BOLLOCK: Mike's a contact for one
21 month.

22 MS. TAYLOR: Well, that is true. Mike has
23 decided to go and do better things and retire.

24 So no questions?

25 CHAIRMAN ALDERSON: There's a question.

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1 DR. ZANZONICO: So what are the choices of
2 what the Commission does?

3 MS. TAYLOR: They will approve it as is or
4 they can approve it with some changes. It is rare we
5 don't get edit type changes. They could ask us to
6 evaluate certain things, factor things in, or they could
7 just flat out deny it and tell us to go do something else.

8 DR. ZANZONICO: And another question, what
9 is the course of action at this point?

10 MS. TAYLOR: I can't even speculate. I
11 don't know what all kind of drop-ins they've had. I
12 don't know all their philosophies on things. We are not
13 really able to speculate.

14 DR. ZANZONICO: But they just don't rubber
15 stamp. They critically review it.

16 MS. TAYLOR: Oh, they critically review
17 it, yes.

18 MR. BOLLOCK: Yes, they are thoroughly
19 reviewing it but it is at their discretion.

20 CHAIRMAN ALDERSON: So are there other
21 questions? Here we have some, yes. Mr. Fuller wants
22 to comment.

23 MR. FULLER: Well, I'll just say this
24 because I know that staff has been dealing with this for
25 quite a while, as Torre said, and we hate to speculate

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1 and it's hard to read the tea leaves.

2 But I will share this. We have heard
3 nothing from any of the Commission offices that would
4 indicate that there is any major problems with this
5 rule. So I think it is fair to be able to say that staff
6 is not anticipating any major or direction to do a major
7 rewrite or send us back to the drawing board or anything
8 like that.

9 MS. TAYLOR: That's fair.

10 MR. FULLER: In the past when we have had
11 that sort of a situation, we would know about it well
12 in advance of getting all the letters in.

13 So, we are not anticipating any major
14 problems.

15 MS. TAYLOR: Thanks, Mike.

16 CHAIRMAN ALDERSON: Yes, Dr. Langhorst?

17 DR. LANGHORST: My question is so the NRC
18 Commissioners vote. Then, there has to be an SRM
19 written, which is that done sequentially, so the SRM
20 can't be written until the vote is in?

21 MS. TAYLOR: Right, the SRM is a blend of
22 all of the Commission questions, directions.

23 DR. LANGHORST: Right. So depending on
24 what's in there, I mean how long does it take for the
25 SRM?

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1 MS. TAYLOR: They give us a time frame
2 usually or typically or we can feed. It depends on the
3 level of effort but in rulemaking, we generally allow
4 for about 30 days to incorporate any edits, changes, or
5 what have you. If they want us to go back and do any
6 analysis, that would obviously take longer.

7 But we have roughly a 30-day window that we
8 try to do what we can --

9 DR. LANGHORST: Right.

10 MS. TAYLOR: -- unless they just inundate
11 us.

12 DR. LANGHORST: So more than likely it is
13 going to be 2018 before the rule is implemented.

14 MS. TAYLOR: At least, yes, for
15 implementation, the effective date. Yes, at least.

16 DR. LANGHORST: For NRC licensees not for
17 --

18 MS. TAYLOR: If we got an SRM next month,
19 it could be published in the fall late this year and so
20 the effective date would be in 2018.

21 DR. LANGHORST: Thank you.

22 MS. TAYLOR: Yes, we have to kind of get
23 through all that.

24 CHAIRMAN ALDERSON: Are there -- oh, yes.

25 MR. FULLER: Just in the way of

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1 information, so during that 180 days, staff's
2 anticipating and planning to do outreach, and training,
3 and webinars, and things like that, too. So that
4 180-day period is not just wasted time. We understand
5 it takes time for licensees to review everything and
6 then make changes to their programs so that they can
7 implement it. And then we are involved in making sure
8 that that process goes as smoothly as possible.

9 So we are kind of -- and of course we do a
10 lot of training on the guidance that also has been
11 drafted that everyone here has reviewed and so forth.

12 So what we are essentially doing and what
13 the 30 days also helps us with is not only getting things
14 published and going through the administrative process
15 but it also gives staff time to review all of the maybe
16 minor changes and so forth, then tweaking the guidance,
17 if need be, and putting together the webinar materials
18 and so forth, and then putting a schedule together for
19 training. So that is kind of the things the staff will
20 be doing between the time that we get the SRM and until
21 the implementation date.

22 MR. BOLLOCK: Yes, and if I can just add
23 onto what Mike is saying, those webinars and the
24 training, we will train our NRC legal staff first,
25 license reviewers, and inspectors, and then Agreement

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1 States, and then we will have webinars available to the
2 public for licensees to ask questions.

3 MS. WEIL: Just for the benefit of newer
4 members of this committee, when did you start this
5 process?

6 MS. TAYLOR: It depends on what stage we're
7 looking at. Let's see. The proposed rule was noticed
8 in July of '14. Is that right, Mike? And the comment
9 period closed in November. But there was something
10 prior to that. And prior to that, I think Mike maybe
11 you can elaborate. I know they had the Working Group
12 worked, you had some public meetings, and I'm not sure
13 of all the details here. I wasn't involved then.

14 MR. FULLER: Well and I was sharing some of
15 this with folks during lunch. And this kind of goes
16 back to my comment before lunch about don't avoid
17 rulemaking recommendations at all costs. If that's
18 what we need to do, that's what we need to do.

19 We're a little gun-shy these days because
20 of this particular rule. This rule started in the very
21 first direction we got for rulemaking from the
22 Commission was in the 2004 time frame. So, we're
23 looking at 13 years ago.

24 But as time went on -- and also we couldn't
25 do it right away because we were in the middle of

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1 rulemaking for training and experience, and you
2 remember all that fiasco. So by the time we got
3 started, the number of things that needed to be changed
4 was pretty big. And then we added the permanent implant
5 brachytherapy medical event criteria part to it, and it
6 just became bigger, and bigger, and bigger. The bigger
7 it gets, the longer it takes.

8 And then we went down a particular road with
9 permanent implant brachytherapy that the Commission
10 rejected and sent us back to the drawing board.

11 So, the lesson learned, at least from
12 staff's perspective, when we can, because we don't
13 always have control, but when we can, we need to take
14 smaller bites at the apple. And if we do that, then we
15 can get through rulemaking in a reasonable amount of
16 time. It is a very deliberative, public, involved
17 process by design but it is reasonable to do these in
18 a few years but not if we make them so big and they become
19 so cumbersome that they almost become unmanageable.
20 And that's kind of what happened to us in this latest
21 rendition.

22 So, Ms. Weil, thank you for that question
23 because I just don't want folks to believe, going
24 forward, that we should always avoid. I mean,
25 obviously, if we can avoid rulemaking, we should or if

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1 it is not necessary. But sometimes if you want what you
2 want and it is going to require rulemaking, then tell
3 us because that is what we rely upon the ACMUI for.

4 CHAIRMAN ALDERSON: Any further comments
5 from the audience? Anything? Others?

6 All right, well thank you very much.

7 MS. TAYLOR: Thank you.

8 CHAIRMAN ALDERSON: And we'll move on,
9 well ahead of schedule here, to the next part of the
10 program, Medical Event Reporting and Impact on Safety
11 Culture. Dr. Langhorst.

12 DR. LANGHORST: Thank you.

13 So, I'm going to ask has everybody read the
14 draft report? I really hope so because I want to try
15 to go through this quickly so we have plenty of time to
16 discuss.

17 So I will remind you the charge to the
18 subcommittee is to explore the impact of medical event
19 reporting and its impact on self-reporting or safety
20 culture, identify potential ways to improve
21 effectiveness of self-reporting in support of culture
22 of safety, and suggest ways to share medical event
23 report and lessons learned with the medical community
24 to promote safety.

25 First off, I want to thank my subcommittee

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1 members. And please forgive me, it breaks my heart that
2 Frank is not here but I thank him very much.

3 So last fall, we started our effort with
4 some of the PSOs, some of the patient safety
5 organizations, and others who are gathering and
6 analyzing medical event and other patient safety
7 information. I felt that was important because we had
8 a lot of new committee members and plus, the last time
9 they reported, they were just getting started and I was
10 very interested to see how they had progressed.

11 Following that, our subcommittee really
12 felt it would be a good idea to bring everybody up to
13 speed on where we have been, what things have been
14 developing, what things have been developing outside of
15 NRC regulatory space, and what are the options currently
16 available at this point in time. So, I appreciate my
17 subcommittee's patience as we were putting that
18 altogether and their very helpful comments in making it
19 the document that it is right now.

20 Oh, I forgot I did this. So, we want to do
21 -- we want to talk about medical use and patient --
22 excuse me, the medical use and patient exposure is
23 different than occupational and public use; the history
24 of medical use regulations; development of safety
25 culture and patient safety programs, especially in

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1 healthcare organizations; and then I want to end this
2 meeting today with exploring the need of us trying to
3 find alternatives to medical event report, should we
4 decide they are necessary, and have our subcommittee
5 then take that information from the discussions today
6 and delve into those a little bit more and develop a
7 report on what it would take to propose those changes.

8 Sorry, I forgot I did all this.

9 Let me remind everybody the fundamental
10 principles of radiological protection. The principle
11 of justification, any decision that alters the
12 radiation exposure situation should do more good than
13 harm. That is so easy to relate in a medical
14 environment. I mean physicians are supposed to do more
15 good than harm in their treatment of their patients.

16 The optimization of protection, the
17 likelihood of incurring exposure, the number of people
18 exposed, and the magnitude of their individual doses
19 should all be kept as low as reasonably achievable,
20 taking into account economic and societal factors.
21 Don't ever forget taking in those economic and societal
22 factors.

23 We have seen some of this in radiology and
24 the Image Gently and Image Safely Programs on the
25 imaging, on the x-ray imaging systems. And we see this

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1 also in trying to be more precise in targeting our
2 therapies to just impact the cancer cells and save the
3 good cells as much as possible.

4 And then the principle of dose limits, the
5 total dose to any individual from regulated sources and
6 planned exposure situations, other than medical
7 exposures to patients should not exceed appropriate
8 limits specified by the commission and, in this case,
9 it is the International Commission on Radiological
10 Protection.

11 So, we were reminded I think earlier today
12 that before the NRC there was the Atomic Energy
13 Commission. And it was in 1957 that the first Part 20
14 was published. And in the first Part 20, medical use
15 was explicitly exempted so that there weren't any limits
16 for patient doses and certain things were exempted, such
17 as certain signage and the exemption of patient
18 excretion to the sanitary sewer, which we still have in
19 place today. So those are economic and societal
20 factors being considered there.

21 In mid-1960, the first Part 35 was
22 established and that helped define how you license a
23 physician to do these types of things and certain
24 institutions. That was the primary focus of that.

25 In 1979, the medical use, there was the

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1 first medical use policy put into place. And that was
2 to help guide NRC actions in establishing new
3 regulations in regard to medical use.

4 It was 1980 when the first
5 misadministration reporting requirement was put in
6 place.

7 And in 1986, that was the first training and
8 experience for medical use types. That's where we
9 first started defining those.

10 It would be nice to be able to go back and
11 look at ACMUI transcripts at that time, but I can't ever
12 find those, if they are even available.

13 So in 1991, the quality management program
14 was required and misadministration reporting was
15 changed a little bit. The training and experience
16 requirements were -- and the QMP was very prescriptive.
17 And in the misadministration reporting, those changes
18 that occurred were to add some dose criteria and the
19 primary reason for that was to rule out some of the less
20 harmful types of events but, in reality, it really did
21 put a dose limit on patient doses because that is when
22 this happened and other things we have had to have a
23 misadministration reporting.

24 There was also, and I didn't put into the
25 report, there was also -- what was the other criteria?

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1 Oh, there was another criteria that wasn't a
2 misadministration but --

3 DR. TAPP: A recordable event.

4 DR. LANGHORST: -- a reportable event.

5 Thank you.

6 DR. TAPP: Recordable.

7 DR. LANGHORST: Recordable. Recordable
8 event.

9 MR. FULLER: We have recordable and
10 reportable and so they are kind of back to the earlier
11 thing that was talked about, there were certain things
12 that did not have to be reported but then we could look
13 at them and we wouldn't do routine inspections.

14 DR. LANGHORST: So during the early '90s,
15 the NRC wrote in their medical use policy that the NRC
16 has the authority to regulate the medical use of
17 byproduct material or radiation of byproduct material
18 to protect the health and safety of patients but also
19 recognizes that physicians have the primary
20 responsibility for protection of their patients.

21 NRC regulations are predicated on the
22 assumption that properly trained and adequately
23 informed physicians will make decisions that are in the
24 best interest of their patients. And so that's tying
25 in our training and experience part.

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1 And that the NRC distinguishes between the
2 unavoidable risk attendant and purposefully prescribed
3 and properly performed clinical procedures and the
4 unacceptable risks of improper or careless use.

5 The NRC is responsible, as part of its
6 public health safety charge to establish and enforce
7 regulations that protect the public from risk or
8 improper procedures or careless use.

9 So, are we transitioning a little to public
10 dose as opposed to patient -- patient safety as opposed
11 to public safety?

12 In 1995, NRC went through a strategic
13 assessment and re-baselining project. That's where
14 the risk-informed performance-based approach was first
15 introduced.

16 In 1997, the patient release criteria
17 change was put into effect.

18 And in 2000, a new medical use policy
19 revised. And this was where we brought into the concept
20 -- brought in the concept that the medical use has to
21 be in accordance with the physician's directions. And
22 so it put a really big emphasis on that written directive
23 in that you are following that written directive.

24 So we were talking about changes in Part 35.
25 The last major change in Part 35 occurred kind of between

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1 2002 and 2005 because there were a lot of regulatory
2 steps that had to be taken to change, in particular,
3 training and experience requirements. And kind of
4 since then, we have been working on trying to update this
5 part of the regulations.

6 I think I will just leave it at that because
7 I think we have discussed this.

8 In the early -- or excuse me -- in the
9 mid-1990s, the Commission issued a policy on
10 safety-conscious work environments and trying to
11 encourage and protect people who raise safety concerns.

12 In 2011, NRC developed its safety culture
13 policy but what is so frustrating from my perspective
14 is that it wasn't a safety culture that was defined. It
15 was a nuclear safety culture. So it really just
16 narrowly focused on what NRC regulates. It's not clear
17 that you are allowed to consider other competing factors
18 but they were promoting safety culture. A good thing.

19 Here are the nine nuclear safety culture
20 traits. You will see that they really don't
21 necessarily only apply to nuclear safety. And you can
22 go on NRC's website. They have wonderful tools to kind
23 of bring your folks up to date on what they mean by these
24 various traits, how you exhibit these various traits,
25 even examples.

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1 Now, they are really focused on reactor and
2 fuel cycle environments. We are not surprised at that.
3 There are some material use. There is a little bit of
4 medical use.

5 Now at the same time as our development of
6 the finishing touches on Part 35 and our new effort to
7 change Part 35, the National Academy of Science and the
8 Institute of Medicine were publishing several reports
9 on patient safety in the environment of health care.
10 These publications are all on the website. So you can
11 get to them very easily.

12 To Err is Human was looking at medical
13 errors and what the healthcare industry needs to be
14 looking at.

15 The 2001 report, Crossing the Quality
16 Chasm, really focused on how to reinvent and foster
17 innovation and improvement in health care with a
18 comprehensive strategy and action plan for the next
19 decade. So how do we address this in the healthcare
20 environment?

21 In 2004, the Patient Safety Report was
22 developed at the request of the Department of Health and
23 Human Services. They asked for a detailed plan on how
24 to achieve an acceptable standard of patient safety.

25 In 2005, Congress passed the Patient Safety

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1 Act and Health and Human Services took that Act and they
2 put into place rules, regulations, and in 2008, the
3 essentially implemented parts of this in regard to the
4 patient safety organizations. I encourage to look on
5 the Academy's website because there are many more
6 patient safety reports that deal with various aspects
7 of patient safety.

8 Too many papers.

9 Okay, there has been also another route of
10 patient safety development with the Medicare program
11 that is charged for oversight of what they call these
12 accrediting organizations. This includes the Joint
13 Commission, the DNV-GL, the Healthcare Facilities
14 Accreditation Program, and the Center for Improvement
15 in Healthcare Quality.

16 Now most of you may be familiar with Joint
17 Commission because they are the big player in this arena
18 but, as the years have gone by since early mid-'60s,
19 early '70s through to now, these accrediting
20 organizations, and please excuse me, we will call them
21 AOs, they are not abnormal occurrences they are
22 accrediting organizations, have focused more and more
23 on the promotion of patient safety culture in healthcare
24 organizations.

25 And reporting to these organizations is

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1 voluntary but if you meet some of the reporting criteria
2 they set, you had better be reporting it, rather than
3 letting them find out that you haven't reported it.

4 So as I said, the Patient Safety and Quality
5 Improvement Act of 2005 established the reason for
6 Health and Human Services to develop 43 C.F.R. Part 3.
7 And we had, last fall, the folks from ROILS, this is
8 sponsored by ASTRO and AAPM, and we had our former
9 chairman, Dr. Thomadsen report to us on the Radiotherapy
10 Incident Reporting and Analysis System.

11 So these are the two registered PSOs that
12 focus on radioactive medical care -- use of radiation
13 in medical care.

14 Again, in the report there is a lot more
15 details on some of these organizations and some of these
16 reporting systems but, again, this is a voluntary
17 reporting system and the purpose is to then send out this
18 type of anonymized information so that people can learn,
19 can see, can develop what's trending and so on.

20 So how could or should the NRC support a
21 positive safety culture at this point in time? I mean
22 in the early years you could say the NRC was the only
23 game in town. I mean you guys were requiring us to image
24 gently, image safely. I mean that was from the get-go.
25 But medical use now, there are significant and mature

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1 patient safety program options that can do a medically
2 professional review of patient events and can look at
3 the overall patient safety in light of making process
4 improvements and it's not limited to nuclear safety
5 culture.

6 Now in our subcommittee report, we have a
7 list of pros and cons of, in this case, applying NRC
8 medical event reporting versus other patient safety
9 programs and I have it as the accrediting organizations
10 or the PSOs.

11 I would ask that we go through these and
12 have a discussion so that we can, our subcommittee can
13 take your thoughts on whether we should be even looking
14 at other changes, other reporting options, and what
15 might be the pros and cons of doing that.

16 So, Chairman Alderson, I have these listed.
17 I don't know if you guys want me to go through these step
18 by step and discuss or we go through them all and then
19 we start the discussion. I'm glad to take your lead.

20 CHAIRMAN ALDERSON: Right. Well, I would
21 just begin by saying for anyone who hasn't looked
22 through the actual written report, it is a 20-page
23 report, I mean a comprehensive historical document to
24 the tracks how this has evolved over a long period of
25 time. So, thank you very much, you and your committee

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1 very much for that.

2 So, we certainly do need to give some
3 attention. There is quite a few of these. In looking
4 through them yourself, do you have, out of these, there
5 must be nine or ten, do you feel that there are three
6 or so that are more important, critical ones? I would
7 suggest if you do, that you might start with those, one
8 by one, and then sort of bundle the others.

9 DR. LANGHORST: Let's look at -- first,
10 let's look at initial patient event review.

11 CHAIRMAN ALDERSON: All right.

12 DR. LANGHORST: So, we were discussing
13 this earlier today about how much time do you have and
14 I would say this one, and excuse me, I will jump between
15 these, and the timing of initial patient event review.
16 You are required, NRC-required to report a medical event
17 within the next calendar day but it is not clear whether
18 you, as a licensee, have time to evaluate the situation.

19 On the AO or the PSOs, personnel are
20 encouraged to report a patient event and even near
21 misses in an effort to evaluate those for process
22 improvement. And the personnel who get that report are
23 required to review it and kind of put it into their
24 patient safety evaluation to determine what level of
25 review and what are the possible process improvements

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1 needed.

2 CHAIRMAN ALDERSON: So let me -- I think I
3 didn't express myself very well. Let me try again.

4 I think given the breadth of this topic and
5 the importance of it, and the discussions that occurred
6 this morning where we learned some of the limitations
7 of the restrictions and how this could go forward, not
8 that anyone is restricting us, but the regulations just
9 provide a pathway that has to be followed in certain
10 ways. Given those ideas, I guess my preference would
11 be to start with a big picture look or the most critical
12 event. These are the three critical questions that we
13 have before us and these other areas support that.

14 And then we could dive into those
15 particular issues. I believe if we just sort of take
16 these one, two, three, four, five, we won't get the big
17 picture.

18 So I would at least like you to start with
19 the big picture and work from there.

20 DR. LANGHORST: Okay. Well, probably the
21 biggest difference between the two is required
22 reporting versus voluntary reporting. And I think if
23 we look at this in a safety culture manner, you want to
24 encourage people to bring these things forward. And we
25 were talking this morning about the perception of

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1 penalty. If you bring this forward, well then you have
2 an NRC inspector coming to help you review the process
3 within a few days of you identifying it with the look
4 of nuclear safety culture; how are you meeting the NRC
5 Agreement State requirements.

6 CHAIRMAN ALDERSON: Right. So are you
7 asking the committee to comment on if they perceive that
8 to be true?

9 DR. LANGHORST: I'm looking for input,
10 yes.

11 CHAIRMAN ALDERSON: Okay, so I think the
12 idea is do you perceive this issue in your own practices
13 being problematic and if so, how might we address it?

14 Has anyone got a comment? Dr. Ennis.

15 DR. ENNIS: So, I guess to me there are a
16 couple of aspects to it. I mean I think at the core what
17 is being articulated, and since I have been on the
18 committee really there has been discussion, is a sense
19 that in a lot of industries, including the medical
20 community, there has been a transition from the required
21 punitive individual kind of approach to a process
22 systems and collaborative safety culture kind of
23 approach.

24 And there is a lot of evidence that that
25 transition in a variety of industries, including

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1 medical industries, has improved quality and a sense I
2 think, among several of us at least, that the same
3 attitudes and approach being brought to bear in our area
4 to improve quality.

5 The aspects that to me stand out the most
6 as most problematic are the disconnect that exists now
7 between the magnitude of a medical event and the
8 response that is required for that medical event.

9 So a medical event, as defined now, at least
10 when it occurs within radiation oncology, the vast
11 majority, although it is small numbers, which is great,
12 the vast majority of those have no clinical
13 ramification. There is just about something didn't
14 happen properly but no patient was harmed; no family
15 member was harmed. But the way it is dealt with it is
16 as through it was a catastrophe.

17 So it is on par, so at my hospital for
18 example, because it is a reportable event to a State
19 agency, it is treated like other reportable events to
20 the State agency. Examples of those reportable events
21 are an unexpected death, a complication, a major
22 surgical complication that was unanticipated, leaving
23 tools of surgery inside a patient's belly. So those
24 kind of events and a medical event are talked about in
25 the same conversation. And from a hospital

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1 administrative point of view, they are the same and that
2 is a major disconnect.

3 So, that is not to say that there are not
4 medical events that are at this level but they are not
5 differentiated in a way that is meaningful. So, the net
6 result, I believe, is a few things. First of all, it
7 creates a negative environment but most importantly for
8 this conversation, it creates an environment where
9 people don't want to or are very afraid to, and then they
10 do report, it is just a major thing, which is not the
11 kind of culture that has been shown in many industries
12 now to lead to real improvements in quality of care.

13 So to the degree that we could do better,
14 this is not a system that would be improving it. So
15 conceptually, I am looking towards an ability to have
16 a system that for events that are not medically as
17 dramatic as an unexpected death or leaving a suture,
18 leaving a clamp in someone's belly, that are not that
19 level of medical complication, should be dealt with in
20 a different way.

21 And the way we deal with medical event now
22 should be reserved for something at that level. What
23 we call this new thing and how we actually deal with it
24 is almost secondary but it ought to be done, in my
25 opinion, in a way that is this just culture kind of

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1 process, whether that means reporting to a PSO only,
2 whether it means reporting to NRC but in a different way,
3 whether it means not an immediate report that is a crisis
4 that is called a reportable event that the hospital will
5 then deal with like these others but is just part of a
6 routine monthly report to the regulators. I can
7 envision a lot of possible details that had to do with
8 it but, conceptually, that's what I see. And I do think
9 it's time to move in this direction.

10 CHAIRMAN ALDERSON: Yes. Okay, I think
11 that is well-formulated and a basis for discussion. I
12 do think it also relates pretty well to what we've
13 discussed a bit this morning. So if I listen to that
14 discussion correctly, you know the idea that we can do
15 this through guidance doesn't really exist. And so,
16 ultimately, you have to decide if this has to be a
17 rulemaking issue, then we have got to say, and it may
18 well be this may be that important that even if it takes
19 three, four years to get it done, getting this done is
20 a really important thing to improve overall safety.

21 Well, that's the basis for discussion.
22 Why don't people discuss what Ron had to say or my
23 comment, and then we will see where we are?

24 DR. DILSIZIAN: I think what we are saying
25 is that medical errors should be reported the way it is,

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1 urgently, 24 hours, 15 days reporting. We don't have
2 to change that.

3 But things that have no consequences or
4 less consequences, either they should not be reported
5 at all, which is what this morning's discussion was, or
6 if they are going to be reported, it should be recordable
7 events without having a visit from the NRC.

8 Those are the three categories I see: not
9 at all; just recording it but no visit from the NRC; or
10 current visits from the NRC for medical errors.

11 DR. LANGHORST: Let's go back to patient
12 safety and the difference between patient safety,
13 public safety, occupational safety. The patient has
14 both the benefit and the risk, you have those tied
15 together, and so that's different from public exposure
16 to radiation that occupational exposure and so on.

17 Is the NRC medical event report system, as
18 it stands today, supportive of patient safety? I think
19 it is not because it is narrowly focused to nuclear
20 safety culture and it is enforced -- I mean that is a
21 punitive sounding word -- it is enforced by compliance
22 issues. And it is reviewed by an inspector who is not
23 medically trained. They may be trained in medical
24 regulations according to the NRC or Agreement State.
25 Do we have in place now options that the NRC could

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1 evaluate that really promote total patient safety? Are
2 they mature enough? Can we do this? And will it help
3 the NRC support patient safety?

4 CHAIRMAN ALDERSON: And what you're doing
5 on these slides, if I am following what you just said,
6 are you suggesting in each of these cases that the AO/PSO
7 plan on the right side of the page is the alternative
8 to the NRC culture on the left?

9 DR. LANGHORST: Potentially, yes.

10 CHAIRMAN ALDERSON: Potentially. And so
11 when you said are they mature enough, whatever, you are
12 referring to the kind of ASO/PSO group. Good, that's
13 fine. It gives you at least a reference to look at these
14 ideas.

15 Mr. Ouhib.

16 MR. OUHIB: Yes, I would have to -- Dr.
17 Langhorst, I would have to perhaps disagree with you to
18 a certain point is that I truly believe that the NRC goal
19 is -- part of it is patient safety and that is the main
20 goal. So I think I will have to openly disagree on that.

21 I think the issue here is that perhaps the
22 NRC has that goal for patient safety, then you have these
23 other organizations that have similar goal but let's be
24 honest, perhaps do it in a very effective way in a sense,
25 and that is reporting these near misses and providing

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1 some feedback, providing additional information that is
2 not available from NRC. They expect you to provide your
3 corrective actions. They expect you to make some
4 correction and all that.

5 However, with these other organizations,
6 you have these expertise available to you that perhaps
7 that can assist you and provide you with some good
8 solutions.

9 So I think the question that might come up
10 is it possible that there is some plan out there where
11 maybe like you were saying that maybe there is some event
12 that do not need to be reported to the NRC but as long
13 as NRC is aware that you are reporting these things to
14 these organizations, that might be satisfactory that
15 we're okay with that, that as long as you can show us
16 that, indeed, you are doing these and so on and so forth.
17 And I think that would be some sort of a happy medium
18 that will ultimately, they are all focused to the same
19 goal, which is the patient safety.

20 CHAIRMAN ALDERSON: Dr. Dilsizian.

21 DR. DILSIZIAN: I just wanted to
22 follow-up. I am hearing you and I just want to clarify.
23 When you say the regulators are not knowledgeable enough
24 about medicine to be able to our patients, they use their
25 degrees of such that may not understand the medicine --

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1 DR. LANGHORST: The inspector coming in.

2 DR. DILSIZIAN: Yes, so that actually
3 emphasizes the issue, right? I don't want them to get
4 involved in the medical practice.

5 DR. LANGHORST: Right.

6 DR. DILSIZIAN: So that would M&M peer
7 review. I want the regulators to be doing what is only
8 narrowly defined.

9 That is why I know you want to put it up to
10 patient safety and I think we should bring it back to
11 nuclear safety, in my opinion because I don't want them
12 to get into the medical aspect of things.

13 DR. LANGHORST: So my point is if they are
14 not able to see the whole expanse, maybe they shouldn't
15 be looking at it. It should be this other group that
16 can look at the whole expanse and address the nuclear
17 safety aspects of things. That's my point.

18 I'm not advocating that we get physicians
19 as NRC inspectors out there inspecting. That's not my
20 point.

21 Now, I wanted to ask you, you would say
22 these organizations. These organizations can be the
23 hospital and their patient safety groups that are
24 meeting the requirements of these AOs.

25 MR. OUHIB: Absolutely.

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1 DR. LANGHORST: Yes.

2 MR. OUHIB: And for me, I fully agree with
3 you and it could be internal. Absolutely. The whole
4 State has certain criteria by which they are claiming
5 to be in touch.

6 DR. LANGHORST: But how NRC plugs into
7 that, you are perfectly correct in could this be a route
8 that we say, could the licensee commit to, when we have
9 these levels of occurrence, we go through either our
10 patient safety reporting system or if you are in a PSO,
11 we commit to making those reports to the PSO.

12 CHAIRMAN ALDERSON: Yes, Mr. Collins has a
13 comment he would like to make.

14 MR. COLLINS: Thank you, Doctor.

15 So I just would offer a couple of thoughts
16 to the conversation and some of this echoes what heard
17 from Mike Fuller and others this morning.

18 From a regulatory perspective, I would
19 caution how much you buy into the broad sweeping comment
20 that NRC inspectors don't have experience with medical.
21 It is true that some of them do not have a medical
22 background but it is also true that we have some very
23 good inspectors who have a lot of clinical experience
24 from prior to coming to the NRC.

25 The other thing that I would say is it is

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1 the inspection process that we go through that helps us
2 gain an understanding of what occurred, both from a
3 nuclear and a patient safety perspective. And if we
4 change the reporting requirements to something else, we
5 have to be careful that we don't end up excluding from
6 evaluation events that occur to gain an understanding.
7 And so we just need to be careful about that.

8 And then the final thing is I would also ask
9 you not to forget that we do use NRC medical consultants
10 to help us understand the medicine piece versus the
11 nuclear and the radiation safety piece. And I know you
12 all know that but there may be members of the public who
13 are listening who don't and that's I wanted to make the
14 comment.

15 CHAIRMAN ALDERSON: So the regulations do
16 drive the culture, including the culture of the
17 inspectors, whether they are expert at medical things
18 or not, they are driven by the culture of the
19 regulations.

20 And one of the things they do bring is
21 objectivity because they are outside the venue in which
22 the problem occurred. That's what I would be concerned
23 about if you are working only with your own hospital
24 safety committee.

25 DR. LANGHORST: Oh, I wouldn't.

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1 CHAIRMAN ALDERSON: Well, let me finish.
2 Because the hospital, if it understands what just went
3 wrong, their goal is, yes, great patient care, but they
4 have got a big business going. And if they see
5 something that is worrisome, they might try to kill it
6 and not just try to cover it up.

7 And so I think that it would be unwise,
8 considering that you're probably going to have to go
9 through a lot of reviews and a lot of different venues
10 of this kind of change eventually occurs to make that
11 the key issue.

12 And independent AO/PSO, perhaps, perhaps
13 in series with the NRC. That might work but the problem
14 is going to be timing and you're still going to need the
15 judgment to separate the really dangerous thing that
16 needs to come quickly from the other that does not.

17 But generally, I think this is going in an
18 interesting direction.

19 Yes, Ms. Weil.

20 MS. WEIL: I would really like to second
21 your concern about the internal review being adequate.
22 You know I always say this, that the best institutions
23 are represented at this table and these institutions do
24 it right but you may not be able to trust the internal
25 review of all institutions. It just may not be adequate

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1 for this purpose.

2 The other thing about it not being internal
3 and being one of these more public PSOs is other people
4 get to see it and you augment that educational purpose
5 and the ability to perhaps have greater impact on
6 patient safety as well.

7 Mr. Collins, I wish you had been here to
8 hear Dr. Ennis' very eloquent comment about the way
9 medical events are currently reported in a way that is
10 just not commensurate with the parallel of -- I'm not
11 going to try to paraphrase it.

12 But there is a real disconnect between what
13 medical errors are in the medical world and what medical
14 events often are. Not always because they can rise to
15 that level but there is a real disconnect and it needs
16 to be fixed.

17 MR. COLLINS: Right and I think we heard
18 some of that from Mike Fuller this morning when he was
19 comparing the perceptions of medical event to the
20 medical community versus the regulator's perspective.

21 CHAIRMAN ALDERSON: Dr. Metter has a
22 comment on this issue.

23 DR. METTER: Well my concern is like
24 exactly what you are saying is like the internal local
25 level of reporting. And I can kind of vouch for that.

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1 I think a lot of what we need to do is educate our
2 licensees that this is not punitive and then promote the
3 safety culture. Because at my institution, when Y-90
4 first came out and that first one we did was sixty- seven
5 percent and that is a medical event. Actually, the
6 month before is when that came out as far as it is not
7 a medical event if you deliver it to stasis. And I found
8 that on the website, and so it wasn't a medical event.

9 But I was brought in by higher ups and I was
10 reprimanded because I was concerned and all that. And
11 that's something like -- you're right, exactly right,
12 it looks bad for the institution and it's there at the
13 local level. And I can vouch for that.

14 CHAIRMAN ALDERSON: Someone who hasn't
15 spoken. Dr. Zanzonico.

16 DR. ZANZONICO: I really want to echo Dr.
17 Ennis' comments in that internally these, what often
18 amount to innocuous, in a medical sense, events are
19 handled by the institution as if it were a catastrophic
20 event.

21 I know in our place a trivial event rises
22 to an Executive VP level and it, frankly, makes no sense.
23 It really doesn't. And another issue is that what
24 Memorial and, I think, many hospitals are concerned
25 about is less the regulatory impact than the PR impact.

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1 And obviously, if these things get into the public
2 press, you know you can't rely on the public making the
3 distinction between something significant and so forth.

4 And so I think there is some value, then if
5 this is not a punitive context of anatomizing all
6 reports to the NRC, assuming we agree those should
7 remain in place in some form. I don't see what the value
8 of identifying an institution is in making such a
9 report. And I think that has -- that, perhaps more than
10 anything, has a chilling effect on possible reports of
11 some events is that the bad publicity is going to bring
12 on the hospital.

13 So I think that's one important
14 consideration that really would promote a non-punitive
15 safety culture environment. Again, I just don't see
16 what the value is.

17 The other issues is I was surprised when we
18 heard yesterday about the discussion of medical events
19 that the inspection of one current event precipitated
20 a review, a retrospective review of what had happened
21 at a place and a number of, a large number of medical
22 events were uncovered. I think that, too, has a very
23 chilling effect on reporting because it may have been
24 that those were correctable and corrected and so forth.
25 And so that would argue against on-site inspections.

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1 And believe me I understand if an inspector
2 shows up and finds evidence current or retrospectively
3 something not being done correctly, they have an
4 obligation to pursue it. But again, I think it really
5 does have a chilling effect that if there is an
6 open-ended retrospective review of practice at a
7 particular place that that, too, has a chilling effect.

8 So, I'm not saying it is necessarily wrong
9 or inappropriate but if the idea is encouraging reports
10 of events in the spirit of improving patient care and
11 public safety, those kinds of things have the opposite
12 effect, namely, publication of a cited institution and
13 the possibility of an open-ended retrospective review
14 of the institution.

15 CHAIRMAN ALDERSON: Yes, Mr. Bullock?

16 MR. BOLLOCK: Just to touch on a lot of the
17 points that we are still going to hear, first off, part
18 of medical event reporting is so that we are aware of
19 things that could be patient or radiation safety. So
20 that is an important aspect of it.

21 Another aspect of it is that we see what
22 events are going on and see if there is some sort of trend
23 so that we can, through a generic communication, or if
24 it needs to go to a higher level and make changes to
25 regulations, to help prevent these events from

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1 occurring again.

2 So those are our primary goals of why we
3 expect medical events to be reported. But we are
4 hearing exactly what Dr. Ennis is saying, it is
5 important that it is commensurate to the actual impact,
6 actual safety impact, the radiation safety impact, the
7 impact to the patients. So we don't want trivial. And
8 we actually do -- I mean I am very experienced on the
9 reactor side and how we do reporting there and what their
10 licensees do for their own corrective action programs,
11 you know there is so much stuff, little things that they
12 see all the time that they correct and it just goes into
13 their system and we just kind of go and say yup, you have
14 got a system that is healthy, you have captured these
15 things. And it hits a certain level and we go in and
16 say yup, you have captured and it is commensurate with
17 the safety impact or the risk on that side.

18 And that really is our goal across the
19 Agency with these. I mean that's then the policy. And
20 so we hear you with the safety culture effect and things
21 that cause chilling effects. So we are very
22 sophisticated when it comes to the reactor side.

23 So these chilling effect things, if the NRC
24 comes in to one of those licensees and the fact that
25 we're there, we are there all the time, is chilling

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1 people from reporting an event, that is evidence of a
2 poor safety culture. We want the people to be able to
3 report when things -- when mistakes are made. Again,
4 it has got to be commensurate, though, with our actions
5 need to be commensurate with the actual safety impact.
6 So what we do and the results then to the licensees,
7 special medical licensees, we want that to be
8 commensurate with it. And we want to hear about the
9 reports because we want to be able to see if there is
10 a trend and we can inform, send out verifications that
11 inform licensees that hey, these are things that are
12 going on; we are seeing trends; to try to minimize them.

13 I think our end goal is we have the same end
14 goal in mind. So, it is very important. And some of
15 the very important points are -- and a good comparison
16 is if you are going to give any recommendations to us,
17 to have those differences or the gaps between what we
18 require in reporting and the real impact relative to
19 other reporting in your realm of expertise.

20 Granted, that being said, we still -- we do
21 understand radiation safety. So we still want some
22 level of reporting to us --

23 DR. LANGHORST: Feedback.

24 MR. BOLLOCK: Right, feedback. Exactly.

25 Because we do understand that we can -- we are the

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1 government and we're here to help but it really is our
2 goal.

3 So I think it is important. We understand.
4 We have had our staff, we have had many discussions on
5 it that it is very important to get that balance. Just
6 but there is, you know if we go to any licensee and we
7 find out -- and this isn't just NRC. This is across --
8 the NRC was very -- they didn't just look at nuclear but
9 across the board in safety culture. And the slides that
10 have the points for healthy safety culture, with that
11 problem identification, and resolution and the
12 leadership safety values and actions, and problem
13 identification -- yes, all those things. If the
14 management of the licensee aren't taking actions,
15 punitive or whatever so that people aren't reporting
16 what they're supposed to, that is indicative of a poor
17 safety culture.

18 Now we do understand if it is because you
19 are reporting something that isn't significant and know
20 we know, the NRC knows, to us, again, once you inform
21 us, you have met our regulation; you are in compliance.
22 So if someone is taking punitive action against you, the
23 chilling isn't us. It is the management and that is
24 true across the safety culture across all industry.

25 So I caution when you start -- I mean we get

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1 the realistic impacts are there but I just caution when
2 you do talk about those types of chilling effects, the
3 bounce back is going to be negative towards that
4 management that takes adverse action against people
5 reporting, doing what they are supposed to at the time.

6 Again, that being said, reporting, doing
7 what they're supposed to be doing, should be
8 commensurate with the safety event.

9 CHAIRMAN ALDERSON: So the concerns, the
10 very legitimate and well-stated concerns that people
11 have been voicing, it seems those are all related to the
12 local implementation of the regs. It is what your local
13 inspectors are doing after this happens. It is not
14 what's happening in this building. It's what's
15 happening in the field that people are concerned about.

16 And even if we lived in an ideal world,
17 where the national leadership of NRC could simply issue
18 a memo that said we want to have everything more of
19 endemic type improvement culture and we would like all
20 of you to lighten up and not go overboard on this and
21 if all of the people in NRC space agreed, you would still
22 have, if Frank were here, he would be telling us you
23 still have every one of those Agreement States and they
24 have got their own State's rights in how to do it. And
25 when I practiced in New York City for many years, you

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1 know New York City is an Agreement State. And they used
2 to always say with pride that we believe that an
3 Agreement State's regulations must be as least as
4 rigorous as those of the national organization.

5 So every such Agreement State, especially
6 yours, Ron, would be there trying to say well, we have
7 to be more rigorous than that. Anyway, this is to get
8 from I think the appropriate concepts that everyone is
9 talking about, to drive that down in this complicated
10 system to the local level. That is phenomenally
11 complex. And I guess --

12 Someone perhaps has their hand up here. It
13 is a solution right now.

14 MR. GREEN: It may be overly simplistic
15 because I deal drugs for a living. But within the next
16 calendar day, wow! It's like you've left a sponge in
17 the patient, my God! But we're not. If that was
18 modified to a more reasonable time period, 48 hours, 72
19 hours. You know it could happen on a Friday. Can I
20 have until Monday to do it? You know something. Could
21 the written report, to give you time to analyze it --
22 because sometimes you report it and then you finally get
23 it, you look at it and go that's not reportable. You
24 finally have the facts in your hands.

25 So if you were to change that first report,

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1 the written report, if it was anonymized when it went
2 in to not stigmatize. You know there are a few things
3 I think we could do within today's framework with minor
4 tweaks that might remove this stigma of the punitive
5 appearance.

6 CHAIRMAN ALDERSON: That may be -- you know
7 it is interesting. It could be the right answer. Just
8 find a couple of the two or three little things. That
9 would probably take rulemaking but find the right two
10 or three little things that you want to change and then
11 it changes everything, just rolls out from that and
12 changes.

13 Darlene had her hand up.

14 DR. METTER: So another thing we had talked
15 about earlier today was we're going out to the societies
16 about the regulators. This could be actually be one
17 component of that.

18 You know the NRC is really here for patient
19 safety and we're here to help for the public and medical
20 events are not bad; they are actually good. And give
21 examples, you know, for example these were trends that
22 occurred and we're going to look at that to help
23 patients.

24 CHAIRMAN ALDERSON: Right.

25 DR. METTER: I think that would be a

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1 positive thing and that would be helpful. And if we're
2 going to all these different organizations, I think we
3 can start with that.

4 CHAIRMAN ALDERSON: It would be positive
5 but I'm not sure that it's the right way to start because
6 you can tell the audience that but the local regulator
7 is living in his current or her current world and they
8 come pound on them, that will be the last time you ever
9 talk at that meeting.

10 DR. METTER: But I think actually but you
11 have to start somewhere. I don't know. What do you all
12 think?

13 CHAIRMAN ALDERSON: Yes, Sue.

14 DR. LANGHORST: Well, I had another topic.
15 So I'm sorry I wasn't answering your question.

16 DR. METTER: Oh, okay. That's fine.

17 CHAIRMAN ALDERSON: So we're all searching
18 for the way to get started with a big complex problem.

19 DR. LANGHORST: What about an alternative
20 pathway that if a licensee is able to show a strong
21 patient safety program, could the NRC allow them to
22 report through that and provide the NRC feedback on
23 that? But this is what we reviewed it; this is how we
24 review it; these are corrective actions.

25 Now, that doesn't necessarily, if you are

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1 internal, you know go outside of your organization but
2 then not all NRC medical events go to everyone, too. So
3 potentially, is that an option?

4 CHAIRMAN ALDERSON: So those are two
5 options. Let's just make sure we keep these in our
6 minds. One option is alternative pathway. Another
7 option we've said is to make changes in details, certain
8 critical details of the current pathway. Those are two
9 things that are out there right now.

10 Was there a hand up over here? Yes, Dr.
11 Tapp.

12 DR. TAPP: With the alternative pathway, I
13 know you wanted to discuss AOs and PSOs here, one of the
14 things for an alternative pathway to work would be would
15 this pathway be able to meet the criteria, the purpose
16 of medical event? And the NRC's point the NRC's main
17 purpose is a medical event is to evaluate and make sure
18 that corrective actions are taken and we will share that
19 necessary to prevent reoccurrence.

20 And the question I would leave up to the
21 ACMUI, I don't know if it would be today or in the future,
22 would be are these PSOs able to do that. Are they able
23 to share this information with others and to let them
24 know what the root cause was and prevent reoccurrence?
25 Could that do maybe even better than the current NRC

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1 medical event criteria?

2 And then in addition to the chilling
3 effect, is that chilling effect the NRC has currently
4 causing underreporting related to PSOs? I believe some
5 are anonymous. Would that maybe make better reporting
6 to increase the purpose of what we are trying to do with
7 medical events?

8 CHAIRMAN ALDERSON: Good suggestion. We
9 have a comment from the audience that we would like to
10 take.

11 MS. TOMLINSON: Sir --

12 CHAIRMAN ALDERSON: Please identify
13 yourself.

14 MS. TOMLINSON: Cindy Tomlinson from
15 ASTRO. So I am going to address a couple of the PSO
16 things in general and then I'm going to talk a couple
17 seconds about ROILS in specific.

18 So for PSOs the whole point of a patient
19 safety organization is that you are reporting patient
20 safety information in a protected environment. And
21 what that means is that you are, for the most part,
22 shielded from being sued and using that information in
23 a law suit. So I mean that is very broad generalization
24 but that is the basic premise.

25 The other premise is is that you are putting

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1 information and then receiving information out. And so
2 the job of a PSO is to analyze the data that has been
3 submitted and look for trends and then offer mitigation
4 strategies.

5 So you know things like time outs, things
6 like having the patient sign the arm that's having
7 surgery, or whatever those things are, those are some
8 of the things that have come from PSOs in general. So
9 I am talking general medical, not specific to anything
10 that the NRC would necessarily be regulating.

11 So yes, so the whole purpose of a PSO is to
12 get information in and then give it out to the broader
13 audience and to their participants.

14 So ROILS, in specific, collects
15 everything. So we collect things from scheduling
16 mishaps, which you know is just I would consider sort
17 of an inconvenience to a patient, not necessarily
18 causing harm, all the way up to something that could be
19 potentially reportable to the State, or to the NRC, or
20 even to FDA, and everything in-between.

21 So things are caught during planning that
22 never ever would reach the patient but it was caught in
23 planning, it was fixed in planning, and then the patient
24 went on to have successful treatment.

25 So we have worked pretty hard to make sure

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1 that we're collecting information that is applicable
2 and useful to our members, to radiation oncologists, and
3 I recognize that most radiation oncologists are not
4 necessarily authorized users. I mean the bulk of what
5 we do is linear accelerators, so there is that.

6 And there are also like hospital-wide PSOs
7 which are going to collect probably not necessarily this
8 type of data but they are going to collect other data
9 and so there are ways, I mean, I think of doing that.
10 But the whole purpose of a patient safety organization
11 is to spit the data back out and give -- you know here
12 is a way to solve this problem; or we saw a trend in this
13 and then we gave you a suggestion; and then we didn't
14 see it again. Whatever that type of thing is.

15 So I think that answers your question but
16 I did just want to just mention that PSOs are a good way
17 of doing things. There are some legal issues as well
18 surrounding that.

19 CHAIRMAN ALDERSON: Thanks very much.

20 MS. TOMLINSON: Sure, not problem.

21 CHAIRMAN ALDERSON: We have some comment.

22 Yes, Mr. Ouhib.

23 MR. OUHIB: Yes, on the alternative
24 pathway, what you want to do is you really want to
25 prevent these from happening to begin with. So when I

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1 look at these and I look at, I hate to mention, an
2 accredited program such as you know ICAPS or whatnot,
3 they have all these in place. And if you don't have it,
4 you're not accredited. That means you are not going to
5 treat the wrong patient because you have things and you
6 are going to show what do you have.

7 And here's what needs to happen, and this
8 is just one example, there are a lot of other things that
9 they have to be in place to prevent and to get to the
10 discussion that we're getting to right now. So my
11 feeling is that if an institution is accredited by such
12 an organization and they have an internal patient safety
13 program, the two combined I think is the ideal world as
14 an alternative pathway.

15 CHAIRMAN ALDERSON: So as we continue this
16 discussion, this is a great report and a great
17 discussion and it is a viable one, also. I think that
18 we should start to think about the fact that we aren't
19 -- I think we are unlikely to finish and resolve this
20 issue today.

21 DR. LANGHORST: That is not my plan.

22 CHAIRMAN ALDERSON: Well I'm glad to know
23 that.

24 DR. LANGHORST: My one plan, though, is
25 should we continue it.

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1 CHAIRMAN ALDERSON: Absolutely.

2 DR. LANGHORST: Okay, that is one
3 question.

4 CHAIRMAN ALDERSON: Those were my next few
5 words.

6 So I think that we are going to ultimately
7 wind up just moving, as we did with Vasken's committee
8 this morning, moving this into a prominent position on
9 the agenda for the fall meeting. And I also understand
10 what's going to happen sometime relatively soon, is
11 different vital members in this discussion are going to
12 look up there at that clock and say it's time for me to
13 leave for my airplane and suddenly, despite what we
14 might want to achieve, one person, then another, and
15 another will disappear from around the table. So I hope
16 what I would like to say, since this discussion is
17 already way over time, but every moment has been worth
18 it, is that we can sort of draw ourselves together with
19 the goal of coming back in the fall, perhaps the
20 committees that are active should start working with one
21 another and come up with an overall approach in the fall,
22 if the agency is willing to accept that approach.

23 MR. BOLLOCK: We will accept. Just be
24 careful in working two subcommittees. You get more
25 than the -- yes, it's just the numbers issue with --

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1 CHAIRMAN ALDERSON: And the number of
2 people that are actively involved, is that what you're
3 saying?

4 MR. BOLLOCK: Correct.

5 CHAIRMAN ALDERSON: We'll work that out.
6 We know we can have up to five, correct?

7 MR. BOLLOCK: Four.

8 CHAIRMAN ALDERSON: Four now? How many do
9 we have on the committee? Four. All right, we will
10 look at the two committees and we'll come up with four
11 --

12 DR. LANGHORST: Or even medical event
13 reporting. I mean maybe it is the chairman --

14 CHAIRMAN ALDERSON: All right, that's one
15 good way. I like that.

16 DR. LANGHORST: And condense that
17 combination.

18 CHAIRMAN ALDERSON: So that would be
19 Vasken, and John, and Sue as an Executive Committee in
20 caucus, as it were.

21 MR. BOLLOCK: Yes, you can back and inform
22 each of your subcommittees.

23 DR. LANGHORST: Right.

24 MR. BOLLOCK: Unfortunately, you can't
25 have all three or two of your subcommittees get

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1 together. We would have to make that, post it as a
2 public meeting.

3 CHAIRMAN ALDERSON: Yes.

4 MR. BOLLOCK: But yes, you absolutely can
5 have your individual chairs of the subcommittees talk
6 to each other.

7 CHAIRMAN ALDERSON: Well you all will talk
8 together.

9 MR. BOLLOCK: So you are informed and then
10 go back to your subcommittees.

11 CHAIRMAN ALDERSON: And then one of you
12 will perhaps decide to put something together and
13 prepare it for the fall meeting.

14 DR. LANGHORST: Absolutely.

15 CHAIRMAN ALDERSON: All right, good.
16 That's an excellent solution.

17 So how about some closing comments then?

18 DR. LANGHORST: So the current report
19 doesn't come to any conclusions, other than let's have
20 the strong basis and let's discuss.

21 So I would ask whether the committee would
22 like to accept this draft report of our subcommittee.

23 CHAIRMAN ALDERSON: Yes, this report, if
24 you have looked at it, there are recommendations at the
25 end but there is nothing that says --

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1 DR. LANGHORST: The recommendation is
2 whether to continue on or -- and to continue on to report
3 back. We will evaluate some of these ideas that have
4 been put forward and discuss that further.

5 CHAIRMAN ALDERSON: So if you all agree
6 that we do want to continue this discussion --

7 DR. ZANZONICO: I agree. The one thing I
8 would like, because there is going to be a paper trail
9 and paper trails sometimes outlive people, is that it
10 just be labeled interim report so that it is clear --

11 DR. LANGHORST: Okay.

12 DR. ZANZONICO: -- that there's more to
13 follow and this is not the final word.

14 CHAIRMAN ALDERSON: So that's an
15 amendment. Do you accept that amendment?

16 DR. LANGHORST: I accept that. That
17 sounds like an excellent idea.

18 CHAIRMAN ALDERSON: So given that this
19 will be an interim report, do the members of the ACMUI
20 support this?

21 (Chorus of yes.)

22 CHAIRMAN ALDERSON: Is anyone opposed?

23 Good, that's unanimously done.

24 DR. LANGHORST: Thank you very much.

25 CHAIRMAN ALDERSON: Approved as an interim

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1 report.

2 And so this particular discussion right now
3 is over but they will be working hard and we will be back
4 at the table discussing this further in the fall.

5 Thank you very much, Sue, for a great
6 report.

7 Well as I said, we are a little behind in
8 time here. The next issue was supposed to start 25
9 minutes ago, approximately, is the annual reporting
10 structure.

11 MS. SMETHERS: This should not take too
12 long. So, we might be able to catch up.

13 Before I begin, I just want to say thank
14 you. We've had an excellent two days of meetings and
15 as the coordinator, I know all the details and I am just
16 so impressed with your presentations and the
17 participation. And I just want to thank the ACMUI, the
18 staff, just for what a great meeting so for.

19 So for the next portion of the agenda, we
20 will be discussing the current reporting structure of
21 the committee and discuss your annual review. We do
22 this on an annual basis, so this should be very familiar
23 to many of you.

24 This chart is very familiar to many of you.
25 This is simply to show how the ACMUI reports to the

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1 Director, Dan Collins, of the Division of Material
2 Safety, States, Tribal, and Rulemaking Programs, which
3 is within the Office of Nuclear Material Safety and
4 Safeguards.

5 And my branch, the Medical Safety and Event
6 Assessment Branch, or MSEB on this chart, is led by Doug
7 Bollock, the Branch Chief. And while the ACMUI does not
8 report directly to the MSEB, we do support the committee
9 in the day to day activities, as you are aware.

10 Our office, NMSS, falls under the purview
11 of the Executive Director of Operations, Victor McCree,
12 who then relays staff's positions to the Commission.

13 And the dotted lines simply are to indicate
14 the open door policy that you can, you are always welcome
15 to discuss comments you may have with any level here on
16 the chart. There should also be a dotted line to the
17 Director, Dan Collins.

18 The reporting structure has been reviewed
19 annually since 2011. And in September of 2012, the
20 ACMUI recommended to have an annual review going
21 forward. So this is our seventh annual review. When
22 the committee was previously presented the option to
23 report directly to the Commission, rather than to NMSS,
24 the committee decided to maintain the current reporting
25 structure.

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1 As many of you should be aware, we have the
2 ACRS, the Advisory Committee on Reactor Safeguards, and
3 they report directly to the Commission.

4 So, on an annual basis, the committee
5 reviews, if you would like to be similar to the ACRS or
6 continue as you have previously.

7 And the next slide, just to indicate, as
8 many of you are aware, we have two meetings at
9 headquarters each year, the spring meeting, which is
10 generally in March or April, and the fall meeting in
11 September or October.

12 We do have ad hoc teleconferences on an
13 as-needed basis and that is usually about two to three
14 years, sometimes more, sometimes less.

15 So at this time, I would like to open up for
16 discussion. Chairman Svinicki did touch on this
17 earlier today. So I think we have discussed it a bit.

18 But I just wanted to pose three questions
19 and open it up for discussion. Is the committee
20 satisfied with the current reporting structure? In
21 other words, would the committee like to continue
22 reporting to NMSS or would they prefer to report
23 directly to the Commission?

24 CHAIRMAN ALDERSON: Report directly to the
25 Commission?

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1 MS. SMETHERS: Directly to the Commission.

2 DR. METTER: I like the current reporting
3 structure.

4 MS. SMETHERS: Okay. Any other comments?

5 CHAIRMAN ALDERSON: Sue.

6 MS. SMETHERS: Dr. Langhorst.

7 DR. LANGHORST: I will just mention for
8 those of you who haven't been on here very long, there
9 are a lot of requirements that go along with you being
10 an advisory committee to the Commission.

11 And I know in looking at it in the past, it
12 would be fairly daunting to get representation that we
13 have here around the table in that environment. And as
14 long as we work well with NRC and NRC's staff works well
15 with us, I think we are very happy.

16 So I think we have come to a really good
17 exchange of ideas.

18 CHAIRMAN ALDERSON: Good. Laura?

19 MS. WEIL: It would probably be useful for
20 the newer members of the committee to know how often the
21 ACRS meets.

22 MS. SMETHERS: Ten times, approximately.

23 CHAIRMAN ALDERSON: Ten times a year.

24 DR. LANGHORST: And the ACRS stands for?

25 MS. SMETHERS: The Advisory --

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1 MS. WEIL: Michelle already said that.

2 MS. SMETHERS: -- Committee on Reactor
3 Safety.

4 DR. LANGHORST: So we're talking about
5 change.

6 CHAIRMAN ALDERSON: Right, so if you were
7 to start reporting directly to the Commission, you would
8 meet a lot more. You would have a lot more written
9 requirements. You would have a lot of other
10 requirements that you don't have now and they are also
11 saying you have a good relationship with the group to
12 whom you report at this point.

13 So yes, Mr. Fuller.

14 MR. FULLER: One thing I might recommend,
15 because you are right, we are in our seventh year of
16 doing these annual reviews and we have had the requisite
17 turnover and so forth.

18 Back the last time we actually officially
19 looked at this and really examined this and reported to
20 the Commission what the wishes of the ACMUI was in 2011,
21 right?

22 MS. SMETHERS: Yes.

23 MR. FULLER: So there is a SECY paper on
24 that and we probably ought to stick it in the binder
25 every year that we do this because if you are on the

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1 airplane, you could read over it. And future, it is
2 again kind of what we were talking about earlier, the
3 more we get down the road, the less we remember.

4 So that SECY paper, and it's not that long,
5 ten pages or less, it really goes into a lot of detail
6 about all of the ramifications, and the history, and the
7 background, and the pros and cons. In fact, we used to
8 refer to it as the pros and cons paper.

9 And so just as a suggestion, perhaps we
10 could, now that we are down the road, six or seven years,
11 maybe we could just start sticking it in the binder for
12 everybody so you can kind of review it. It's just a
13 thought.

14 CHAIRMAN ALDERSON: So I am gathering that
15 there is a consensus around the table that we would like
16 to continue with our current reporting structure. Is
17 that sense true?

18 (Chorus of yes.)

19 CHAIRMAN ALDERSON: There's the answer to
20 your first question.

21 MS. SMETHERS: Great, thank you. And then
22 the second question, do you agree with the frequency of
23 two face-to-face meetings each year?

24 (Chorus of yes.)

25 CHAIRMAN ALDERSON: That seems to be a

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1 consensus.

2 MS. SMETHERS: Would anyone like more or
3 less?

4 CHAIRMAN ALDERSON: I think they're okay
5 where we are. I think that's what people are saying.
6 If you only met once a year, you would have so much, I
7 mean it just wouldn't work. Two is reasonable.

8 MS. SMETHERS: Great. Okay and then
9 lastly, what other changes would you like to see, if any?

10 CHAIRMAN ALDERSON: Well see, we just
11 spent the last hour --

12 (Laughter.)

13 DR. LANGHORST: We would like to see
14 changes, if possible, on what is required for security
15 background of our membership because I mean it is just
16 terrible that someone is on the committee for two years
17 and still is not a full member.

18 MR. BOLLOCK: Yes, unfortunately, that is
19 outside of our control. It is nothing that any of the
20 members -- there is no real reason other than the
21 backlog, the true backlog.

22 MR. COLLINS: Well, I'm tying into what
23 Doug said. This is Dan Collins for the transcript.

24 The Agency, as a whole, is looking at what
25 is required for security background checks for all

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1 employees, based on their position responsibilities.
2 And so as part of that, we are having a dialogue with
3 the Office of Administration in terms of how that might
4 improve things for ACMUI and other consultants, if you
5 will. So, more to come.

6 CHAIRMAN ALDERSON: Good.

7 MS. SMETHERS: That concludes this
8 portion.

9 CHAIRMAN ALDERSON: Yes, good.

10 Now, so I would suggest -- and please, you
11 know ACMUI members and NRC respond. I would suggest
12 that we not do what is next in the program, which is take
13 a 30-minute break. I would suggest that we move on so
14 that we can, if people are willing and-- the NRC is
15 willing, we would just go on and move our way through
16 the agenda because an important issue that we need to
17 discuss, and it does have some discussions points in it,
18 are the proposed dates for the fall meeting. And I hope
19 that we can have a certainly reasonable quorum here to
20 have that discussion.

21 MS. SMETHERS: Do you want to discuss that
22 now or --

23 CHAIRMAN ALDERSON: That would be fine
24 with me, if others are willing to do that.

25 MS. SMETHERS: The one request I would

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1 have, we will be covering the recommendations and I just
2 need to print that out for the committee. So, if at the
3 very end -- we could talk about the date right now.

4 CHAIRMAN ALDERSON: So, I want to put on
5 the floor one thing that I'm aware of but just for side
6 discussions that other people may not be aware of. And
7 I want to compliment Sue Langhorst on everything that
8 she brings to this organization, including this latest
9 initiative. And since we are going to discuss that in
10 the fall, I think that we need her here. And it turns
11 out that she tells me that her off date rotation, her
12 rotation off date is September 28th. So we would have
13 to meet before that time for her to be here as a full
14 functioning and voting member. And I think that if we
15 can accommodate that in any way, we should do it.

16 So, I want to put that out in front of
17 people.

18 MS. SMETHERS: I can share I have seen
19 everyone's schedules. It was very challenging to find
20 a meeting date that worked for everyone. So October --
21 there were two dates in October that we were able to
22 accommodate everyone's schedule. However, I know the
23 second choice if we can't do October would be September
24 11th and 12th.

25 CHAIRMAN ALDERSON: Okay.

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1 MS. SMETHERS: And I believe Dr. Palestro
2 had a conflict but could maybe work with those dates.

3 DR. PALESTRO: I can do 11 to 12, not 12 to
4 15.

5 CHAIRMAN ALDERSON: Okay. So 11-12 is
6 sort of on the table right now then as the possible
7 meeting date. So, I'm looking around. If no one
8 objects to 11-12 --

9 MS. SMETHERS: Monday, Tuesday.

10 DR. ZANZONICO: Well, there's no notation
11 on 7-8, September 7-8. Does that mean something?

12 MS. SMETHERS: It didn't. If I sent that
13 out -- there were about four people or more on every date
14 that were not available. The only dates that we had at
15 least two people or less available were the 11th, 12th,
16 and 13th of September --

17 DR. ZANZONICO: Okay.

18 MS. SMETHERS: -- and October 17th, 18th,
19 and 19th.

20 DR. ZANZONICO: Okay.

21 CHAIRMAN ALDERSON: All right, so having
22 heard that and having heard Dr. Palestro say he could
23 make the Monday-Tuesday, are we in agreement, then?
24 Will we be able to meet on the 11th and 12th of September.

25 I'm hearing people say yes so I think that's

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1 the committee's choice.

2 MS. SMETHERS: Okay.

3 CHAIRMAN ALDERSON: September 11-12.

4 MR. COLLINS: So, Dr. Alderson, if I might
5 just for a second, one of the potential challenges of
6 September is the availability of NRC travel funds to
7 support the meeting in this fiscal year.

8 CHAIRMAN ALDERSON: In this fiscal year.

9 MR. COLLINS: Right so October would be the
10 next fiscal year. And we're checking with our budget
11 people now to see what we could support. But if we can
12 support a September, we will, but we might have to revert
13 back to the second choice of October.

14 So we will get back to you on that.

15 CHAIRMAN ALDERSON: Right. So let me then
16 just raise a point of order, and you will tell us -- tell
17 me what the rules are in this regard. So when each of
18 us are coming on, we see the frustration of delay so
19 we're encouraged to get all our paperwork in and work
20 hard to get approved, fully approved as soon as we can.
21 What now happens, though, and I didn't understand this
22 either in the beginning, whatever that date is, well
23 that's sort of an out date. You know four years later,
24 that's an out date or re-up date. And there doesn't
25 seem to be much flexibility in that.

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1 So for example September the 28th is
2 virtually at the end of the month. And if the latitude
3 existed where the Agency would just say oh, well, Dr.
4 Langhorst, we will continue her through some sort of
5 amendment for the next three weeks and she can attend
6 the October meeting as a full member. That would solve
7 this problem without any issue.

8 I'm told that that doesn't exist, that that
9 flexibility doesn't exist. If it does, then maybe this
10 isn't as big an issue as we thought.

11 Can someone from the NRC comment?

12 MR. COLLINS: So there are some
13 flexibilities to be able to extend a term. We would
14 need to send a paper up to the Commission but I would
15 think that that would be a short thing to do. But the
16 first step is for us to figure out the travel funding
17 situation.

18 CHAIRMAN ALDERSON: Sure, well if you have
19 the funding --

20 MR. COLLINS: Then it's not a problem.

21 CHAIRMAN ALDERSON: -- then it's not a
22 problem.

23 MR. COLLINS: Then if it is, if we do need
24 to go to an October meeting then we will need to look
25 at potentially extending Dr. Langhorst for one -- long

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1 enough to support that one meeting.

2 CHAIRMAN ALDERSON: Yes, okay.

3 MS. HOLIDAY: Dr. Alderson, this is
4 Sophie. I could just add onto what Mr. Collins just
5 said.

6 Yes, there is a possibility for us to extend
7 her but what it would take to do that is a Commission
8 paper. And the only time that that ever happened was
9 when they granted Dr. Malmud a third term. That has not
10 happened since then and because it was such a rare
11 occasion because we needed that turnover back then, the
12 ACMUI membership terms were much shorter. They were
13 not four years. I believe they were two or three years
14 and it just wasn't sufficient time. So if staff were
15 to pursue that option, it would take a SECY paper and
16 Commission approval.

17 CHAIRMAN ALDERSON: Just for her to be
18 extended for three weeks?

19 MS. HOLIDAY: Just for her to be extended
20 at all.

21 MR. COLLINS: Yes, for any extension.

22 For any period of time but that doesn't mean
23 it's impossible.

24 MR. BOLLOCK: Yes, and a lot of that is how
25 receptive management is. And given the current state

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1 of how long it takes for us to get the clearances and
2 without the other options, as we were discussing
3 earlier, they may be more receptive.

4 CHAIRMAN ALDERSON: We assume one way or
5 the other, Sue, you'll be here with us in the fall.
6 Okay.

7 MS. SMETHERS: So considering all of that,
8 would you like to choose September 11th and 12th as your
9 first choice and then we can check into these different
10 --

11 CHAIRMAN ALDERSON: Yes, I think that's
12 what the committee has already agreed to. If we have
13 to go to an October date, then you have to re-look at
14 everyone and just make sure that Dr. Langhorst can be
15 there and that you can extend her but we hope that it
16 will work in September.

17 MS. SMETHERS: Can you scroll down,
18 Sophie, to October?

19 So the 18th and 19th, there were some
20 conflicts but people were able to adjust so that
21 everyone could attend if needed. So that would
22 probably be a good second choice, if you would like.

23 Okay.

24 CHAIRMAN ALDERSON: Okay, that takes care
25 of that one.

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1 So what's on the agenda is this ACMUI will
2 discuss medical topics of interest previously
3 identified. I think we have been doing that quite
4 extensively. So I guess I would ask if there are any
5 additional topics that people would like to put on the
6 table at this time.

7 Hearing none, I think that we should move
8 to the administrative closing.

9 While we're doing that I will just remind
10 people I think we will have a busy meeting in the fall
11 because we have this extremely important safety culture
12 item that's going to be on the agenda.

13 We have the subcommittee, the new
14 subcommittees on the Icon Gamma Knife, the release
15 criteria, and the nursing mothers. We have checked
16 with Michelle. We have looked at it. We have a charge
17 for each of those committees. We have talked to the
18 chairs. We have the membership, including the people
19 who volunteered to serve on a Patient Release
20 Subcommittee. So we have all of those put together and
21 so the chairs are now charged and they are ready to move
22 out, call a conference call, do other things they need
23 to do.

24 Yes?

25 MS. WEIL: I would be grateful to be

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1 included on the Patient Release Subcommittee.

2 CHAIRMAN ALDERSON: All right, Laura Weil
3 would like to be on the Patient Release Subcommittee.
4 Pat, you are the chair.

5 DR. ZANZONICO: Yes.

6 CHAIRMAN ALDERSON: So that's fine.

7 MS. WEIL: Thank you.

8 CHAIRMAN ALDERSON: So Laura is added to
9 that. So we're in good shape on that. We have, again,
10 the big safety culture issue to discuss. That will be,
11 however we manipulate this, Dr. Langhorst's last
12 meeting. And we are also going to honor Frank in a more
13 formal way in the fall. So those are all right there,
14 before we even talk about the rest of the agenda, we have
15 all of those things to do.

16 MS. SMETHERS: So if I may, at this point,
17 we are going to go through all the action and
18 recommendations. And if you have any modifications,
19 please mention them at this time and we will talk about
20 the staff contacts for different subcommittees.

21 So beginning with Item 1, the committee
22 requested that the recommendations and actions
23 pertaining to the Part 35 rulemaking be reviewed during
24 the fall 2017 ACMUI meeting and that additional time be
25 provided to review each item during the opening portion.

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1 Item 2, Dr. Alderson formed a subcommittee
2 to review the recommendations from Elekta to consider
3 amending the licensing guidance physical presence
4 requirements for the Elekta Gamma Knife Icon.

5 DR. ZANZONICO: Michelle, could I --

6 MS. SMETHERS: Yes.

7 DR. ZANZONICO: Can you just review for us
8 quickly what designations open and otherwise mean,
9 exactly.

10 MS. SMETHERS: Sorry, designations?

11 DR. ZANZONICO: Where it says open. Can
12 you explain what that means?

13 MS. SMETHERS: So could we scroll up to the
14 top here, Sophie?

15 So for status, we track these. We have it
16 going back from 2007 to the present. And so we keep
17 these and then as they close, as the subcommittee
18 reports or the action is closed, then we will mark this
19 closed. But for now, they are all new actions. We keep
20 them as open until it changes.

21 And then in the status column, we just
22 indicate if it is an NRC action or an ACMUI action.

23 DR. ZANZONICO: So open means that there is
24 nothing pending in terms of some definitive action.

25 MS. SMETHERS: We're working on it.

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1 (Simultaneous speaking.)

2 MS. SMETHERS: Did that answer your
3 question?

4 DR. ZANZONICO: Yes.

5 MS. SMETHERS: Okay, great. So for Item
6 2, just finishing up, the subcommittee membership
7 includes Dr. Suh as chair, Dr. Ennis, and Ms. Laura Weil.
8 The NRC point of contact will be Sophie Holiday.

9 Item 3, Dr. Alderson requested an update on
10 source security initiatives involving Category 3
11 sources from NRC staff at the fall 2017 ACMUI meeting.
12 If Irene Wu is there, we will request that she present.
13 Otherwise, we will find the point of contact.

14 For Item 4, Dr. Alderson formed a
15 subcommittee to review the SECY paper on patient
16 release. And the subcommittee will be comprised of Dr.
17 Zanzonico, as chair, Dr. Langhorst, Dr. Palestro, and
18 Ms. Weil. NRC staff point of contact will be Donna-Beth
19 -- Dr. Donna-Beth Howe.

20 Item 5, Dr. Alderson formed a subcommittee
21 to review the nursing mother guidelines. The
22 subcommittee charge is to review the radiation exposure
23 from diagnostic and therapeutic radiopharmaceuticals,
24 including brachytherapy to the nursing mother and
25 child. The subcommittee has grown since we discussed

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1 it last. The subcommittee will be comprised of Dr.
2 Metter, as chair, Dr. Dilsizian, Dr. Palestro, and Dr.
3 Zanzonico. The NRC staff point of contact, at this
4 point, is Dr. Said Daibes.

5 Item 6, the committee endorsed the medical
6 event reporting for all modalities, excluding Permanent
7 Implant Brachytherapy Subcommittee report. And we
8 keep that as open, since the staff will be looking at
9 that report. We would close it once we have either
10 implemented or evaluated whether to include
11 recommendations.

12 Item 7, the subcommittee endorsed the
13 Training and Experience for All Modalities Subcommittee
14 status report. Again, the same, we keep that open for
15 now.

16 Item 8, the Patient Intervention
17 Subcommittee will amend its subcommittee report and
18 will report at the ACMUI fall 2017 meeting or by
19 teleconference to discuss their amended report.

20 So, I will work on that after and you can
21 determine if you want to do it by teleconference or at
22 the next meeting.

23 CHAIRMAN ALDERSON: And that's been rolled
24 into this new idea that the chairs of these various
25 related initiatives will talk to one another.

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1 MS. SMETHERS: I believe Item 9. Okay,
2 Item 9, the committee recommended to 1) amend the title
3 of Medical Event Safety Culture Subcommittee Report
4 from a draft report to an interim report; and 2) to
5 continue future discussions on this topic; and 3) to
6 endorse the interim report.

7 Lastly, the committee tentatively
8 scheduled the fall 2017 meeting for September 11th and
9 12th, 2017. The backup dates are October 18th and 19th,
10 2017, pending travel funding and Dr. Langhorst's term
11 ending.

12 That's all I have.

13 CHAIRMAN ALDERSON: So it's typical
14 writing in language that all those things say that I
15 asked this and I asked that. I mean it was all based
16 on the consensus of what we came to after those
17 discussions but that's how you write it.

18 MS. SMETHERS: That's how we've done it.

19 CHAIRMAN ALDERSON: Okay, that's fine.

20 MR. BOLLOCK: Right, you as the chairman,
21 you could direct the subcommittee or ask the committee
22 to form a subcommittee. That is in your discretion.

23 CHAIRMAN ALDERSON: Right, so that's how
24 it's recorded. Okay.

25 MS. SMETHERS: Any questions, comments,

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1 updates? Katie.

2 DR. TAPP: I know it's not an action for
3 getting to close but Dr. Suh's Subcommittee on Medical
4 Event Reporting Excluding Permanent Brachytherapy
5 provided a final report. So once we go through that
6 report and we close that out, my understanding that
7 would be, unless Dr. Suh would like to continue or the
8 ACMUI would like to continue, that subcommittee, I
9 believe is done.

10 Is there any actions we need to take for
11 that subcommittee to be closed?

12 MR. BOLLOCK: Not in my opinion.

13 MS. SMETHERS: So it's understood that the
14 subcommittee is closed.

15 CHAIRMAN ALDERSON: That still doesn't
16 mean that Dr. Suh can't provide an opinion to others who
17 are engaged in this whole safety culture discussion.

18 MS. SMETHERS: So what I would do is go back
19 to the old charts and look for that subcommittee, where
20 it was formed, and then just mark it as closed and take
21 it off the list for now.

22 DR. TAPP: I just wanted to verify that
23 that was the consensus.

24 MS. SMETHERS: Thanks. That's all I have.

25 MS. HOLIDAY: Can I just make one point of

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1 clarification? So for historical knowledge, just a
2 couple years back, we decided that once a subcommittee
3 was formed by the ACMUI chairman, it was only listed for
4 that one recommendation chart and then it's dropped off
5 because NRC doesn't take action on the formation of
6 subcommittees. Items are listed as open or closed or
7 delayed pending when NRC staff takes action on that
8 item.

9 So for all of the Part 35 rulemaking items,
10 those things remain open until the rule itself becomes
11 finalized. So just like these various reports that the
12 committee has endorsed will remain open until staff does
13 something or takes some type of action in response to
14 the committee's reports. I just wanted to clarify that
15 for you.

16 CHAIRMAN ALDERSON: Okay, thank you.

17 MS. SMETHERS: Thanks, Sophie. That's
18 all I have.

19 CHAIRMAN ALDERSON: Very good. Is there
20 any other business to come before the ACMUI at this time?
21 We discussed open forum. We did. We sort of rolled
22 right through it but we're there again because the floor
23 is open for any new items or things that haven't been
24 discussed up until this point that people want to raise.

25 Mr. Green.

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1 MR. GREEN: Just in brief, as we are
2 looking at training, experience, and possibly looking
3 at a way to bracket what has been done, perhaps for
4 endocrinologists, one drug, not a whole panoply of
5 everything that is in 200 or 300, there are five current
6 alpha and beta FDA approved radiopharmaceuticals that
7 can be used in unit dose form. I was wondering if the
8 committee as a whole is aware of these five drugs and
9 wanted to have information on them.

10 CHAIRMAN ALDERSON: Just for our
11 edification, just list them or name them.

12 MR. GREEN: Xofigo, radium-223
13 dichloride, Metastron, strontium-89 chloride,
14 Quadramet, which is samarium-153 lexidronam, Zevalin,
15 which is Y-90 ibritumomab tiuxetan, and I-131 sodium
16 iodide capsules or solutions, which would be the current
17 FDA approved alpha and beta or beta gamma that would be
18 in the 300.

19 CHAIRMAN ALDERSON: Yes, I think that
20 things we're doing are going to obviously have some
21 impact potentially on all of those at some point.

22 Any comments from the FDA on that, Mr.
23 O'Hara?

24 DR. O'HARA: I don't have any comments on
25 that.

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1 CHAIRMAN ALDERSON: Are there any other
2 items of new business that people wish to bring forward
3 at this time?

4 Yes, Dr. Suh.

5 DR. SUH: It's not really new business but
6 you know just keeping with the theme of safety culture,
7 is it possible to show what type of penalties are being
8 assessed each year? I don't think I've ever seen that.
9 Like fiscal year 2014 receives a number, \$10,000 and
10 2016 it is \$100,000, just to get a sense of what that
11 -- I think it is that perception and reality.

12 MR. BOLLOCK: Yes, we can provide that.
13 And if the committee would like, you could put in the
14 list for us to --

15 MS. HOLIDAY: So the wonderful thing is
16 that Sophie's now handling enforcement. And I think
17 what you are referring to is possibly civil penalties.
18 And so the NRC has a public website that lists escalated
19 enforcement actions that we issue whenever they happen.
20 And that is available to anybody to look at.

21 But like Doug said, we can compile it and
22 send it to the committee.

23 MR. BOLLOCK: And also I mean do you -- so
24 I should ask the committee. That's for civil penalties
25 Severity Level III and above. However, I don't believe

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1 we have on the public site available the lower like the
2 Severity Level IV or V. So that would take -- we could
3 only -- I think we could supply the NRC's numbers for
4 those but that is other enforcement actions, violations
5 but at lower levels that didn't result in civil
6 penalties. Would you like that information as well?

7 DR. SUH: I think yes, just to get an idea
8 of what the count is. I have no idea. There should be
9 a penalty for all these reasons. Again, I think there
10 is that perception and reality that you talked about
11 earlier is the medical event reporting.

12 MR. BOLLOCK: So would five years of
13 information of civil penalties and then amounts at like
14 the lower levels, would that suffice, a five-year trend?

15 MS. HOLIDAY: Just to give you a general
16 idea, your civil penalty amount depends on the type of
17 licensee that you are. Generally, your industrial
18 licensees have a higher civil penalty threshold than
19 your medical licensees. And then from there, it is
20 based on your severity level of violation. If you are
21 Severity Level I, II, III, that would dictate the dollar
22 amount that you get as well.

23 MR. BOLLOCK: And to clarify for my staff,
24 for when I task Sophie to get that, are you only
25 interested in medical licensees or are you also --

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1 DR. SUH: It is for me. I don't want to
2 speak for the committee.

3 (Simultaneous speaking.)

4 MR. BOLLOCK: Medical only, okay.

5 DR. TAPP: Just to clarify, just NRC
6 tracking.

7 MR. BOLLOCK: Yes, we only have NRC
8 information so it is only our licensees in the 13 states
9 where we have jurisdiction.

10 DR. SUH: Just because we know that each
11 year there is approximately 50 --

12 MR. BOLLOCK: Right.

13 DR. SUH: -- I mean it is give or take. So
14 just to get a sense of what the trend line looks like.
15 Is it going up? Is it going down?

16 MR. BOLLOCK: Right.

17 DR. SUH: It would be nice to see that.

18 MR. BOLLOCK: Okay, we can get you that
19 information and give you some perspective.

20 CHAIRMAN ALDERSON: Any other items?

21 Hearing none, I think we stand adjourned.

22 (Whereupon, the above-entitled matter
23 went off the record at 2:54 p.m.)

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