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on the Medical Uses of Isotopes

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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 and 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, intra-operative modalities, various  
5 radiation oncology modalities ranging from two  
6 dimensional 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 say , 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.  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. The point that he

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1 made was that Mr. Costello's presentation in March of  
2 2015 was concerning particularly about Y-90  
3 microspheres specific to the issue as well you can have  
4 the patient's artery contract 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 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? --

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

20 DR. LANGHORST: Thank you.

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

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

24 MR. FULLER: Just in the way of  
25 information, so during that 180 days, staff's

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

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

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

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

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1 public for licensees to ask questions.

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

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

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

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

23 But as time went on -- and also we couldn't  
24 do it right away because we were in the middle of  
25 rulemaking for training and experience, and you

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

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

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

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

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1 want and it is going to require rulemaking, then tell  
2 us because that is what we rely upon the ACMUI for.

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

5 All right, well thank you very much.

6 MS. TAYLOR: Thank you.

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

11 DR. LANGHORST: Thank you.

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

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

24 First off, I want to thank my subcommittee  
25 members. And please forgive me, it breaks my heart that

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1 Frank is not here but I thank him very much.

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

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

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

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

7 Sorry, I forgot I did all this.

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

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

22 We have seen some of this in radiology and  
23 the Image Gently and Image Safely Programs on the  
24 imaging, on the x-ray imaging systems. And we see this  
25 also in trying to be more precise in targeting our

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1 therapies to just impact the cancer cells and save the  
2 good cells as much as possible.

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

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

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

24 In 1979, the medical use, there was the  
25 first medical use policy put into place. And that was

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1 to help guide NRC actions in establishing new  
2 regulations in regard to medical use.

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

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

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

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

23 There was also, and I didn't put into the  
24 report, there was also -- what was the other criteria?  
25 Oh, there was another criteria that wasn't a

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1 misadministration but --

2 DR. TAPP: A recordable event.

3 DR. LANGHORST: -- a reportable event.

4 Thank you.

5 DR. TAPP: Recordable.

6 DR. LANGHORST: Recordable. Recordable  
7 event.

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

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

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

25 And that the NRC distinguishes between the

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1 unavoidable risk attendant with purposefully  
2 prescribed and properly performed clinical procedures  
3 and the unacceptable risks of improper or careless use.

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

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

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

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

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

23 So we were talking about changes in Part 35.  
24 The last major change in Part 35 occurred kind of between  
25 2002 and 2005 because there were a lot of regulatory

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1 steps that had to be taken to change, in particular,  
2 training and experience requirements. And kind of  
3 since then, we have been working on trying to update this  
4 part of the regulations.

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

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

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

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

25 Now, they are really focused on reactor and

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1 fuel cycle environments. We are not surprised at that.  
2 There are some material use. There is a little bit of  
3 medical use.

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

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

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

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

24 In 2005, Congress passed the Patient Safety  
25 Act and Health and Human Services took that Act and they

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

7 Too many papers.

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

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

24 And reporting to these organizations is  
25 voluntary but if you meet some of the reporting criteria

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1 they set, you had better be reporting it, rather than  
2 letting them find out that you haven't reported it.

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

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

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

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

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

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

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

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

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

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

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

10          CHAIRMAN ALDERSON: All right.

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

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

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

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

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

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

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

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1 an NRC inspector coming to help you review the process  
2 within a few days of you identifying it with the look  
3 of nuclear safety culture; how are you meeting the NRC  
4 Agreement State requirements.

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

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

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

13 Has anyone got a comment? Dr. Ennis.

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

23 And there is a lot of evidence that that  
24 transition in a variety of industries, including  
25 medical industries, has improved quality and a sense I

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1 think, among several of us at least, that the same  
2 attitudes and approach being brought to bear in our area  
3 to improve quality.

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

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

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

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1 is a major disconnect.

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

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

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

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

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

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

23 DR. DILSIZIAN: I think what we are saying  
24 is that medical errors should be reported the way it is,  
25 urgently, 24 hours, 15 days reporting. We don't have

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1 to change that.

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

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

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

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

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1 they mature enough? Can we do this? And will it help  
2 the NRC support patient safety?

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

8 DR. LANGHORST: Potentially, yes.

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

14 Mr. Ouhib.

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

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

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1 not available from NRC. They expect you to provide your  
2 corrective actions. They expect you to make some  
3 correction and all that.

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

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

19 CHAIRMAN ALDERSON: Dr. Dilsizian.

20 DR. DILSIZIAN: I just wanted to  
21 follow-up. I am hearing you and I just want to clarify.  
22 When you say the regulators are not knowledgeable enough  
23 about medicine to be able to understand our patients,  
24 they use their degrees as such but may not understand  
25 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 not include  
7 M&M peer review. I want the regulators to be doing what  
8 is only 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 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 unavailable were the 11th,  
16 12th, 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.)

24

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