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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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MEETING

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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

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

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

C-O-N-T-E-N-T-S

P R O C E E D I N G S

8:00 a.m.

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

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

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

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

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

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

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

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

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

transparency, education, and adoption of best practices?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you.

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

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

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

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

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

CHAIRMAN ALDERSON: Dr. Ennis would like to comment.

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

DR. ZANZONICO: Yes, I'm ambivalent.

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

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

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

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

Sorry, I just had that opinion.

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

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

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

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

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

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

CHAIRMAN ALDERSON: Thank you, Dr. Langhorst.

Dr. Ouhib.

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

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

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

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

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

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

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

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

So are you suggesting then that we should

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

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

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

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

CHAIRMAN ALDERSON: Dr. Langhorst.

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

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

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

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

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

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

MS. WEIL: Three zeros.

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

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

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

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

CHAIRMAN ALDERSON: Yes, Mike Fuller.

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

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

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

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

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

so forth and so on.

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

So, I just offer that.

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

CHAIRMAN ALDERSON: Yes, Dr. Ouhib.

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

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

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

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

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

Thank you very much.

DR. LANGHORST: Is there a written report

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

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

DR. LANGHORST: Yes.

CHAIRMAN ALDERSON: Is there a motion?

DR. ENNIS: So moved.

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

DR. ZANZONICO: There is.

CHAIRMAN ALDERSON: Is there discussion?

All in favor?

(Chorus of aye.)

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

All right, the next --

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

CHAIRMAN ALDERSON: Ah, that we did not approve.

DR. PALESTRO: We did not --

CHAIRMAN ALDERSON: -- formally approve. All right. I'm sure that you've all read it and are familiar with it.

Is there a motion that someone would like to make?

DR. METTER: So moved.

CHAIRMAN ALDERSON: There is a motion --

MS. WEIL: Second.

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

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

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

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

DR. DILSIZIAN: Thank you very much.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN ALDERSON: Thank you, Dr. Dilsizian.

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

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

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

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

CHAIRMAN ALDERSON: Dr. Ennis.

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

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

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

CHAIRMAN ALDERSON: Mr. Ouhib.

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

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

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

Just a thought.

CHAIRMAN ALDERSON: Dr. Langhorst.

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

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

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

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

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

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

MR. OUHIB: Yes, Patient Safety Organizations.

CHAIRMAN ALDERSON: Thank you.

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

CHAIRMAN ALDERSON: Right, thank you.

Other comments or questions? I have a question.

DR. ZANZONICO: Can I just --

CHAIRMAN ALDERSON: Yes.

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

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

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

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

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

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

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

CHAIRMAN ALDERSON: That's a rule change.

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

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

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

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

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

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

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

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

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

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

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

If it is a database of information that we

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN ALDERSON: Thank you.

We have hands raised by Dr. Palestro and Ms.

Weil. Dr. Palestro.

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

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

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

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

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

CHAIRMAN ALDERSON: Ms. Weil.

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

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

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

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

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

CHAIRMAN ALDERSON: Dr. Howe.

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

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

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

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

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

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

CHAIRMAN ALDERSON: Very good. Mr. Ouhib.

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

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

So I think let's grab these opportunities.

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

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

Dr. Langhorst.

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

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

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

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

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

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

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

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

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

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

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

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

MR. BOLLOCK: And actually, if you were

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

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

CHAIRMAN ALDERSON: Okay.

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

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

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

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

Right.

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

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

MR. FULLER: Just to clarify that recommendation.

MR. BOLLOCK: Right.

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

MR. BOLLOCK: Right. Yes.

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

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

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

So, that needs some clarification.

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

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

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

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

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

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

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

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

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

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

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

Yes, Laura?

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

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

CHAIRMAN ALDERSON: Dr. Ennis?

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

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

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

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

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

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

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

the ACMUI to the medical community.

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

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

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

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

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

CHAIRMAN ALDERSON: Dr. Tapp.

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

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

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

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

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

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

CHAIRMAN ALDERSON: Yes, Mike?

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

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

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

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

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

Thank you very much.

DR. LANGHORST: Or we could do a short

teleconference on it before then.

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

Very good. Thank you very much.

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

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

CHAIRMAN ALDERSON: Sorry?

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

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

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

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

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

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

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

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

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

requirements under OMB.

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

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

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

Do you have a question, Mike?

MR. FULLER: No.

MS. TAYLOR: Oh.

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

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

So no questions?

CHAIRMAN ALDERSON: There's a question.

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

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

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

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

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

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

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

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

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

and it's hard to read the tea leaves.

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

MS. TAYLOR: That's fair.

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

So, we are not anticipating any major problems.

MS. TAYLOR: Thanks, Mike.

CHAIRMAN ALDERSON: Yes, Dr. Langhorst?

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

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

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

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

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

DR. LANGHORST: Right.

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

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

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

DR. LANGHORST: For NRC licensees not for --

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

DR. LANGHORST: Thank you.

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

CHAIRMAN ALDERSON: Are there -- oh, yes.

MR. FULLER: Just in the way of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

All right, well thank you very much.

MS. TAYLOR: Thank you.

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

DR. LANGHORST: Thank you.

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

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

First off, I want to thank my subcommittee

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

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

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

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

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

Sorry, I forgot I did all this.

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

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

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

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

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

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

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

In 1979, the medical use, there was the

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

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

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

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

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

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

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

DR. TAPP: A recordable event.

DR. LANGHORST: -- a reportable event. Thank you.

DR. TAPP: Recordable.

DR. LANGHORST: Recordable. Recordable event.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In 2005, Congress passed the Patient Safety

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

Too many papers.

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

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

And reporting to these organizations is

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

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

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

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

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

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

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

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

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

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

very much for that.

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

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

CHAIRMAN ALDERSON: All right.

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

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

needed.

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

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

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

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

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

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

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

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

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

Has anyone got a comment? Dr. Ennis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. LANGHORST: Potentially, yes.

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

Mr. Ouhib.

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

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

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

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

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

CHAIRMAN ALDERSON: Dr. Dilsizian.

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

DR. LANGHORST: The inspector coming in.

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

DR. LANGHORST: Right.

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

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

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

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

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

MR. OUHIB: Absolutely.

DR. LANGHORST: Yes.

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

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

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

MR. COLLINS: Thank you, Doctor.

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

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

The other thing that I would say is it is

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

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

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

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

DR. LANGHORST: Oh, I wouldn't.

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

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

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

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

Yes, Ms. Weil.

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

for this purpose.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN ALDERSON: Yes, Mr. Bullock?

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

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

occurring again.

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

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

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

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

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

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

DR. LANGHORST: Feedback.

MR. BOLLOCK: Right, feedback. Exactly. Because we do understand that we can -- we are the

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

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

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

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

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

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

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

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

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

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

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

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

So if you were to change that first report,

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

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

Darlene had her hand up.

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

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

CHAIRMAN ALDERSON: Right.

DR. METTER: I think that would be a

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

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

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

CHAIRMAN ALDERSON: Yes, Sue.

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

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

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

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

Now, that doesn't necessarily, if you are

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

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

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

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

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

medical event criteria?

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

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

MS. TOMLINSON: Sir --

CHAIRMAN ALDERSON: Please identify yourself.

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

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

The other premise is is that you are putting

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

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

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

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

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

So we have worked pretty hard to make sure

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

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

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

CHAIRMAN ALDERSON: Thanks very much.

MS. TOMLINSON: Sure, not problem.

CHAIRMAN ALDERSON: We have some comment. Yes, Mr. Ouhib.

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

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

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

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

DR. LANGHORST: That is not my plan.

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

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

CHAIRMAN ALDERSON: Absolutely.

DR. LANGHORST: Okay, that is one question.

CHAIRMAN ALDERSON: Those were my next few words.

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

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

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

MR. BOLLOCK: Correct.

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

MR. BOLLOCK: Four.

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

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

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

DR. LANGHORST: And condense that combination.

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

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

DR. LANGHORST: Right.

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

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

CHAIRMAN ALDERSON: Yes.

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

CHAIRMAN ALDERSON: Well you all will talk together.

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

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

DR. LANGHORST: Absolutely.

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

So how about some closing comments then?

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

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

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

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

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

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

DR. LANGHORST: Okay.

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

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

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

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

(Chorus of yes.)

CHAIRMAN ALDERSON: Is anyone opposed?

Good, that's unanimously done.

DR. LANGHORST: Thank you very much.

CHAIRMAN ALDERSON: Approved as an interim

report.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN ALDERSON: Report directly to the Commission?

MS. SMETHERS: Directly to the Commission.

DR. METTER: I like the current reporting structure.

MS. SMETHERS: Okay. Any other comments?

CHAIRMAN ALDERSON: Sue.

MS. SMETHERS: Dr. Langhorst.

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

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

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

CHAIRMAN ALDERSON: Good. Laura?

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

MS. SMETHERS: Ten times, approximately.

CHAIRMAN ALDERSON: Ten times a year.

DR. LANGHORST: And the ACRS stands for?

MS. SMETHERS: The Advisory --

MS. WEIL: Michelle already said that.

MS. SMETHERS: -- Committee on Reactor Safety.

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

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

So yes, Mr. Fuller.

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

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

MS. SMETHERS: Yes.

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

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

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

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

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

(Chorus of yes.)

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

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

(Chorus of yes.)

CHAIRMAN ALDERSON: That seems to be a

consensus.

MS. SMETHERS: Would anyone like more or less?

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

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

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

(Laughter.)

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

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

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

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

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

CHAIRMAN ALDERSON: Good.

MS. SMETHERS: That concludes this portion.

CHAIRMAN ALDERSON: Yes, good.

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

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

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

MS. SMETHERS: The one request I would

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

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

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

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

CHAIRMAN ALDERSON: Okay.

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

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

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

MS. SMETHERS: Monday, Tuesday.

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

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

DR. ZANZONICO: Okay.

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

DR. ZANZONICO: Okay.

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

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

the committee's choice.

MS. SMETHERS: Okay.

CHAIRMAN ALDERSON: September 11-12.

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

CHAIRMAN ALDERSON: In this fiscal year.

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

So we will get back to you on that.

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

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

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

Can someone from the NRC comment?

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

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

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

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

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

enough to support that one meeting.

CHAIRMAN ALDERSON: Yes, okay.

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

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

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

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

MR. COLLINS: Yes, for any extension.

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

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

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

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

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

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

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

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

Okay.

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

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

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

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

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

Yes?

MS. WEIL: I would be grateful to be

included on the Patient Release Subcommittee.

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

DR. ZANZONICO: Yes.

CHAIRMAN ALDERSON: So that's fine.

MS. WEIL: Thank you.

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

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

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

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

DR. ZANZONICO: Michelle, could I --

MS. SMETHERS: Yes.

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

MS. SMETHERS: Sorry, designations?

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

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

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

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

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

MS. SMETHERS: We're working on it.

(Simultaneous speaking.)

MS. SMETHERS: Did that answer your question?

DR. ZANZONICO: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

That's all I have.

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

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

CHAIRMAN ALDERSON: Okay, that's fine.

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

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

MS. SMETHERS: Any questions, comments,

updates? Katie.

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

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

MR. BOLLOCK: Not in my opinion.

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

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

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

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

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

MS. HOLIDAY: Can I just make one point of

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

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

CHAIRMAN ALDERSON: Okay, thank you.

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

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

Mr. Green.

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

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

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

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

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

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

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

Yes, Dr. Suh.

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

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

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

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

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

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

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

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

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

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

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

(Simultaneous speaking.)

MR. BOLLOCK: Medical only, okay.

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

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

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

MR. BOLLOCK: Right.

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

MR. BOLLOCK: Right.

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

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

CHAIRMAN ALDERSON: Any other items?

Hearing none, I think we stand adjourned.

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

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