UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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MEDICAL EVENT SUBCOMMITTEE (MESC)

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MEETING

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Tuesday, June 28, 2005

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The meeting was conducted by teleconference, pursuant to notice, at 1:00 p.m, Leon S. Malmud, M.D., Chair, presiding.

COMMITTEE MEMBERS PRESENT:

LEON S. MALMUD, M.D.	Chair
EDGAR BAILEY, Ph.D.	Member
DOUGLAS F. EGGLI, M.D.	Member
ALBERT RAIZNER, M.D.	Member
SALLY SCHWARZ, R.Ph.	Member
RICHARD J. VETTER, Ph.D.	Member

SUBCOMMITTEE MEMBERS PRESENT:

JEFFREY F. WILLIAMSON, Ph.D.	Chair
DAVID DIAMOND, M.D	Member
RALPH P. LIETO	Member
SUBIR NAG, M.D.	Member

NRC STAFF PRESENT:

THOMAS H. ESSIG	Designated Federal Official
NEELAM BHALLA	
IVELISSE CABRERA	
CYNTHIA FLANNERY	
DONNA-BETH HOWE, Ph.D.	
ANGELA McINTOSH	
MOHAMMAD SABA	
RONALD ZELAC, Ph.D.	

ALSO PRESENT: LYNNE FAIROBENT AAPM
GLORIA ROMANELLI, ACR
ROSHUNDA DRUMMOND, ASTRO

P-R-O-C-E-E-D-I-N-G-S

MR. ESSIG: Okay. Let me begin with my opening remarks, if I may. As the designated federal official for this meeting, I'm pleased to welcome you to this publicly noticed conference call meeting of the ACMUI.

My name is Thomas Essig. I am branch chief for the Material Safety Inspection Branch, and have been designated as a federal official for this advisory committee in accordance with 10 CFR, Part 7.11. This is an announcement meeting of the committee. It's being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

The meeting was announced in the June 14, 2005 edition of the Federal Register. The function of the committee is to advise the staff on issues and questions that arise on the medical use of by-product material. The committee provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the Commission. The NRC solicits the views of the committee and values them very much.

I request that whenever possible we try to reach a consensus on the various issues that will be

discussed during this conference call, and we also value minority or dissenting opinions. If you have such opinions, please allow them to be read into the record.

As part of the preparation for this meeting, I have reviewed the agenda for members and employment interests based on the general nature of the discussion we're going to have today. I've not identified any items which pose a conflict of interest for the members. If, however, during the course of our business, other members determine that they have a conflict of interest in matters before the committee, please state it for the record and recuse yourself from that particular aspect of the discussion.

At this point, I would merely acknowledge the members of the committee who have indicated that they are present. I will go down the list of eight that I have. If somebody has joined us, a committee member, who's name I don't read, please acknowledge.

Dr. Douglas Eggli, nuclear medicine physician.

DR. EGGLI: Present.

MR. ESSIG: Dr. David Diamond, radiation oncologist.

DR. DIAMOND: Present.

MR. ESSIG: Dr. Subir Nag, radiation oncologist.

DR. NAG: Yes.

MR. ESSIG: Ms. Sally Schwarz nuclear pharmacist.

MS. SCHWARZ: Present.

MR. ESSIG: Dr. Richard Vetter, radiation safety officer.

DR. VETTER: Present.

MR. ESSIG: Dr. Jeffrey Williamson, therapy physicist.

DR. WILLIAMSON: Here.

MR. ESSIG: Dr. Albert Raizner, interventional cardiologist.

DR. RAIZNER: Present.

MR. ESSIG: And Mr. Ralph Lieto, nuclear medicine physicist.

MR. LIETO: Present.

MR. ESSIG: Are there any members of the committee who have joined us in the interim?

DR. NAG: What about Dr. Potters? Is Dr. Potters here?

MR. ESSIG: Is Dr. Potters here?

DR. WILLIAMSON: No. I guess nobody

informed him of the meeting until I did today, so he's going to try to join us, but may not be able to.

MR. ESSIG: Okay.

MS. McINTOSH: I sent him an email invitation. This is Angela McIntosh of the Nuclear Regulatory Commission staff. I did send him an email invitation, Dr. Williamson, when I sent it to the committee. So maybe he just didn't read it or whatever.

DR. WILLIAMSON: Could be.

MR. ESSIG: In the absence of the chairperson, Dr. Leon Malmud, I will conduct today's meeting as designated federal official. Following the discussion of the agenda, I will at my option entertain comments from the members of the public who are participating with us today.

The purpose of today's meeting is to hear the report from the Medical Events Subcommittee, chaired by Dr. Jeff Williamson, and reporting to the full committee. I would just take a second and allow the members of the NRC staff to introduce themselves. We'll just go around the table here because there may be members of our staff speaking. We just want to do kind of a sound check and make sure that the court reporter and members can hear us. As I mentioned, this

is Tom Essig.

MS. FLANNERY: Cindy Flannery, F-L-A-N-N-E-R-Y.

MS. McINTOSH: Angela McIntosh, M-c-I-N-T-O-S-H.

DR. ZELAC: Dr. Ronald Zelac, Z-E-L-A-C.

MS. BHALLA: Neelam Bhalla. That's B-H-A-L-L-A.

MR. SABA: Mohammed Saba, S-A-B-A.

MR. ESSIG: Okay. Dr. Donna-Beth Howe was with us. She just stepped out of the room momentarily, but she should return shortly.

MR. ESSIG: Okay. I believe now we are ready to begin with the report of the subcommittee.

Jeff, I'll turn it over to you to present your report. Summarize it in whatever fashion you feel appropriate for the committee as a whole.

DR. WILLIAMSON: Okay. Well, thank you.

I'm very pleased that during our last non-public telephone conference, the Medical Event Subcommittee was able to achieve a consensus approach to the revision of the medical event rule to permanent interstitial implants.

We adopted a different strategy than we tried in the past. We made no effort to state our

conclusions or recommendations in rule language. Due to the technical complexity of the task, we have become mired in basically legal questions of how to interpret the existing rule and what is the best way to state the new consensus in rule language, so we abandoned that approach, and we simply stated our recommendations in ordinary language.

Well, they lack maybe the precision of rule language. I think taken as a totality, the recommendations represent a coherent and consistent view. So it is in this form we would like to present these to the ACMUI and get your feedback, and hopefully approval of the approach. Then my understanding is that the staff will attempt to take this approach and create a rule language draft that I would assume we would get to review at a subsequent meeting. I guess we can start.

DR. NAG: Are you basically going to follow the memo you sent out June 21 or is there any late revision to that?

DR. WILLIAMSON: The most recent one I believe was sent out by Angela McIntosh -- was it the 24th of June? But I believe it says up in the upper right-hand margin, "Revised 21 June 2005." And the name of the document is Medical Event Subcommittee

Meeting Summary and Draft Recommendations to the ACMUI. So that is the document we'll be referring to. I thank you for bringing my neglect of mentioning it to your attention.

DR. NAG: Everyone has this document that we can follow.

DR. WILLIAMSON: Mr. Chairman, I suggest we just step through it point by point, and determine whether there is a consensus on the different issues or not.

MR. ESSIG: Please do.

DR. WILLIAMSON: Okay. Well, the document is divided into three parts, Parts A, B and C. Part A is essentially our view of the status of the current medical event rule and associated definitions. It contains some critique of the existing rule and concerns that have been developed and articulated both by the subcommittee and the staff. I don't think there is a motion in Section A, but I will ask the ACMUI if there are any questions or concerns about any of the material in Part A of this document on pages 1 and 2.

MR. ESSIG: Dr. Williams, there was a break in the conversation. Did somebody join us?

DR. MALMUD: Dr. Malmud.

MR. ESSIG: Excellent. I will turn over

the gavel to you, sir.

DR. MALMUD: Thank you.

MR. ESSIG: We just started. Dr. Williamson is running down through the points in the June 21st version of the subcommittee's report.

DR. MALMUD: Yes, I heard.

MR. ESSIG: Okay.

DR. MALMUD: He's looking for a motion or approval.

DR. WILLIAMSON: Well, I'm not sure in Part A there's any action item in it or a motion to be made. I think Part A could be considered as a whereas component.

I was just asking if there were any questions or concerns about Part A, which is really not an action item in itself.

DR. MALMUD: None from Malmud.

DR. NAG: I suggest we go on to Part B, and on this portion of Part B we go ahead and have the voting and so on.

DR. WILLIAMSON: All right. Is the preference of the ACMUI to through Part B point by point?

DR. NAG: At least the main point. We may not need to go through all the rationales, but

let's go through the main point.

DR. MALMUD: Okay. Which one shall we begin with?

DR. WILLIAMSON: Let's start with point B1, which I can read. "For all permanent implants, ME should be defined in terms of total source strength and planted in the treatment site, not in terms of absorbed dose." So I guess this is a motion, maybe.

MR. LIETO: This is Ralph Lieto. I second.

DR. MALMUD: It's been moved and seconded. Is there any discussion? If not, may we call the vote?

All in favor?

(Chorus of ayes)

DR. MALMUD: Any opposed?

DR. WILLIAMSON: All right, point 2, B2, which is entitled, Treatment site accuracy, ME pathway. "Specifically, the Medical Event Subcommittee recommends that any implant in which the source strength implanted in the treatment site deviates from the written directive by more than 20 percent, in either direction, should be classified as an ME." That is another motion.

DR. NAG: Could we add "total source strength" rather than just "source strength"?

DR. WILLIAMSON: That is a good correction, yes. Let's amend the motion as suggested by Dr. Nag so it now will read, "Specifically, MESC recommends that any implant in which the total source strength implanted in the treatment site deviates from the written directive by more than 20 percent, in either direction, should be classified as an ME."

DR. NAG: I second the motion.

DR. MALMUD: All in favor?

(Chorus of ayes)

DR. MALMUD: Any opposed? Carries.

DR. WILLIAMSON: We move on to point B3 on page 3, Wrong site medical event pathway. "The Medical Event Subcommittee recommends that the revised wrong-site medical event criterion distinguish between two scenarios: tissue or organs immediately adjacent to the treatment site and organs that are distant from the treatment site. For permanent implants, tissues that are more than 2 to 4 centimeters from the treatment site boundary can be considered distant as dose has fallen to subtherapeutic levels."

I think it's necessary for me to at least summarize the sub-bullets, 3a, d and c, because

they are part of the motion. So for adjacent tissue wrong-site medical event -- this is bullet B3a -- we propose, implants in which more than 20 percent of the source strength -- I guess it should be total source strength -- documented in the pre-implantation written directive implanted in tissue or organs adjacent to the treatment site should be classified as ME. That's point a.

Point B is entitled, Distant organ wrong treatment site ME. For erroneous implantation of radioactive seeds in an organ distant from the intended treatment site, the Medical Event Subcommittee recommends that such implants be classified as MEs if 1) seeds are actually implanted in a distant organ; 2) the dose of a distant organ exceeds 5 Rem; and 3) the excess dose to the organ is at least 50 percent greater than the dose that would have been delivered had the seeds been implanted in the correct tissue volume.

Point C states, "For both adjacent and distant wrong-site MEs, it is important to exclude seeds that were correctly implanted but subsequently migrated as grounds for an ME."

That is the end of the motion. I'm sorry it's so long.

DR. NAG: Again, I second that motion.

DR. MALMUD: The motion's been moved by Williamson; seconded by NAG. Any discussion?

DR. RAIZNER: Just a question. The definition of the distance in this motion, it states 2 to 4 centimeters. How will you decide whether 3 is outside the treatment site? In other words, giving a range, is there an advantage to doing that or should we define a specific distance, such as 4 centimeters?

DR. NAG: The reason we left that somewhat vague is that it depends on the organ we are implanting. For example, if the tissue adjacent to that organ is not critical, I have no problem it being defined as 4 centimeters; whereas, if the adjacent tissue is something critical, like the rectum or bladder, then we have to be a little tighter. So that's we have that range of 2 to 4.

DR. RAIZNER: So will there be specific distances for specific organs or left as the 2 to 4?

DR. WILLIAMSON: Remember, there's a distinction being made between adjacent and distance. Adjacent is not exactly defined, but the intent of the subcommittee was an adjacent organ is organ that is in contiguity or in contact with the treatment site. So the rectum would be an adjacent organ. And,

presumably, any part of the rectum -- whether it's 2 or 3 centimeters away -- would be considered an adjacent organ.

What would be a good example of a tissue that's not in contact with the prostate here that we could use to illustrate a distant organ?

DR. NAG: The penis, for example, it went down to the lower part. That's not really adjacent because you have the bulb, and then if it goes to the penile tissue, that would be a distant organ.

DR. WILLIAMSON: Yeah. I think, to be honest, we really haven't crafted an exact definition. A reasonable approach would be to say that a distant organ is one whose closest boundary to the treatment site perceives the less than 5 percent of the dose. That would probably be a reasonable characterization that we might be able to live with.

DR. VETTER: So who is left to interpret whether 2 or 4 is appropriate in any given medical event?

DR. NAG: I think this is where we can leave it to the discretion of the medical person who is going to be reviewing it. And that is why we gave that 2 to 4 centimeter leeway. If it is a critical organ, we would take the lesser number, and if it's a less

critical organ, we'll take the larger number. But this gives some room for using some of the clinical judgment, rather how important it is.

MR. LIETO: Dr. Nag and Dr. Williamson, the concern that I'm getting is that if we are going to turn this over to NRC staff to craft regulations from, I think they're going to need sort of a cut-off level. I don't know if we want to say 4 centimeters or 2 centimeters, or we want to say less than 5 percent of the absorbed dose. I would defer to the two of you and Dr. Diamond to maybe come up with the right cut-off level. I can sympathize with Dr. Vetter and the other that we probably are going to need to give guidance to NRC staff if we want them to craft it in the regulation.

DR. MALMUD: Is 3 centimeters a number beyond which you think you would ever normally go?

DR. NAG: If we have to give only one number, I'll go for 4 centimeters.

DR. WILLIAMSON: I guess this is a situation where if you ask three people, we'll come up with three different criteria. I would go for a dose-based criterion. Perhaps, what we need to do is accept that in the rule language that the staff craft -- that we need to work on devising a single

definition. I think a reasonable approach would be to, off line, examine dose fall off versus distances, and try to come up with something reasonable. Maybe at this time, without doing a little thought and research into the question, it might be difficult to come up with a really good defensible criterion.

DR. MALMUD: Not being a radiotherapist, I'm just asking a naive question. Is there ever a situation in which you would accept going more than 3 centimeters away from the target?

DR. WILLIAMSON: Let me explain the rationale of having to make this distinction. The reason for wanting to distinguish between adjacent and distant organs is that in adjacent organs, it is frequently necessary to implant some small number of seed, usually a small minority of the total number of seeds implanted. The reason for doing this is the medically legitimate need to provide adequate coverage of the treatment site. So we wanted to give a fairly generous criterion for that compartment of tissue, which would allow implants to be performed. So there the criterion's plus or minus 20 percent.

The distance site criterion is also needed because there certainly have occurred situations where the wrong side of the patient's body has been

treated by an external beam field or the applicators, or needles, have been erroneously inserted into the wrong part of the patient's body. So in that situation, we wanted a much tighter criterion because it was felt that, giving 20 percent of a therapeutic dose, even to a small volume, could be potentially serious. So we wanted a tight criterion there.

It's kind of a balancing act. We could make, for example, the distance very large, then there would be no problem with physicians having the flexibility to implant target volume using the hairy target tissue as legitimate places. But then if some wrong or critical organ lies 3 to 5 centimeters away and there were an erroneous implantation, that kind of medical event would escape this rule.

So it's a bit of a compromise, I guess. So if we make it too far away, we undercount events. If we make it too close, we would limit the flexibility of the practitioner to perform good implants.

DR. MALMUD: I recognize that, but I'm simply asking a follow-up question to the question that stimulated this aspect of the discussion. And that is, if the range and the recommendation is 2 to 4 centimeters, which is vague, does anyone think that 3 centimeters is a number beyond which we would

consider something to be of this administration?

DR. NAG: Well, in the medical setting we have to make this applicable to both the prostate implant as well as permanent implant. But in other organs where you don't have a boundary, and you may have to over-implant, I prefer the 4 cm. I think 4 cm I can live with.

DR. MALMUD: Looking again to try to simplify this so that those who interpret regulations will not be dealing with ambiguous numbers, is 4 centimeters a better number, rather than 2 to 4, stating 4?

Q I'm not a clinician, obviously, but it seems to me, considering the two sets of cases, 3 might be a good compromise. I think 4 is a bit big for prostate, and being the situation where you have a reasonably, well-encapsulated target that can be radiographically visualized.

In the post-operative setting, where you're doing some implants without a tissue boundary, already I think there's a warning in the bullet B2, I guess, which says you're going to have to really exercise some clinical discretion in imposing this rule because there are some cases where there simply isn't a well-defined boundary. So there's already, I think,

enough give and take in the system that 3 cm would work.

DR. DIAMOND: I concur with Dr. Williamson. I think 3 centimeters would strike a reasonable balance, particularly since we're primarily dealing with prostate brachytherapy. Furthermore, I agree with Dr. Raizner that by leaving it nebulous, set between 2 cm, it's going to make it very difficult for the NRC staff or the agreement state staff to have guidance on this issue. So I think simply compromising the 3 centimeters would yield a useful balance between clarity of the rule and ability of staff to enforce.

DR. MALMUD: Thank you, Dr. Diamond. Is that a recommendation to amend the motion to be 3 centimeters instead of 2 to 4?

DR. WILLIAMSON: I would accept that as a friendly amendment to what I just read.

DR. MALMUD: So Dr. Diamond's amendment, as a friendly amendment, is seconded by Dr. williamson. Any further discussion?

DR. ZELAC: Dr. Malmud?

DR. MALMUD: Yes, sir? Who's speaking?

DR. ZELAC: This is Dr. Zelac.

DR. MALMUD: Dr. Zelac?

DR. ZELAC: One suggestion for a word,

which I believe has been omitted from the text in B(ii). It reads currently, "The dose of the distant organ exceeds 50 REM." In parallel with B(iii), it should read, "The excess dose of a distant organ exceeds 50 REM."

DR. MALMUD: Dr. Zelac, thank you for bringing that to our attention.

DR. WILLIAMSON: I think that's very good, yes. So the excess dose. I will accept that as a second friendly amendment.

DR. MALMUD: Dr. Williamson is in a friendly mood. Are they both seconded by Dr. Diamond and Dr. Nag?

DR. NAG: Yes.

DR. MALMUD: Thank you. Any other discussion? All in favor?

(Chorus of ayes)

DR. MALMUD: Any opposed? The motion carries unanimously again.

Thank you, Dr, Williamson. Will you continue?

DR. WILLIAMSON: Yes. We now move on to motion B4, located on the top of page 4.

"Given a source-strength-based ME criterion, it is reasonable to require that the AU

complete the written directive for a permanent implant before the patient is released from licensee control."

MR. LIETO: This is Ralph Lieto. I second.

DR. NAG: This is Dr. Nag. Again, I know what we are trying to say, but we have already written the directive before we started the implant. So basically what we want to convey to the people I think is that if anyone wants to revise the written directive, the revision has to be done before the patient is released from the licensee controls. I don't know if that is made clear in what we have written here.

DR. DIAMOND: Perhaps if we said something like, given a source-strength-based medical event criteria of 20 percent, it is reasonable to require that the AU complete any revision to the written directive for permanent implant for the patient is released from licensee control.

DR. NAG: Right, right. I mean, that I will agree to.

DR. WILLIAMSON: That was certainly one of the intents. I think perhaps in phrasing it, or in our original discussion, we were guilty of thinking in terms of rule language rather than ordinary language

because the way the current rule is written, it really doesn't talk about revisions. It talks about completing the written directive -- I've lost my train of thought.

Would you repeat what your amendment was to this?

DR. NAG: What we suggested was, is it reasonable to require that the authorized user completes any revisions to the written directives before the implant, et cetera. Just add the word "complete any revisions to the written directive."

DR. WILLIAMSON: Yeah, I've got that here.

Dr. Zelac, is that clear to you, what the meaning is?

DR. ZELAC: Yes, it is.

DR. WILLIAMSON: Okay. Well, then I think that I'll read the amended motion.

"Given a source strength-based ME criterion of 20 percent, it is reasonable to require that the AU complete any revisions to the written directive for permanent implants before the patient is released from licensee control."

UNIDENTIFIED SPEAKER: I would second that revision.

DR. MALMUD: The motion's been moved and seconded. The revision, all in favor?

(Chorus of ayes)

DR. MALMUD: Any opposed? All right. Unanimously again, Dr. Williamson.

DR. WILLIAMSON: Okay. Item number 5 on page 4. Dose-based medical event pathway for permanent implants. "In addition to incorporating the activity-based, medical event pathway, described above into Part 35, the Medical Event Subcommittee recommends retaining a limited dose-based medical event criterion. An implant is a medical event if the dose calculations used to determine these total source strength documented in the written directive are in error by more than 20 percent."

DR. MALMUD: Are you seeking comments, Dr. Williamson?

DR. WILLIAMSON: Yes, this is a motion. I guess I first seek a second.

DR. MALMUD: Is there a second to Dr. Williamson's motion?

DR. NAG: Dr. Nag seconds the motion.

DR. MALMUD: Thank you.

DR. WILLIAMSON: Okay. And now comments and discussion.

MS. FAIROBENT: Dr. Malmud, this is Lynne Fairobent.

DR. MALMUD: Yes?

MS. FAIROBENT: I have a question on this, and also I guess on the one above it. When you're saying by more than 20 percent, I'm assuming in all these cases you're talking 20 percent in either direction.

DR. NAG: Yes.

DR. WILLIAMSON: Yes.

DR. MALMUD: That is correct.

DR. NAG: We can add that in by more than 20 percent in either direction.

DR. WILLIAMSON: I think that is a good idea. The last sentence of the amended motion now reads, "An implant is a medical event if the dose calculations used to determine the source strength documented in the written directive are in error by more than 20 percent in either direction."

DR. MALMUD: Thank you.

DR. NAG: I think the examples that Dr. Williamson has given serve to clarify exactly what we mean.

DR. MALMUD: Thank you, Dr. Nag.

MS. SCHWARZ: I have a question also in

regard to what Lynne Fairobent suggested. Is number 4 also being modified to account for 20 percent in either direction?

DR. WILLIAMSON: Point number 4 makes reference to point G2, where it is clearly specified. This is on page 2 that it's in either direction. So number 4 is not meant to be a stand-alone statement of the source-strength-based ME criteria. It's merely saying that the source strength; that the ME criterion of B2, given that criterion, it is reasonable to require that the AU complete any revisions to the written directive.

DR. NAG: Actually, for number 4, even if you are given a source strength-based medical event criteria, you don't even need to put the 20 percent. The sentence would still be very appropriate.

DR. WILLIAMSON: Well, with a criterion of 5 percent, it might actually be very difficult. But given the criterion in point 2, it is a reasonable additional requirement.

MR. LIETO: Just a point of clarification. To answer Sally's question that the intent was that the 20 percent applies in either direction, I think that's correct.

DR. WILLIAMSON: Yes, that is the intent

that's clearly stated in bullet 2.

DR. NAG: Can we go into a vote?

DR. MALMUD: Yes. Jeff Williamson?

DR. WILLIAMSON: Yes?

DR. MALMUD: That is a motion for a vote, right?

DR. WILLIAMSON: Correct. It's been seconded.

DR. MALMUD: And it's been seconded. All in favor?

(Chorus of ayes)

DR. MALMUD: Any opposed? Carries. Next?

DR. WILLIAMSON: Okay. We have now completed, basically, the approval of the Medical Event Subcommittee proposed revised approach to medical events. We now go to Part C, which is risk communication, which, I'll remind everybody, was one of the charges that the Commission gave us in pursuing this activity in their staff requirements memorandum following our briefing with them in 2004.

It starts out with a problem definition, which is point 1. I don't know if I need to repeat this. I'll just ask if there are any concerns, if

anyone on the ACMUI feels that we have not properly characterized the problem of risk communication.

DR. NAG: Jeff, would you just summarize in one sentence what you are trying to sell in that paragraph? I think that's all we need.

DR. WILLIAMSON: You've really put a challenge in front of me. Okay. Well, I think the major point of this paragraph is that the process of investigating an enforcement that follows the report of a medical event is viewed by the regulated community as being very punitive in itself because of the way the reporting rule is written and the associated procedures. This is the essential concern. The concept being pushed is that NRC ought to look at the way medical events are defined and the enforcement procedures that are associated with their investigation, and try within their framework to make it as much like the industry standard as possible. That's my summary of problem definitions.

Does anyone feel it's inaccurate or requires further clarification?

DR. NAG: I think it's okay the way it reads now.

DR. MALMUD: With the approval of Dr. Nag, does anybody else have an opinion?

MR. ESSIG: Dr. Malmud, this is Tom Essig. I just have a clarifying question.

DR. MALMUD: Yes?

MR. ESSIG: Under problem definition, item c, where it talks about reactive IT inspections, I'm not sure what reactive IT inspections are.

DR. WILLIAMSON: I thought IT was when you send a team of investigators the next day after someone revokes --

MR. ESSIG: Okay. That's incident investigation team, which is the highest level of investigation the agency does. For example, in 1992, when we had the Indiana-Pennsylvania medical event, where the patient died due to radiation exposure, that was an IT. Those are very rare occurrences. We are not proposing handling medical events in all cases. Only a very small subset of them would ever become an IT.

DR. WILLIAMSON: Well, I believe that Washington University, one that gave 50 milli REM to a thigh of a patient, where I was involved, was handled in that way. Yes, that's right.

Would you recommend that I just delete the word, the qualifier, IT? Tom, would you recommend I just delete IT?

MR. ESSIG: Yes.

DR. WILLIAMSON: I think that's fine.

MR. ESSIG: Because, in general, we do say reactive inspections, which can be reactive to anything, not only medical events, but other types of items that the licensees report.

DR. WILLIAMSON: Okay.

Any more questions, or should we move on?

MR. ESSIG: One further comment. On that same line, "in the same way as potential nuclear reactor disasters," it's probably --

DR. WILLIAMSON: Hyperbole.

MR. ESSIG: Yeah.

DR. WILLIAMSON: All right. I have no problem deleting the phrase, "in the same way as potential nuclear reactor disasters."

MR. ESSIG: Okay, thank you.

DR. WILLIAMSON: Does anyone on the subcommittee have an objection to deleting that hyperbolic phrase?

MR. LIETO: I don't mind replacing the word "disaster" maybe with "problems," but I think we do need to keep the comparison, in terms of reporting mechanism, between medical scenarios and reactor

concerns being handled in the same way. That needs to be I think referenced in the document.

DR. WILLIAMSON: Okay. Well, I think, Tom, there was a valid intent trying to be expressed here. What this is, is a piece of feedback from the community more or less. Often we tend to, in our experience, find that the NRC reaction is way out of proportion sometimes to the significance of the event. And that, in a sense, if part of the regulated community's perception of medical event enforcement and management being punitive.

MR. ESSIG: What I would suggest here is rather than make the linkage to a nuclear power plant, there are numerous other analogies one could draw from what I would call the materials license arena, where many times we have reported to our operations center events involving a sealed source, mismanagement of seal source, loss seal source, exposure of an individual, that sort of thing, outside of the medical community. These are industrial radiography and numerous other sealed sources that are used by materials licensees. So I think a comparison with that would be fair, would be a better comparison.

MR. LIETO: Tom, I think the issue is not so much the comparison as to the reporting, where

this gets reported to and how this gets into the public venue.

MR. ESSIG: Well, no, I'm talking about the same thing. The radiography events that are reported to the operation center end up in the public domain just like medical events do. That's why I thought that was an appropriate comparison.

DR. WILLIAMSON: I tend to agree with Ralph. We're trying to bring something to your attention that is a subjective reaction on the part of a community. This is really how it seems.

MR. ESSIG: Okay. If that's your perception, I can't argue with perception.

DR. WILLIAMSON: I think disasters is hyperbolizing a bit.

DR. NAG: I would say as eventual nuclear reactor accidents.

DR. WILLIAMSON: Yeah, maybe that's a better way.

DR. BAILEY: This is Ed Bailey. I just got on the line.

DR. MALMUD: There are two things. Number one, would you please use your name before you speak since the stenographer is having difficulty keeping up. The second one is that someone has some

papers that are rattling near a microphone that are causing a bit of interference. Thank you. Please go on.

DR. WILLIAMSON: Maybe this is a reasonable middle ground in the same way as nuclear reactor accidents.

MR. ESSIG: Would you settle for event, nuclear reactor events? I mean, an accident is pretty serious. That implies we've had a potential core damage event, major releases to the environment, like a Three Mile Island. That was an accident. So I think event might be a better perspective.

DR. MALMUD: Mr. Essig, I am in favor of accepting your recommendation, since you have much more day-to-day interaction with the terminology than we do.

MR. ESSIG: I mean, I'm suggesting that, but yet it's being presented as a view from the user community. I'm not trying to direct what that perception ought to be.

DR. MALMUD: Oh, I understand.

DR. WILLIAMSON: I propose we rephrase it as this: "Reactive inspections are perceived by the regulated community," or "Reactive inspections, following medical events, are perceived by the community to be handled in the same way as potential

nuclear reactor events, which jeopardize the health of large numbers of individuals." Maybe that gets the point across.

What do you think, Ralph?

MR. LIETO: I think just simply saying nuclear reactor events, period, would be good, Jeff.

DR. WILLIAMSON: All right. Well, if everyone agrees on that, that's fine with me.

MR. ESSIG: Fine with me.

DR. WILLIAMSON: Okay. Any more concerns with this paragraph?

DR. MALMUD: Apparently none, Dr. Williamson.

DR. WILLIAMSON: We will move on, then, to point C2, which is a recommendation. I'll read it.

"The role of the 10 CFR 35.3045 medical event reporting rule as a technical quality performance indicator should be decoupled from its use as a patient harm index. To this end, the patient reporting requirement 35.3045(e) should be amended to require informing the patient and/or friends and relatives only if the licensee determines that the medical event may have harmed the patient, could potentially harm the patient, or is materially relevant to the patient's future medical treatment decision."

DR. NAG: Seconded.

DR. MALMUD: It's been moved and seconded. Any discussion?

DR. ZELAC: Dr. Malmud?

DR. MALMUD: Yes?

DR. ZELAC: This is Dr. Zelac. I simply wanted to point out that in earlier considerations of this issue by the Commission, it says here in the Federal Register as parts of statements of consideration, "The Commission's position has been, and perhaps still continues to be, that if individuals are identified in records of agencies, that those individuals know of it." This is a mechanism for being sure that an occurrence involving a person who was being written up in an agency record, that that individual was aware of that fact, and that fact alone. If there was potential for harm or actual harm, that would, of course, be part of it, but that wasn't the underlying reason.

DR. MALMUD: Thank you for that clarification.

Dr. Williamson?

DR. WILLIAMSON: I think our response would be that the identity of the individual is not supposed to be contained in any agency record.

DR. MALMUD: Dr. Zelac, does that assist you?

DR. ZELAC: I'm simply bringing the Commission's perspective to your attention.

DR. MALMUD: Thank you, Dr. Zelac.

DR. WILLIAMSON: I would comment that I think that the subcommittee members are aware of the Commission's basis for rejecting this the last time around, which was about three or four years ago. But the dilemma that the reporting rule places the physician in is one of the aspects of the medical event reporting system that is viewed as punitive, namely the dilemma being a contradiction between what is medically best for the patient and maintaining privacy of the patient, the medical information. The rule can place you in a bind where you have to violate one or the other.

DR. MALMUD: Thank you, Dr. Williamson.

With the history given by Dr. Zelac, can we move forward?

DR. WILLIAMSON: Yes.

DR. MALMUD: I think the ball is in your court, Dr. Williamson.

DR. WILLIAMSON: Okay. Well, I think we have a second for the motion, so we need to call for a

vote.

DR. MALMUD: All right. All in favor of the motion?

(Chorus of ayes)

DR. MALMUD: Any opposed? Motion carries unanimously.

DR. WILLIAMSON: Point 3. This is a general recommendation; it's not very specific. "The subcommittee recommends that NRC staff tries to make the ME reporting and subsequent enforcement processing more like that of the regulated community's own QA practice of follow up and QA process review that occurs following detection of a delivery error or potential error."

We further comment, "Comprehensive institutional QA programs are based upon three broad principles: simply making an error is not grounds for disciplinary action; institutional QA findings and deliberations are not discoverable and cannot be used to increase its liability; error reports are inputs through a systematic effort for improving planning, delivery, safety, QA, and documentation processing."

This is recommended as a general, philosophical guidance statement that should be used to fine tune policy operating procedures, NRC operating

procedures.

DR. NAG: Again, I second the motion.

DR. BAILEY: I have some concerns about whether or not this can simply make this information non-discoverable, and I can also state that during an investigation someone might use it and say it's not discoverable.

DR. MALMUD: Who's speaking, please?

DR. BAILEY: Ed Bailey.

DR. MALMUD: Thank you. Would you repeat your concerns?

DR. BAILEY: Yes. I don't know whether simply saying it's non-discoverable, number one, makes it not discoverable. Number two, having a statement like that could lead an institution to say that they would not provide that information to an investigator.

DR. WILLIAMSON: Well, I think the implication of this principle, the rationale of stating this is that QA procedures work effectively with any institution because they're not punished for having them. If you create a situation where every time you make an error, you're going to be severely punished as an institution, you erode the incentive for institutions to go to lengths to detect these errors and correct them. We believe that this is the position

that NRC has placed institutions in with respect to ME reporting.

DR. DIAMOND: Jeff, I understand what you're saying, but I also just want to agree with Dr. Bailey that with respect to C3(b), unfortunately, in many states, institutional QA findings and deliberations are discoverable. So even though that may be your intent and the spirit, that carries no legal weight.

DR. WILLIAMSON: Yeah, I understand. It isn't the specific recommendation that NRC do anything, but it's kind of a guiding principle.

DR. DIAMOND: Yes, and I concur with that spirit. Again, I'm not a lawyer, but I can just tell you that with several states, including the state of Florida, indeed, with institutional QA committees, that is now all discoverable, and it's basically causing hospitals across the state to do away with quality assurance committees.

DR. WILLIAMSON: I understand what you're saying. I think the implication is not that these procedures in the private sector are absolutely not discoverable, but to the extent that they are shielded from discovery, QA functions more effectively.

MR. LIETO: I think from the

subcommittee's perspective, I think our intent was that we wanted to separate what was being reported versus what would be available upon review by inspectors in the course of a normal audit or follow through of a medical event report. So by putting something into an urgent 24-hour reporting mechanism that immediately goes out into a web site and so forth, as opposed to conducting an investigation and a "QA follow-up mechanism," that would be available for inspection. We wanted to distinguish between the two.

DR. WILLIAMSON: We're going to cover all of the points Ralph just made when we come to item 4. I'll just point that out. I would suggest deferring some of the points until then.

I have a proposal of how to clarify 3a, b, and c. I think that maybe what I should do is restate them as principles rather than as absolute statements of fact. In fact, if an employee makes lots and lots or errors, they may be subject, eventually, to disciplinary action. So it's not meant to be a statement of fact that says a hundred percent of the time when an error is made by some employee, the employee is never disciplined. The point here is to articulate a principle that you avoid punishing employees and staff for reporting errors because you

want to encourage the process. I could go through a, b, and c and convert them to principles language rather than statement of fact language, and I think that would address the issue that Mr. Bailey has raised.

DR. MALMUD: Any further comments?

DR. WILLIAMSON: But I don't think I could do that on line in 30 seconds.

DR. MALMUD: Okay. Dr. Williamson?

DR. WILLIAMSON: Yes?

DR. MALMUD: Where are we now?

DR. WILLIAMSON: So I guess we have an amended proposal point 3 -- there are three points, a, b, and c -- so as to make the subpoint a, b, and c read as principles rather than as statements of facts.

DR. MALMUD: Does the committee agree with that?

MR. LIETO: Mr. Chair? This is Ralph Lieto.

DR. MALMUD: Yes, Ralph?

MR. LIETO: Jeff, would you accept if we made the part of 3, starting with comprehensive institution of QA programs a, b, and c as a rationale, and the recommendation would be the first sentence? Does that make sense?

DR. WILLIAMSON: Yeah, the

recommendation is the first sentence, in fact, and the sort of body of what's being recommended is contained in the last sentence of the full paragraph 3, plus the points a, b, c. But I do understand Mr. Bailey's point that it sounds like a, b, and c are factual claims rather than principles, so I have no problem rewriting them to be more clear in that regard.

DR. MALMUD: Once again, Ralph Lieto and Jeff Williamson, what is your recommendation to the committee?

MR. LIETO: I would maybe amend the motion to just reflect that our action item, if you will, is just the first sentence of item 3.

DR. MALMUD: Is that agreeable with you, Dr. Williamson?

DR. WILLIAMSON: Yeah, that's fine.

DR. MALMUD: So that's an amended motion.

DR. WILLIAMSON: I won't delete the material; I'll just rephrase the material.

DR. MALMUD: Any further discussion of that motion? And it's second by Mr. Lieto? If not, all in favor?

(Chorus of ayes)

DR. MALMUD: Any opposed? No

opposition. Okay, it carries.

DR. WILLIAMSON: All right. Now we come to point 4a. As we get deeper and deeper into this document, the proposals are less and less defined, so it may be appropriate for the ACMUI actually to have some substantive discussion on these issues. I'll just point that out. But I will read point 4a as a motion.

"To the extent possible, NRC's ME reporting and follow-up procedures should be designed so as to minimize licensee liability. Keeping ME reports, or at least the licensee's identity out of the public record is probably the most single useful improvement NRC could make in this regard."

DR. NAG: When we have our QA meetings, we bring out all the possible problems because they are not discoverable, and our QA meetings, we are shielded, and, therefore, we bring out not only the problem but how they can be solved, and that leads to improvement in the treatment of the patient. If the report can be seen by everybody, that causes embarrassment, and you are less likely to self-report. One of the premier points about self-reporting is that by self-reporting you should not be discriminated.

DR. WILLIAMSON: Can you rephrase that, please, Dr. Nag?

DR. NAG: Oh. One of the principles of self-reporting is that by self-reporting, you should not be penalized. Therefore, having the identity out is going to be really important. And we want to convey that to the NRC.

DR. WILLIAMSON: Are you agreeing?

DR. NAG: Yes. I'm agreeing with this, but I'm explaining why we wrote that sentence.

DR. RAIZNER: Can I make a suggestion on that sentence? The way it reads, "designed so as to minimize licensee liability," sounds somewhat self-serving and maybe inappropriately so. But if it were phrased, "designed so as not to increase licensee liability," that would convey the point that I think you're trying to make, without making it look self-serving.

DR. WILLIAMSON: I agree.

DR. BAILEY: Would you mind rephrasing that? You were breaking up when you were saying that.

DR. WILLIAMSON: Okay. Here is the proposed revision by Dr. Raizner, of 4a.

"To the extent possible, NRC's ME reporting and follow-up procedures should be designed so as not to increase licensee's liability."

DR. MALMUD: Good. Is that clear?

DR. BAILEY: It's clear to me.

DR. MALMUD: Is that acceptable?

DR. BAILEY: Yes.

DR. MALMUD: All in favor?

(Chorus of ayes)

DR. MALMUD: Any opposed? It carries.

Dr. Williamson?

DR. WILLIAMSON: Okay. Proposal 4b.

"NRC should develop a more nuanced and graded enforcement response process that ties the intensity and immediacy of its enforcement response to the risk to the individual patient and the public health implications of the event. For example, for relatively minor MEs, where public health and safety is not in question, NRC could hold off on reactive inspections of the licensee, pending a satisfactory investigation and quality improvement response on the part of the licensee. Thus, MESC recommends that NRC manage minor MEs much like reportable events in the old Part 35."

So the basic idea is if you do a good job investigating, and following up, and introducing corrective action in the wake of a medical event, you won't necessarily have the wrath of the regulatory agency visited upon you.

DR. BAILEY: I would ask NRC, if they don't already, in fact, do that. I don't think they go out on every ME that's reported.

MR. ESSIG: Yeah, you're correct, Ed, because it's a question of resources. We don't have unlimited resources to go out on every medical event, so we minimize the number of reactive inspections that we need to go on to those that I would call more significant and more egregious.

DR. WILLIAMSON: Well, that's good. Then this is a very easy recommendation to carry out. And it was the intent that this be dealt with at the level of enforcement policy rather than creating a more complex reporting rule, like the old rule, which had recordable events and mis-administrations. We didn't mean to imply that should be done.

DR. MALMUD: Okay. Do we still need 4b?

DR. WILLIAMSON: I think it's useful.

DR. NAG: I think we ought to agree on it. We can vote upon it.

MS. SCHWARZ? Jeff, can I make a suggestion? Instead of saying "hold off on reactive inspections," could you just say "minimize"?

DR. WILLIAMSON: Yes, I think so.

DR. MALMUD: All right. We have 4b.

MR. ESSIG: Dr. Malmud?

DR. MALMUD: Yes?

MR. ESSIG: We are talking off line, and what I just said regarding our reaction to medical events may not be totally correct. We need to check the inspection manual. It might be that there is a requirement that we, in fact, have a reactive inspection to each medical event. I think the recommendation, though, is one that we could certainly accept as a recommendation. But I just wanted to clarify for the record that my statement that I made earlier, in response to Mr. Bailey's comment, may not have been totally correct.

DR. MALMUD: Thank you, Mr. Essig.

So the motion for 4b has been moved by Williamson, seconded, and is now open for discussion, if there is any more discussion.

DR. WILLIAMSON: Yes. It's been amended by Sally Schwarz to replace the word "hold off" by "minimize".

DR. MALMUD: Yes.

MR. ESSIG: I must tell you, as a matter of usage, I would be more enthusiastic about this if we said that "the NRC is encouraged to develop a graded ME enforcement response process" rather than the wording

that we've used.

MR. LIETO: Mr. Chair, I was just going to make the same comment. I think the term "more nuanced" might not be very clear to us non-Readers Digest aficionados. If we could maybe just use your terminology, I would accept that.

DR. MALMUD: If I may, I'll make a motion to amend, which would say that "the NRC is encouraged to develop a graded ME enforcement response," et cetera.

MR. ESSIG: Dr. Malmud, just one clarification. The current enforcement process is already graded in the very real sense. What may not be graded, and I think the point that's being made here, is the reactive inspection.

DR. WILLIAMSON: Okay. Then the phrase, "more graded" actually makes sense in relation to current policy.

DR. WILLIAMSON: So if it reads, "NRC is encouraged to develop a more graded ME enforcement process that ties the intensity and immediacy of the enforcement response to" --

MR. ESSIG: It's not the enforcement response, though. The enforcement action is considered separately as part of the inspection, and the

enforcement is already tied to the intensity, and the immediacy, and so on. What isn't tied to that is the inspection itself and whether or not to go on a reactive inspection.

DR. WILLIAMSON: Okay. Should I replace the word "enforcement" with "inspection response"?

MR. ESSIG: Yes.

DR. MALMUD: So Williamson asked the question, and Essig gave the answer, which was yes.

DR. WILLIAMSON: All right. So now let me read the first sentence of the amended motion.

"NRC is encouraged to develop a more graded ME enforcement response that ties the intensity and immediacy of the inspection response to the risk to the individual patient and public health implications of the event."

DR. MALMUD: Okay. Mr. Essig, does that sound more in line with what you would hope for?

DR. HOWE: This is Dr. Howe. You needed to replace "enforcement" at the beginning of the sentence with "inspection", "the immediacy of its inspection response."

DR. MALMUD: Thank you, Dr. Howe.

DR. HOWE: And then, "the graded ME inspection response." So every time you have

"enforcement," say "inspection."

DR. WILLIAMSON: All right. What I'll do is I'll delete the first occurrence of "enforcement," since I think it's redundant. We already have "inspection response." So I'll say, "NRC is encouraged to develop a more graded ME response process that ties the intensity and immediacy of its inspection response to the risk of," et cetera.

DR. MALMUD: Dr. Howe?

DR. HOWE: Much better.

DR. MALMUD: Thank you, Dr. Howe. Thank you, Dr. Williamson.

We now have a multiply-amended statement, which has been read to us by Dr. Williamson, and I assume it's been seconded. Any further discussion of it? If not, all in favor?

(Chorus of ayes)

DR. MALMUD: Any opposed? It carries unanimously again. Thank you. That's item 4b on page 6.

We are now left with item 4c on page 7. Dr. Williamson?

DR. WILLIAMSON: Yes. I will read the proposed motion.

"Change the 24-hour operation center reporting procedure. Minor medical events having little potential for harm, to either the patient involved or the general public, seem to be equated with nuclear reactor events which have the potential to harm entire populations." This is one that maybe needs to be a little more specific, so I entertain the ACMUI's suggestions, once it's seconded.

DR. MALMUD: Is there a second? Do we have a second?

DR. NAG: Yes, Dr. Nag seconds.

DR. MALMUD: Dr. Nag seconds. Now, is there any further discussion?

DR. WILLIAMSON: Ralph, this was your proposal.

MR. ESSIG: The point I wanted to make is that there's a very broad spectrum of events that are reported to our operations center, ranging from those that have very little dose to consequence. For example, moisture density gauge that is used during construction of highways gets run over by a bulldozer. The gauge is not even particularly damaged. I mean, the source is still in tact, but the gauge is unusable. That gets reported to our operations center quite often. So it's events like that that we need to be

aware of that could possibly impact source integrity, source misusage, loss sources; a broad spectrum of events that are associated with that.

If we didn't have it reported to the operations center, we basically have no other place to report it other than a written report, which is our other option. But reporting to the operations center enables us to keep on top of events. We have a daily discussion of events with our original offices, and our management is briefed here. The events are always put in perspective in terms of their significance, if it involves exposure to an individual, or a loss source, or whatever it may involve. So I think to consciously delete a source of information on events, the committee is certainly free to make that recommendation if it chooses. But I'm just suggesting that it's one that we could not use.

DR. WILLIAMSON: The intent is not to suggest that the events not be reported to NRC in one form or the other. If you accept that a reasonable goal is to try to encourage licensees to participate in a more positive way that buys in to NRC's effort to quantitate these events -- this is one of the issues; that having to report it within 24 hours by telephone, before you've done a full investigation and so forth,

definitely seems like the message to the licensee is that the event is being elevated in significance, public health significance, far beyond what is usually the case.

MR. LIETO: I would underscore Jeff's statement with the 24-hour reporting. Secondly, I don't know of any non-criminal situation, any type of medical situation to be reported with such urgency to such a public reporting mechanism in the practice of medicine. So why are we having to be held at such a high level -- that no other event, in the practice of medicine -- regarding these situations. Again, we're not saying they don't have to be reported, but I think the public reporting in such a short time is really uncalled for.

DR. NAG: I think it's the same basis as external beam. We had the same level, more than 20 percent difference. The urgency is not that if that patient was treated by external beam.

DR. MALMUD: Dr. Nag, are you concurring or disagreeing?

DR. NAG: I'm saying that I agree with both Dr. Williamson and Dr. Lieto that there should not be a 24-hour rule. There's really no need for a 24-hour rule. The magnitude is not that huge.

DR. WILLIAMSON: Maybe we need to give some more positive suggestion of what should be done in lieu of the 24-hour oral reporting procedure. Perhaps we should say "a written report within seven days."

DR. NAG: Yeah, within a week was what I was thinking.

DR. WILLIAMSON: "A written report within seven days."

DR. BAILEY: My only problem with that suggestion as a comment is the use of the word "minor ME," without that being defined really. So it's all in the eye of the beholder what a minor ME is as opposed to a major one.

DR. WILLIAMSON: I guess that's a good point. How about deleting the word "minor," and just "MEs in general should be reported within seven days"?

DR. NAG: I would go for that.

DR. MALMUD: Jeff, are you amending your statement under c?

DR. WILLIAMSON: Well, I guess I'm suggesting that I could if it's met with support from the committee.

MS. SCHWARZ: I have a question in regard to external beam, what would be the requirement for reporting on external beam.

DR. WILLIAMSON: Is that Sally?

MS. SCHWARZ: Yes, this is Sally Schwarz.

DR. WILLIAMSON: At this time, unless it's Cobalt-60 teletherapy or gamma stereotactic, there's no requirement from NRC to report external beam at all. I think the agreement states, often would have parallel reporting requirements, and probably mechanisms to NRC. Maybe Mr. Bailey could comment.

DR. BAILEY: Yes. Many states have adopted similar reporting requirements for any type of therapy procedure, whether it be external beam or not. In fact, I think we've had some of the more serious ones occur when the machine produced external beams.

DR. VETTER: As I understand the history of this, I think the intent was that any medical event that causes or could cause a major health effect or death in a patient needs to be reported immediately so that the NRC can get a medical consultant on site rather quickly. Is that not the case?

DR. MALMUD: The question is addressed to a member of NRC staff?

DR. VETTER: Correct.

MR. ESSIG: Dr. Vetter, this is Tom Essig. I believe that's the case. What you've said is

true, unless the other energy staff around the table have any additional comments.

DR. HOWE: I think the intent certainly is to have the very severe ones reported immediately so we can get a consultant out there right way. But I don't think we have a limit that it's just the severe ones that have to be reported immediately. I don't know if that's ever been the direction of the Commission, that we just report immediately.

DR. RAIZNER: Can I make a suggestion on phrasing this recommendation? To provide, "MEs having little potential for harm, to either the patient involved or the general public, may be reported within seven days," and just leave it at that. That would separate out what is being called here minor MEs from the current policy. I think it would be assumed that major, catastrophic MEs would be reported within 24 hours as is currently required.

DR. WILLIAMSON: I think that's a very reasonable proposal because we have actually invoked the criterion of major and minor, and defined it in the previous paragraph. I'll point out here that in paragraph C2, we basically say that reporting requirement 35.3045(e) should be different, depending upon whether the ME has harmed the patient, could

potentially harm the patient, or is materially relevant to the future management of the patient. So that's a criterion that's already been articulated in this document, so we could just invoke that criterion as suggested by Dr. Raizner.

We could leave, perhaps, the first sentence and simply add a sentence saying, "MEs that the licensee has determined have not harmed the patient, could potentially harm the patient, or are materially relevant to the patient's future medical treatment decisions, need not be reported orally to the 24-hour operation center, but may be communicated by a written report within seven days."

DR. MALMUD: Is there a second to that? That's a revision of c. Is there a second to Dr. Williamson's last statement?

DR. NAG: Dr. Nag seconds.

DR. MALMUD: Dr. Nag seconds. Any further discussion? If none, all in favor?

(Chorus of ayes)

DR. MALMUD: Any opposed? None. It carries unanimously.

Dr. Williamson, that completes the items on that list, does it not?

DR. WILLIAMSON: It does. I would just

close by asking if the ACMUI members have any additional suggestions on the topic of risk communication that would be reasonable to add to this list of recommendations. The concept of risk communication was not to us a very well-defined charge. This is how we chose to work with it, but there may be other ideas which are worth exploring.

DR. MALMUD: Is there anyone who wishes to explore that at this time? I do not hear a response of enthusiasm for reviewing that issue at this time.

DR. WILLIAMSON: Okay.

DR. MALMUD: Are you completed, Dr. Williamson?

DR. WILLIAMSON: I am completed, except I have one follow-up question.

DR. MALMUD: Why don't you go ahead with your follow-up question before my comment?

DR. WILLIAMSON: My follow-up question is what process do we follow after this point?

DR. NAG: What do you mean? I thought we make the recommendations to the committee, and this ACMUI committee recommendations goes to the NRC officials for implementation, right?

DR. WILLIAMSON: Well, I think that's what we should discuss. I guess there's one minor

issue. I assume what I should, since I have taken all of the notes about the minor changes to this document, go ahead and make those changes and resubmit this to the ACMUI.

DR. NAG: Yeah, I think that you have been involved from the beginning, and you know all the nuances. It would be easier if you would revise it, maybe circulate, and, hopefully, there will be no additions to it.

DR. WILLIAMSON: Yes, I would hope so. My understanding is, then, that the staff is going to take this and convert it to some other format and make a set of recommendations to the Commission. Is that correct?

DR. MALMUD: I believe, Dr. Williamson, that the next step is that the subcommittee presents it to the committee.

DR. NAG: I thought the subcommittee has given it to the committee.

DR. MALMUD: Yes, and that the committee then presents it to the NRC as a recommendation.

DR. NAG: Well, that is what we are doing now.

DR. MALMUD: And the NRC is then free to accept the recommendation as it stands, or to make

changes to it, or even to ignore it if it wishes to.

DR. WILLIAMSON: Well, that's true in the long run, but there is a detailed process that's going to be followed because this whole activity was instituted by the commissioners in their staff requirements memo of spring 2004. So what the staff is going to do is develop a white paper, and then present that to the Commission to satisfy their staff requirements memo.

DR. MALMUD: Yes, but we will have fulfilled our task, I believe, by having had the subcommittee and the committee meet and make the recommendation, will we not?

DR. WILLIAMSON: Well, my concern is that I don't know what will happen to these recommendations after they leave our hands and what kind of paper will go forward to the Commission. What I would like to make a plea for is that the subcommittee, or if not the full ACMUI, get an opportunity to review the white paper that NRC prepares, especially any rule language that they adopt to express these recommendations. I think it would be very useful to both the NRC and to the regulating community if we could have the possibility of some

feedback at that time.

DR. MALMUD: So you are requesting that once we will have submitted this material to the NRC, that it give us the courtesy of the opportunity to review the document as they have prepared it?

DR. WILLIAMSON: That's correct.

DR. NAG: I wish to be a little stronger than that. I think we could demand it because we have made the recommendation. When you convert those into legal terms, some of the sense may be totally lost or totally distorted. And you want to make sure that what we said in principle is what is written in the legal document.

DR. WILLIAMSON: I would concur with Dr. Nag and suggest we rephrase my slight request to a demand.

MR. ESSIG: May I comment?

DR. MALMUD: Please do, Tom.

MR. ESSIG: The process -- I've believed we've touched on it from this point -- is now that the committee has accepted all of the parts of the subcommittee's recommendations, Dr. Williamson, then, will incorporate all the comments, and then he will provide this to you, Dr. Malmud. A way of doing it would be to attach a cover memo on ACMUI letterhead,

and attach the subcommittee's report, a memo from yourself to Dr. Miller, saying attached is the ACMUI report, which was discussed in a conference call of June 28, 2005, so on and so on. We are submitting it to you as a recommendation. And if you want to tie in to the SRM, you certainly can.

The process from that point, then, is Dr. Miller will get it. He'll provide copies to his staff, and we will engage with the rulemaking and guidance branch, who also reports to Dr. Miller, and they will commence prioritizing this activity amongst the other rules that they have in front of them.

When we actually start putting pen to paper in terms of crafting the rulemaking language, ACMUI will be intimately involved in that. We will certainly circulate any proposed rule language to you well ahead of the time that we will present it to the Commission. So you will have several bites at the apple, so to speak. We'll have your recommendations, and then we'll incorporate those into rule language.

DR. WILLIAMSON: I have a question for you, Tom.

MR. ESSIG: Yes?

DR. WILLIAMSON: What gets submitted to the Commission on July 28th, by that deadline that

Angela has referred to in the past?

MR. ESSIG: I'll ask either Dr. Zelac or Angela to speak to that.

DR. ZELAC: This is Ron Zelac. The deadline of July 28th had been predicated upon having final recommendations from the Advisory Committee at the end of April, so we could, May, June and July, prepare a paper which would present staff's recommendations to the Commission with respect to the acceptability of the current medical event definitions and criteria.

Prior to this discussion and prior to all of this dealing with the Medical Event Subcommittee on Prostate for Permanent Brachytherapy, you may recall that the entire committee considered the broader questions of, for example, the 20 percent criteria as it applied to other modalities for treatment. Recommendations were made, and they are in the record, of the ACMUI's meeting with respect to all of the other modalities except this one, permanent implant brachytherapy. This has been the missing piece.

By today's activity, the entire gamut of recommendations needed from the Advisory Committee to staff have now been at least finalized if not formally conveyed, and we are now in a position to move forward

with those recommendations to craft a commission paper in response to its direction, its staff requirements memorandum, to simply bring to the attention of the Commission what staff's opinion is, with input from the Advisory Committee, on the question of the suitability of the current definitions of medical event.

Now, as I was saying, the July 28th deadline had been crafted, based upon the assumption that we would have recommendations from the Advisory Committee by the end of April. Since that did not occur and we are now two months later, we are probably talking of at least a two-month extension before we will be submitting two the Commission that paper.

DR. WILLIAMSON: Okay. Then I guess the request/demand would be, can we have an opportunity to review your draft of the white paper before it's sent on to the Commission? Can we at least be able to offer our feedback on it?

MR. ESSIG: You certainly can. I mean, you have to handle it as a pre-decisional document, which means it cannot be shared outside the committee.

DR. WILLIAMSON: Well, all of this has been handled as pre-decisional anyhow.

MR. ESSIG: Yeah, but I just wanted to make that special emphasis on a paper that's going

directly to the Commission.

DR. WILLIAMSON: Well, yeah. I guess I would suggest a motion, Dr. Malmud, in that we ask that the NRC give the ACMUI an opportunity to review and offer feedback on the proposed commission white paper before its submission to the Commission.

DR. MALMUD: Is there a second to that motion, which is a request?

DR. NAG: Dr. Nag seconds.

DR. MALMUD: It's seconded by Nag. All in favor?

(Chorus of ayes)

DR. MALMUD: Any opposed? So it is a unanimous recommendation of this committee that we be given that courtesy.

MR. ESSIG: Dr. Malmud, this is Tom Essig again. I would just add that we cannot build into the schedule a large amount of review time for the ACMUI. We might be talking on the order of two weeks or so.

DR. MALMUD: That would be two weeks more than we've had in the past in some cases, and, therefore, would be welcomed by the committee.

MR. ESSIG: Okay.

DR. MALMUD: Is there any more business

that you wish to present, Dr. Williamson?

DR. WILLIAMSON: No, we are very pleased to have completed out task as a subcommittee.

DR. MALMUD: Thank you. I have one item I wanted to add, and that is an extremely grateful statement on the part of the chairman to Dr. Williamson for a yeoman's job in husbanding this through the process, and, of course, the other members of the committee who participated, and whose emails I have seen flying back and forth with their comments. It's been a lot of effort, and we are all very appreciative of the time and talent that you've put into this.

Is there a motion for adjournment of this meeting?

MR. ESSIG: Dr. Malmud?

DR. MALMUD: Yes?

MR. ESSIG: You might at this juncture -- since the subcommittee has completed its business and the full committee has probably completed most of its business -- offer the floor to any members of the public who haven't already spoken and wish to make comments at this time. We have just a few minutes remaining in the call.

DR. MALMUD: Thank you, Mr. Essig, for reminding me of that. I've been hearing these little

beeps over the phone, which I assume are the timers telling us that we're running out of time.

MR. ESSIG: Yeah, we're down to 10 minutes.

DR. MALMUD: By all means. Are there any comments from members of the public or other participants in this conference call? I hear none. Thank you.

Mr. Essig, any other items?

MR. ESSIG: No.

DR. MALMUD: Not having heard any comments from the members of the public or others who are on this call with us, I do want to thank you for your participation in the call, and your willingness to stay with us for the period. I also apologize for having been late for the committee meeting. My colleague is out of town and I am running both departments, and actually treating a patient with radio-iodine while you were waiting for me. I'm sorry.

MR. ESSIG: That happens.

DR. MALMUD: It is our policy to do that personally. We don't allow technologists to administer the dose, so you have to excuse me.

At any rate, we should not be meeting on a regular basis over the course of the summer. I wish

you all a healthy, happy, and enjoyable summer, and if needed, we will contact you by email. Once again, thank you all for your participation, and especially you, Dr. Williamson, and the others who worked with you so diligently on crafting this document.

DR. WILLIAMSON: I would like to thank my subcommittee members, all of whom contributed substantially and intellectually in terms of their ideas to this proposal, and also to our consultant, Dr. Potters.

DR. MALMUD: Thank you all.

Is there a motion for adjournment?

UNIDENTIFIED SPEAKER: So moved.

DR. MALMUD: Seconded? Than you all. Good bye.

(Whereupon, the foregoing matter went off the record at 2:53 p.m.)

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