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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES

(ACMUI)

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TUESDAY,

OCTOBER 20, 2009

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ROCKVILLE, MARYLAND

The Committee convened in Room EBB01-13/15 at the Executive Boulevard Building, 6003 Executive Boulevard at 8:00 a.m., Leon Malmud, Chairman, presiding.

COMMITTEE MEMBERS:

LEON MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D., Vice Chair

DOUGLAS EGGLI, M.D.

DARRELL FISHER, Ph.D.

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JENNIFER RAND

GRETCHEN RIVERA-CAPELLA

GLENDA VILLAMAR

JENNY WEIL

RONALD ZELAC, PH.D. (via telephone)

MEMBERS OF THE PUBLIC:

CURTIS ANDERSON

DAVID BURTON

JOHN CREASY

MEMBERS OF THE PUBLIC: (cont'd)

LYNNE FAIROBENT

KAREN LANGLEY (via telephone)

MELISSA MARTIN

RICHARD MARTIN

ROBERT MASSEY

EIPING QUANG

GLORIA ROMANELLI

IRA SCHNEIDER (via telephone)

A G E N D A

P R O C E E D I N G S

(8:03:06 a.m.)

CHAIR MALMUD: Good morning, everyone, and welcome to the second day of session. The program today begins with a presentation on New Security Regulations by Ms. Horn, who will provide an overview of the new regulations under 10 CFR Part 37. When you speak, please introduce yourself so that the court stenographer may attribute your words of wisdom to yourselves. Thank you. Good morning.

MS. HORN: Good morning. My name is Merri Horn. I'm a Senior Project Manager in the Division of Intergovernmental Liaison and Rulemaking in FSME. I'm the overall Project Manager for the Part 37, though I am not the only person working on that. We actually have a very large group. There are several NRC people, as well as a lot of state people that are working on this effort.

Because the proposed rule is pre-decisional, I cannot go into a lot of detail on the provisions, or into the reasons of the provisions. However, because we have posted preliminary rule language for public comment, some of the aspects of the proposal are already publicly available, so from

that standpoint we can certainly provide information.

The primary objective of this rulemaking is to provide reasonable assurance in preventing the theft or diversion of Category 1 and Category 2 quantities of radioactive material.

CHAIR MALMUD: Excuse me. I'm just greeting members of the public. Good morning. Welcome to the meeting. Would the members of the public who are on the call please introduce yourselves.

MS. LANGLEY: Karen Langley, University of Utah.

CHAIR MALMUD: Thank you.

DR. ZELAC: This is Ronald Zelac.

CHAIR MALMUD: Thank you. Good morning. And I'm sorry for interrupting.

MS. HORN: No problem. In developing this proposed rule, we considered the various security orders that were issued to the licensees, lessons learned from implementation of the orders, and doing the inspection against the orders, recommendations from the Independent Review Panel, and the Materials Working Group, and a petition of rulemaking filed by the State of Washington related to transportation

issues.

We also considered stakeholder input received on the technical basis for transportation security. There were several public meetings on that, I believe January `08 time frame. And they also issued it for public comment. And we also considered the input that was received on the preliminary rule language that was posted for public comment.

The proposed rule would create a new Part 37. This part would contain the security requirements for Category 1 and Category 2 quantities of radioactive materials. It would also contain security requirements for the transportation of small quantities of irradiated fuel, basically, less than 100 grams.

We created this new part, because we felt it would be easier to use, the requirements would be easier to find for both the licensee, and for the public that may have interest in it. If we intersperse them in Part 73 with the Reactor Security Requirements, and the Fuel Cycle Requirements, it would have been very complicated, because you've got what applies. We could have put them in various places in the Part 30, but, again, we thought it would be easier if they were all in one place, and ease of

use is a very definite benefit. We're also making conforming changes to other parts of the Code of Federal Regulations, so you'll find pointers, like in Part 30, Part 35, Part 34, that point you to the requirements in Part 37.

The major provisions are contained in three subparts. Subpart B contains requirements for the Access Authorization Program. Subpart C contains requirements for the Security Program during use, and Subpart D contains Transportation Security provisions. Kind of in a nutshell, I'm just going to give you the highlights of each of the subparts.

The Access Authorization program requires that anyone with unescorted access to Category 1, or Category 2 quantities of radioactive material undergo a background investigation that includes fingerprinting, a criminal history records check, along with several other elements that are listed in the rule. Licensees would be required to have procedures to implement the program. That's a little bit different. They weren't required by the orders. They will be required to protect the information obtained during the investigation, and to keep various records.

There are several categories of

individuals that would be relieved from the fingerprinting and other aspects of the background investigation. The licensee would still have to make a determination on whether they should have access to the material, or not. It doesn't grant you access, it just means you don't have to do the background investigation portions. As part of this, reviewing officials would need to be fingerprinted under the rule.

The Security Program, during use, would require the development of a security plan, so you would actually have to develop an actual written security plan that would need to be approved by various individuals in your organizations. The licensees would be required to coordinate with local law enforcement agencies that would provide response to any threat to the facilities. Licensees would be required to have procedures, conduct training, and keep records.

Again, the orders did not actually require the development of procedures and training. I suspect that most likely you did that, because how else would you implement them, but the rule actually will require that now. Licensees would be required to establish security zones around the material, and to monitor and

detect unauthorized entry into the zone. This could be as simple as having -- when you're using the material, having someone in the area. It could be direct surveillance, that person would prevent anyone from getting into whatever zone that you've established. Licensees would be required to respond to any theft, sabotage, or diversion of material.

The Transportation Security Program would include verification of license authorization when transferring Category 1 quantities of radioactive material. This would mean that you would need to call whatever agency issued the license, and check is this a valid license? Are they authorized to receive this material? And it would be a simple yes or no. It's not an approval from the licensing agency, but just a verification that whoever you're sending the material, is actually authorized to receive it.

Licensees would be required to conduct preplanning and coordination activities with the receiving licensee. And in the case of Category 1 shipments, with state officials.

For Category 1 shipments, advance notifications to the states and NRC would be required. Licensees would be required to maintain constant control and surveillance during transit, and to have

communication capabilities to summon assistance for shipments. These are very similar to what was in the orders.

For Category 1 shipments, movement control centers, and telemetric position monitoring would be required, as well as procedures and training. You wouldn't have to use GPS. You could use some other type of system, but GPS would meet the requirements for this.

Kind of our time line. The preliminary rule language was posted for public comment in the fall and spring. The Transportation was, I believe, posted in November, and the others were in the April-May time frame. We considered the comments in finalizing the proposed rule language.

The proposed rule is due to the Commission this fall, sometime probably in early December. If approved by the Commission, the proposed rule will be published for public comments. We can't predict how long it will take the Commission to approve the rule, or whether they will. That's always hard to tell. We are proposing an extended comment period, 120 days versus our normal 75 days. We felt that this was a fairly large rule. It's actually three rules combined, when you get right down to it. And it's

fairly complex, so we're giving more time. I will note that since we are planning to give more time, we are unlikely to entertain any requests for an extension, so the 120 days will be the comment period.

We are planning to develop guidance documents, and those will be available for public comment during the comment period on the proposed rule, because, as everyone knows, the details is really when you go to implement, so the guidance will have more of that type of information.

We are currently planning to hold at least one workshop on the guidance. I don't know when, or where that will be, but it will be during the comment period on the proposed rule. And then the final rule will be due to the Commission about a year after publication of the proposed rule. And that will somewhat depend on the number of comments that we receive, and various things. If there's few comments, which I don't think there will be in this case, we will get it up sooner, about a year. And then after the Commission -- assuming the Commission approves the final rule, we're suggesting a 180-day implementation date after the final rule is published.

With that, I would entertain any questions.

CHAIR MALMUD: Thank you, Ms. Horn. Are there any questions, or comments?

MR. MATTMULLER: Steve Mattmuller. In previous discussions on security, we've talked about the sources used in blood irradiators in chem labs, but with irradiated fuel, when it says less than 100 grams, is that referring just to the Uranium content, and/or could you give examples?

MS. HORN: It is the Uranium content. That would be irradiated fuel. That's just for the transportation aspects of it. When we looked at the regulations, we realized that we had a slight gap. We had requirements for shipping irradiated -- large quantities of irradiated fuel, but there was actually a small gap at 100 grams and less, that we didn't have requirements, so this is filling that gap.

MR. MATTMULLER: And would these by, typically, the fuel from a research reactor?

MS. HORN: You know, to be honest, I'm not sure. I think a research reactor would probably be higher than that.

MR. LEWIS: Yes. It's, typically, individual things that are sent for analysis at a place like Vallecitos, or some -

MS. HORN: It's a very small quantity.

There's also an activity limitation.

CHAIR MALMUD: Any other questions, or comments?

MEMBER LANGHORST: Sue Langhorst. Merri, I was really impressed with how it call came together. I know you guys had three working groups on that, and covered -- I think you guys did well in meshing it all together.

My predecessor, Dr. Vetter, had commented on one missing part, which was the service providers. And that was a very important piece to us.

MS. HORN: We actually felt that that was covered, because there was already a provision in there that you could transfer the approval from one -- the background investigation information from one licensee to another. But we originally felt that would cover it, but we are -- we did go back, and we are actually adding that provision.

MEMBER LANGHORST: Okay.

MS. HORN: Make it very clear.

MEMBER LANGHORST: Yes, that does not cover it.

MS. HORN: Actually, I think that it would, but we're making it explicitly clear that that is provided for.

MEMBER LANGHORST: And a second question I have, one of the things that I pointed out in my comments to you all was, there was a 60-day provision of your background investigation documents had to be -- couldn't be older than that to make your determination. But, yet, you could send background documentation to other licensees, and it would be much older than that, and they could use that. So, I was confused.

MS. HORN: It was intended to be that the initial approval of somebody, that the information would only be valid for that long. We're actually taking another look at that. We received several comments in that area.

MEMBER LANGHORST: Yes.

MS. HORN: And I'm not sure what the final outcome will be, but we are taking another look at that.

MEMBER LANGHORST: That would be near impossible for us, for many people.

MS. HORN: Yes, you don't want someone to rely on information that's a year old in granting someone -

MEMBER LANGHORST: Right. But under our experience, when we had to go to a lot of different

states, if a person has lived in a lot of different states, some states are better than others in responding to us. And that has been a frustration on our part, that we can't get our people through, because we don't hear back from these entities. And it's not really clear how much we have to document the effort we take to show that yes, we did try to get that information. So, that would be a very important piece in the guidance documents.

MS. HORN: We are looking at them, like I said. We had actually received comments on the preliminary, so we actually extended it from what it was in the preliminary rule language. And we are taking a second look at that, actually, a third look at that.

MEMBER LANGHORST: Okay. Thank you very much.

CHAIR MALMUD: Dr. Howe.

DR. HOWE: I'd like to point out that normally when you think about Uranium, you're thinking about fuel, but Uranium targets to make Moly would be captured probably in the under 100 grams. So, I think you need to keep that in mind. I don't know if your rule says specifically fuel, or it says under 100 grams.

MS. HORN: It says irradiated fuel.

DR. HOWE: Okay. You probably ought to consider that there are other irradiated Uraniums.

CHAIR MALMUD: Other comments, or questions?

MEMBER GILLEY: Merri, will this be a Compatibility B for the agreement states? And what is the implementation date for the agreement states?

MS. HORN: The easy question first. It will be the normal three-year implementation period. That's what we're suggesting. The Commission could decide other. I don't think they will, because the orders are out there, and would stay in place until various states got their requirements in place.

The rule has various compatibilities. I think it's a four-page table that's in the Federal Register Notice that outlines the compatibilities for each section and subsection. The large majority -- there's a large majority of them are probably B, but there are a few Cs in there, and there's even, I believe, a couple of Ds, some of the record keeping things. But the main requirements are mostly B.

MEMBER GILLEY: One of the issues with the agreement states, of course, is doing the background check on the reviewing official, and the access of

that reviewing official to the actual material, unauthorized access. I'd just like to bring that up for the record.

MS. HORN: Yes. No, we're very aware that that is a major issue with the states.

CHAIR MALMUD: Thank you. Other comments or questions?

VICE CHAIR THOMADSEN: Thomadsen. The qualifications for the reviewing person, do they have to be an authorized user now, under the rule?

MS. HORN: We want the reviewing official to be fingerprinted, and the mechanism by which we can do that, if they have to have authorization to material, because that's the way the Energy Policy Act is written. In reality, if you didn't want to give them -- I mean, if it was an HR person, you could probably work around that a little bit. But, in reality, yes, we are requiring then that they would be permitted to have authorization to the material, because that's our mechanism to different fingerprinting.

VICE CHAIR THOMADSEN: At our facility, the University of Wisconsin, in order to have authorization to have access to material, you have to explicitly say what your protocol is that you're going

to be doing, and which material it is. I'm not sure the mechanism you could use to authorize this person as a user, when they aren't going to be using.

MS. HORN: We recognize that this is an issue, and in the Federal Register in the proposed rule, we're actually specifically inviting comment on this issue, so we encourage you to comment on that aspect.

CHAIR MALMUD: Sue.

MEMBER LANGHORST: Sue Langhorst. Dr. Thomadsen reminded me of a question that I had, too. For Gamma Knives, one question I submitted was whether the Gamma Knife, itself, could be considered as the - I forget the term now - the area. What is the?

MS. HORN: Oh, the security zone.

MEMBER LANGHORST: The security zone. If the unit, itself, could be considered the security zone, because of the difficulty of getting into it, to the sources.

MS. HORN: That would be an implementation issue. I'm inclined to say no, but I'm not familiar enough with the Gamma Knife. Medical isn't an area that I'm real familiar with.

MEMBER LANGHORST: Right. So that was a question that I submitted, and that would make things

easier, too, and still give the level of security that you all are looking for.

MS. HORN: Those are the types of things that will be addressed in the guidance.

MEMBER LANGHORST: Thank you.

CHAIR MALMUD: Any other questions, or comments? Questions from the public? If not, we'll move ahead to the next item on the agenda.

DR. HOWE: Thank you, Merri.

CHAIR MALMUD: We're a bit ahead of the schedule. Dr. Howe will do the next presentation on the Potential Changes to 10 CFR Part 35, and seek Committee advice. Dr. Howe.

DR. HOWE: Thank you, Dr. Malmud. I never know whether mine is going to be ahead of schedule, or way behind. It depends on the interest level.

At our last meeting, we brought up an issue about training and experience provided in the 35.400 and 600 use of materials at medical institutions. And what I'd like to do is, the first three slides that I'm presenting are really a summary of what happened at the last ACMUI meeting. So, what I'd like to have you do is just take a few minutes and review those first three slides. And then if you look up when you're done, I'll know.

Okay. It looks like most people have finished. Essentially, the question we brought to you in the last ACMUI meeting was whether the use of the word "medical institution" in the training experience for 400 and 600 was too limiting. And the ACMUI decided that it was, and recommended adding clinic, but not private practice.

We're bringing a different question back to you now. And the question we're bringing to you now is, do we even need to use the term "medical institution" in Part 35? It only appears in four places, the definition of 35.2, the training and experience requirements in 35.490, 491, and 690. It's on slide -

CHAIR MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: Do you have a more formal definition of the term "medical institution"?

DR. HOWE: We have a definition in 35.2. And in 35.2, it is a place that has two or more medical specialties. We've had confusion on how to interpret that, whether it meant you had to have two different radiation specialities, or you just had two different medical specialities. At NRC, we're a little bit more liberal on reviewing it. In agreement states, they may be a little bit more conservative on

what that definition is.

MEMBER GILLEY: I don't think it's -

(Off mic comment.)

CHAIR MALMUD: Is the stenographer able to hear that?

MEMBER GILLEY: I'm sorry.

CHAIR MALMUD: Could you please repeat that, please.

MEMBER GILLEY: Debbie Gilley. Many of the agreement states have a different definition for medical institution, because it is not a Compatibility B issue. I believe it's a Compatibility D, but I'd have to verify that.

DR. HOWE: Yes. So, we took the question back, and we looked at it, and we talked about. We said do we even need the definition of a medical institution? It only appears in these places. You've opened the training and experience requirements to a medical institution, plus a clinical practice. You did specifically exclude private practice, so keep that in mind. So, we thought that -- the question we bring to you today is, would it be acceptable to take out medical institution all together, and I gave you an example of that in the next slide, which shows that 35.490(b)(1)(ii), instead of reading, "Would 500 hours

of work experience under the supervision of an authorized user meet the requirements in 35.490, or equivalent agreement state requirements at a medical institution?" And you had agreed to add, "or clinic involving", and then you continue with the regulation.

We would just drop out the "at the medical institution or clinic", at the end. So, it would just say that 500 hours of work experience under the supervision of an authorized user who meets the requirements in 35.490, or equivalent agreement state requirements.

Now, you'll note that we have modified this language in your Draft Final Rule, so that you don't have to meet requirements in 490, which tied you to the rule after 2002, but that you were an authorized user. So, we opened that up a bit. But the idea is, do we need to even specify where you receive this supervised work experience?

CHAIR MALMUD: I see some anxiety among members. Dr. Suleiman?

MEMBER SULEIMAN: Yes. Again, some very specific questions. Does this work experience imply with humans, or it could be training on the equipment? And, if that's the case, could that training be considered work experience if they're at the

manufacturer's facility, which is not a medical institution, and they're getting trained? Now, if the answer to the first question involves human use, then forget the second question.

DR. HOWE: Okay. Just to clarify, if I use 35.490 as an example, the experience -- "the supervised work experience is ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys, checking survey meters for proper operation, preparing, implanting, or removing brachytherapy sources, maintaining running inventories of material on hand, using administrative controls to prevent a medical event involving the use of byproduct material." It doesn't specifically say human use, but the implication, and how we've interpreted it is, this is actual patient -

MR. EINBERG: Dr. Malmud?

CHAIR MALMUD: Chris.

MR. EINBERG: May I interrupt here? I hate to interrupt this good discussion here, but we have Dr. Miller here, who like to make a presentation. And he's on a very tight schedule right now. Could we take a few minute break from this discussion?

CHAIR MALMUD: Certainly. Thank you.

DR. MILLER: As has become the custom, I

like to come over for presentation of certificate of appreciate for members who are going to be leaving the Committee. And the honoree today is Dr. Eggli. So, if I could ask him to come up. Before I present him the certificate, I wanted to read a few of his accomplishments.

As a Nuclear Medicine Physician on ACMUI, he's been with the Committee since 2003. He's aided NRC by reviewing and commenting on rulemaking and guidance documents for nuclear medicine. He served on numerous subcommittees, the New Modality Subcommittee, the Dose Reconstruction Subcommittee, and Chairing the Board Certification Pathway for ABR Diplomats Subcommittee. And I've always thought of Dr. Eggli as the training guru on the Committee.

(Laughter.)

DR. MILLER: If I could just read the certificate, so the recorder can hear it. "This is a Certificate of Appreciation presented to Douglas F. Eggli, M.D., in recognition for your service as a member of the Advisory Committee on the Medical Use of Isotopes, which resulted in a significant improvement in the Nuclear Regulatory Commission's understanding and use of byproduct material in medicine." And it's dated October 2nd, 2009, and signed by Chairman

Jaczko.

(Applause.)

DR. MILLER: I'll get of the way, and let you finish this good discussion.

CHAIR MALMUD: Thank you, Dr. Miller. Thank you, Dr. Eggli. We were discussing the proposed change in the terms. And there was concern about whether this included working with patients, as opposed to without patients, as opposed to animal research. And Dr. Howe was answering the question by reading the definition. We're at that point now.

DR. HOWE: And I think if you took a very liberal interpretation of this, all of this could be done without a person involved. So, your point might be that we would have to tighten this up to make sure that we're talking about patient-related -

CHAIR MALMUD: May I suggest, if the existing term, "at a medical institution", be replaced by "medical provider, with a medical provider". The same problem occurred a while ago with JCAHO, when there was a Joint Commission for the Accreditation of Hospitals, and they realized that they had more to inspect than just hospitals, so they used -- expanded the term to be other organizations. But it's only a suggestion. I'd be happy to hear better suggestions,

by all means.

DR. GUIBERTEAU: Mickey Guiberteau. I think one of the -- I'm having a little bit of difficulty understanding the intent of even putting a medical institution in the rule. The reason for that is, one of the objections to private practice is that the term is, I guess at best ambiguous, and at worst meaningless, because it applies to multiple settings, including institutional settings.

I think if the intent of a medical institution is to reflect the quality of the training, I don't believe that's necessarily the case. And that since it's required to be under an authorized user who meets the similar requirements, it seems to me that the burden is on the authorized user.

I do, also, believe that the term "provider" in most of CMS' sense, and one of the things that most physicians object to is that it's applied to physicians, in general, that we are medical providers. And that, also, would really go back to the authorized user. I don't believe the term "provider" really is specific enough to cover all of the things that you might intend, given the fact that it's been in use for so long by CMS to refer to physicians.

DR. HOWE: Just a point of clarification. The reason that medical institution is in here is a long historical reason, so one of the things I presented at the last meeting was that medical practice has changed. When medical institutions were put in as part of the requirements, probably back in the `60s, that was to insure that you were getting your training for these more complicated things at hospitals, because you didn't have individual standalone clinics. So, that's why it's in there now, and that's why we're questioning whether in today's climate of medical care it is still appropriate to use that term.

DR. GUIBERTEAU: May I respond?

CHAIR MALMUD: Please, do.

DR. HOWE: And so your arguments essentially support -

DR. GUIBERTEAU: Well, my feeling is, you're going in the right direction by suggesting it be taken out, because I think any other definition would also be imprecise, and not inclusive.

I feel very strongly, being involved in a lot of training issues, that the burden is really on the authorized user providing the training, because medical institutions include a huge variety of

institutions and clinics that are subsets of institutions. I think that's very difficult, so I think the burden -- if you leave that out, then you're back to the authorized user, who is really the person who is providing the training.

CHAIR MALMUD: Dr. Thomadsen.

VICE CHAIR THOMADSEN: In 35.51(a)(2)(ii), you use the term "clinical radiation facilities". And it seems like that could cover all that we want it to.

DR. HOWE: That's a good suggestion.

VICE CHAIR THOMADSEN: It wasn't mine, really.

(Laughter.)

CHAIR MALMUD: Dr. Thomadsen, you made the suggestion, however. We'll credit you with it. Let me explain what one of my concerns is.

Human nature doesn't change, regulations change. In the first decade of the 20th century, Abraham Flexner inspected American medical schools, recommended the closure of a good number. Physicians then were willing to sign documents that they had trained physicians in training, and it turned -- it became evident that the basis for signing the documents was an exchange of funds, rather than genuine training.

There's a certain cynicism which I don't wish to adopt, but there's a certain reality, which we have to be faced with, as well. And when an individual is given that authority, in the absence of any oversight, let us say at a single office, one runs the risk of that occurring again. And, therefore, having this occur in an institution in which there is some oversight by at least one other party, and we've seen examples of this in practice, where the physicist is an important component with the radiation oncologist, et cetera, I think it behooves us in our protection of the public to be assured that we're not unleashing the possibility that that which happened before the first decade in the 20th century, doesn't recur in the first decade of the 21st century.

DR. HOWE: And I know what you're expressing was a primary concern to the medical group in the `80s, before more people did manual brachytherapy, gamma knife, outside of hospitals. And that was one reason they insisted it be medical institution, so that they would have a group to give -

CHAIR MALMUD: I'm also concerned -- excuse me. I'm also concerned about the issue of documentation. Is the individual authorized user

required to document those hours, so that there is a possibility of review, and confirmation of those hours, in the event that an untoward event occurs, and the ability of the individual is challenged.

DR. HOWE: As the NRC training and experience forms are set up right now, I believe that the 500 hours of work experience, you have to identify who the authorized user was, and you have to indicate what license they're on. But the only individual that has to sign the training and experience is the preceptor. So, the authorized user providing the 500 hours of supervised work experience does not have to sign, because the regulations don't say that he signs. It just says it has to be provided by an authorized user.

CHAIR MALMUD: Thank you. Is there anyone else who has the same concern that I do with respect to oversight and documentation? Dr. Suleiman.

MEMBER SULEIMAN: That was my intent, in the first place. I was clearly looking at it from a different perspective. I could see you would have facility creep. You start to get away more and more from human access, and somebody will be at some other site where it's clearly not a clinical environment, and very limited. And they'll say oh, we'll just put

the 40 hours you were here for the week, or whatever. So, you slowly creep away.

And I've known individuals, I won't go into any further detail, that say oh, that's not a problem. We'll just document that this way, or that way. But human nature being what it is, and that this is formal training, I am concerned, because there are loopholes here. And when you look at the broad distribution, I -- let me say this, because I've said it before, the people at this table, the people in this room represent the cream of the crop, represent the upper percentiles. When you get out into the real world, you have a much broader distribution, and don't forget about the fringes. So, it's that group that you're addressing, and those are the people that will find these loopholes, and take advantage of them. So, I don't know whether that's real, or not. I don't know what the experience of the NRC is reviewing the authorized user documentation, but I've had too much experience with human nature, and given the opportunity for a large number of people, somebody will take advantage of it.

CHAIR MALMUD: Dr. Eggli, you had a comment. Thank you.

MEMBER EGGLI: My comment was I agree with

the concern about human nature. I'm not sure there's an easy way to solve this particular question, because the issue that, as when it came up originally, is that some modality training, in fact, may have to be done outside of the institutional setting, because the institution may not offer the full spectrum of the modalities, and they have associates who do.

I think if it's clear that, essentially, the training achieved in a freestanding location is still the responsibility of the preceptoring institution/individual at the training institution, that may be a solution to that, which is, essentially, to make the -- if it's a residency training program, to make the residency training program responsible for the quality of training received at a freestanding location, so that somehow it does devolve back to a supervised program that isn't just one individual signing a preceptor statement.

CHAIR MALMUD: Dr. Guiberteau. Oh, excuse me.

DR. HOWE: Let me just make a quick comment on that. This particular section, you are not required to be in a residency program. So, this -

MEMBER EGGLI: Is this the alternate pathway, effectively?

DR. HOWE: Well, it's in both, but it also - the supervised work experience is not, necessarily, tied into a residency program, so you don't have that assurance that you are looking for, that it's tied to a residency program. It can be given anywhere. Okay?

CHAIR MALMUD: Dr. Guiberteau.

DR. GUIBERTEAU: I agree with Dr. Malmud's concerns. I do feel, however, that in the many programs, both in diagnostic, and therapeutic radiology with which I'm familiar, that the point that Dr. Eggli is making is very important. I think that if you require it to be in an institution, in many cases this would disqualify training that's provided in freestanding centers that are affiliated with an institution, such as a medical school.

I also have concerns that in an institution, that the definition of institution, as was read, that it really doesn't provide you with any guarantee of oversight at all. It just says more than one medical specialty. Is that not correct? And we don't know what those two might be, so they may, or may not be related. But I do have the concern, and I'm not sure how you would solve this, that rather than requiring it be in a medical institution, that at least that institution is affiliated with either some

kind of training program, or some kind of larger entity, would be in the best interest of, I think, the public safety. It, however, may limit many programs, and many instances of those who are not in programs, to obtain these new trainings.

CHAIR MALMUD: Other comments?

MS. FLANNERY: I just want to add that if this section was removed from the section that Donna Beth had described in 400 and 600, and what I mean is the phrase, "requirements at a medical institution", then those paragraphs would read the same as the equivalent paragraphs for 200 and 300 uses. So, if you look at the equivalent paragraphs discussing the supervised work experience under 35.290, and 35.390, it reads, "Work experience under the supervision of an authorized user who meets the requirements of 35.390, or equivalent agreement state requirements."

So, I guess the point I want to make here is that leaving it in there would have, I guess, caused inconsistency between the requirements for the different uses. So, I just wanted to add that there is a difference, I guess, among the work experience requirements for 200, 300, 400, and 600 uses.

The other thing I just wanted to add is that, for all of those requirements for supervised

work experience, it's still required for the proposed AU to get their work experience under an existing AU.

CHAIR MALMUD: Thank you for bringing that to our attention. So, this would make the change consistent with the other paragraphs related to 200, 300, and 600.

DR. HOWE: 200 and 300, 100, 200, 300, which are your -- generally considered your diagnostic and therapeutic nuclear medicine.

CHAIR MALMUD: All right.

MS. FLANNERY: So, paragraphs -- the requirements for 400 and 600 uses right now have a more prescriptive requirement of having that supervised work experience at a medical institution. Whereas, 200 and 300 uses do not have that requirement currently.

CHAIR MALMUD: Thank you. Dr. Eggli.

MEMBER EGGLI: Doug Eggli. I'm actually quite comfortable with that. When I first started, there was a phrase that was used that I haven't heard as much lately, but it was "risk-informed regulation". And as the numbers go up from 100, to 200, to 300, to 400, to 600, the risk to patients and public safety also go up. So, I'm comfortable with the training and experience regulations for Part 400, and Part 600 uses

to be more prescriptive than the training requirements for Part 100, 200, or 300, because, in fact, the risks associated are greater, as the number goes up. So, I'm personally comfortable with that. I don't think that that level of consistency is necessary, and I think that makes a risk-informed regulatory environment.

CHAIR MALMUD: Dr. Thomadsen.

VICE CHAIR THOMADSEN: Not that I disagree with what you said at all, exception in the regulation, the 390 requires 700 hours of training, whereas 490 is only 500 hours. So, as the number goes up, it doesn't look like the required training goes up.

DR. HOWE: But you have to consider that in 400, you're also required to have a residency program before you get to the 500 hours. So, in 390 you're not required to have a residency program, so the hours in 400 are really much greater than in 300.

CHAIR MALMUD: Thank you for that clarification. Dr. Howe's recommendation for us to consider is deleting the words, "at a medical institution", which would bring consistency with the other -- with 100, 200, and 300. Am I correct, that's as it was explained to me.

DR. HOWE: That's correct.

CHAIR MALMUD: I still have my concern. I'm not arguing the wisdom of the consistency. It makes sense. I'm concerned, though, about whether or not there is any documentation required, as we move away from oversight. I'm used to -- I speak from a very parochial perspective. I'm used to an institution all of my career in which we have attendings overseeing fellows, who are overseeing residents, who are overseeing interns, who are overseeing students.

(Background noise.)

DR. HOWE: Yes, we can hear you. You're not on mute.

MS. COCKERHAM: Could those on the phone please press Star 6 to mute your line.

CHAIR MALMUD: And it has not been unusual for a student to ask a question, which edifies all of us. We had assumptions which were invalid, so there's a series of peer reviews. And that leads to, I think, fewer errors than would have occurred otherwise.

When we begin to move into smaller settings, whether they are under the umbrella of the institution, or not, there are fewer individuals working together, and watching what each other might be doing. And as we get into a satellite office,

let's say the satellite office has the gamma knife, or just an ordinary radiotherapy unit, not a gamma knife, we then create the possibility of kindness on the part of the AU toward the trainee, in not requiring all the details, that all the Is be dotted, and the Ts be crossed, because the AU feels that the individual has the requisite ability.

And, then, if a problem occurs in that trainee later on, and we're asked for the documentation, and it doesn't exist, that would concern me, for our having allowed that to occur. So, my question is, does the -- must the AU, who is, after all, offering this training, keep any record of the training that was offered? Is that a requirement?

DR. HOWE: That is not a requirement. There needs to be documentation on the form, or in a letter, but we don't require that there be something at the facility that backs that up.

CHAIR MALMUD: Therefore, with the absence of peer oversight, or collegial oversight, even in a "private office", which may, or may not be associated with an academic institution, or a training program, we run the risk of an individual not really being trained. That's what I'm trying to avoid, without being unduly prescriptive. You don't want to get in

the way of the training, at the same time, we want to be able to set up a system, or approve of a system, since we're not setting it up, that meets requirements that are consonant with our understanding of human behavior at its worst.

DR. HOWE: Dr. Malmud, I think what I'm hearing in the discussion is that even though this appears to be a simple change, there may be a lot of concern, and underlying unintended consequences that are a concern to almost everyone at this table. It may be that instead of making a decision on this today, we may want to set up a subcommittee that can really hash out the concerns that everyone has.

CHAIR MALMUD: I'll take that as a suggestion which we can follow, but may I just ask one more question? Would it be onerous for the AU to keep track of what the AU is doing with the trainee? Would that prevent us from accessing AUs who are willing to train by giving them an undue burden? I have to ask someone else that question.

DR. HOWE: I would ask Dr. Eggli.

CHAIR MALMUD: Dr. Eggli.

MEMBER EGGLI: For the Part 390 uses, which is what I preceptor, we do keep records. And we keep a file on everybody that we've ever written a

preceptor statement on going probably back to the beginning of time. I look at this as sort of self-defense, in a sense, because I never know when somebody might come back and ask me to document the training credentials, so we do keep records on everybody we write a preceptor statement for, and we keep them nearly forever.

DR. HOWE: Dr. Eggli, you've stated in other public meetings with the ACMUI that you do not keep the documentation that would support the alternate pathway. You keep documentation to support the Board Certification -

MEMBER EGGLI: The Board Certification. That is true. That is true.

DR. HOWE: So, this would be at the level of the -

MEMBER EGGLI: This is more like the alternate pathway.

DR. HOWE: Yes.

MEMBER EGGLI: Yes, you're right.

CHAIR MALMUD: Rob.

MR. LEWIS: Thank you. You, Dr. Malmud, have raised a very good question that I think we need to take back and look at, because I can't understand why we would have any regulation that there isn't some

kind of auditable record that the licensee can -- if I'm an inspector, and I went in, and show me that you're meeting this regulation, it's the licensee's burden to do so. And they usually have to do so through documentation. And if we have a situation where we aren't creating that environment, we need to look at what we're doing.

CHAIR MALMUD: Thank you. My observation is that the individual who works in the satellite office, whether it's a private venture, or not, is, from my perspective, is competent, in general, as is the individual at the university. But there's always a tendency among all individuals to want to be generous, and considerate of the person being trained. And when there is absolutely no oversight, we run a risk, which does not exist when there is oversight, whether it's large private office with multiple people present, or a large practice. It doesn't matter whether it's a so-called private setting, or academic setting. That risk will always exist. So, we tend to document what we do. And my concern is the concern that I mentioned. We have a comment from a mEMBER of the public. Actually, NRC.

MS. BHALLA: Yes. This is Neelam Bhalla, and I work for the NRC. And I'm in the rulemaking

division. So far as it being a burden, as it is, we have some of the rulemaking, potential rulemaking where it seems like there is -- it's a burden for the authorized user to be providing attestation documents, so added to that, if the authorized user is also required to keep that documentation, that may be like adding more on the authorized user who will be providing this certification, or providing the documentation. So, therefore, the responsibility would really be on the person, or on the individual user, who would be requesting that documentation. And, therefore, it should not be -- or, perhaps there would be an added burden on the authorized user who will be providing that documentation to keep now a record of what all this individual has provided. And, therefore, I just wanted to say that we -- as it is, we have request, and I believe it has come through the ACMUI all the way to the Commission, that there is already the authorized user feels the burden of providing attestation requirements. And added to that, if the authorized user now has even to keep a record of what all he has provided, there may be some sort of an issue there.

CHAIR MALMUD: If I may, I believe that -- what I do in nuclear medicine, which is not,

necessarily, applicable here, but what I do is to certify, for example, the residents need to have had three cases of I-131 therapy, less than 33 millicuries. I certify it. I give them a copy, and I say this is your responsibility. I may be retired, I may be dead. Some day you're going to need this document. It is your's. Don't expect to find a copy of it here at the university. I'm giving it to you now. I do keep a copy, but that's not what I'm telling them. I'm telling them it's their responsibility.

When I was Honorably Discharged from the Air Force, they gave me a document and said you may never need this again. On the other hand, you may. And, sure enough, 35 years later, I needed it for the first time, but it was my responsibility, and that's what I do with them. So, I don't think that the record keeping is an issue. I think it's simply a matter of having a form which says that A, B, C, and D are part of what I trained, check off that they got A, B, C, and D, sign it, give them a copy, and that's it. But that's what I do. It may be that this is more complex. You would know that better than I. We have a number of comments. Dr. Suleiman.

MEMBER SULEIMAN: I know FDA across a wide

range of programs, I mean, when we don't spell it out prescriptively in the regulations, or it's not, necessarily, addressed in guidance, the responsibility is on the end. I mean, if an inspector goes in and wants to look at something, they're not going to take somebody's word for it. They're going to want to see record keeping, and documentation.

I guess my question is, is the practice out there such that people who are doing this are, in fact, keeping necessary records, or whatever? Do we want to get prescriptive? Can this be addressed by policy without having to be spelled out within regulation, or is this being done so prevalently across the board that we really don't have to worry about it?

CHAIR MALMUD: Dr. Eggli.

MEMBER EGGLI: Well, maybe Jim can help me with this, but Part 400, and Part 600 uses require three years of training, I believe, in a certified program. So, in a sense, I don't understand an alternate pathway concept, because in reality, there is no alternate pathway for 400 or 600, because you must train for three years in a certified program.

My recollection of the discussion was that this was a question of providing training for trainees

in these certified programs in a setting where that certified program did not physically have all the modalities, and had affiliated freestanding programs that provided the experience that they weren't able to provide. And I thought that that's why the clinic piece was added in the recommendation last time, not to serve as a true alternate pathway, but to add legitimacy to the affiliated training sites that provided training, essentially, for radiation therapy residents. Jim, do I misremember this? It's possible.

MEMBER WELSH: Jim Welsh. That's my recollection of it, as well. For example, many residency programs might not be located in a city or town that has a whole lot of cervical cancer. Therefore, GYN brachytherapy experience might have to be sought at another institution. Pediatrics is the same situation. Not every place does prostate brachytherapy, but it's an integral component of radiation oncology training. So, if it's not done at the parent institution, it needs to be taught elsewhere.

The burden of documentation in these situations is on the trainee, who has to, at the completion of that residency program, show that they

have the 500 hours of work experience, and be able to state exactly where and when it was obtained. And then, ultimately, it's signed off on by the residency program director. So, there is documentation, but it's not the authorized user who is keeping the records, it's the one who is seeking to become an authorized user. Of course, in reality, the authorized user probably has a xerox copy of all this, but it's the trainee's responsibility for procuring, and securing that information, that documentation.

CHAIR MALMUD: Dr. Thomadsen.

VICE CHAIR THOMADSEN: I was just concerned that the NRC might not have understood the concern with the attestations. And the ACMUI can correct me if I'm wrong, but I believe that what we were saying is that people did not like to like to have to attest to the competence of the person getting the preceptor statement. It is not that they objected to the documentation. And, in fact, what we recommended is that the attestation say that the student has completed the course of study, as opposed to that the person is competent in the use of the study. So, it's not -- the objection was not to the documentation, but what was being attested to in those documents.

CHAIR MALMUD: Your memory is correct. Dr. Eggli.

MEMBER EGGLI: There was, however, a second part to this that Dr. Howe was referencing, which did refer to the, in particular, the American Board of Radiology Diplomats who had a gap, and the issue of the alternate pathway. And there are two kinds of document keeping. The clinical experience document keeping, how many therapies, and the distribution of that kind of experience I do keep. However, what I don't have is documentation of the didactic training to the level of that the alternate pathway requires documentation, so many hours on this topic, so many hours on that topic. Because, for the Board Certification pathway, that's all rolled in, and there is no specific training requirement for any number of hours of any specific didactic component, so the records that I don't keep are the kind that would satisfy alternate pathway for the didactic training.

The clinical experience part are records that I do keep, but I'm not required to keep. So, that was the issue on the alternate pathway versus the Board Certification pathway.

CHAIR MALMUD: Dr. Guiberteau.

DR. GUIBERTEAU: I think we need to

consider that there are two types of training that we're kind of pushing together here. One, is the training that's received in an ACGME-accredited residency, but there is -- in terms of the progression of technologies, particularly in diagnostic radiology, and nuclear medicine, and in radiation oncology, those persons who have already completed their training will likely not go back to residency to obtain that training. And it is extremely important in order to have enough people who are well-trained to do these new procedures, that there is a pathway that they can do it outside of an ACGME institution.

I think the point here is that this needs to be -- this provision needs to be there. I do -- I, personally, believe that at a medical institution, as a medical institution is defined, does not really satisfy the concerns of oversight. I do not believe, as Dr. Thomadsen pointed out, that the concern about the burden on authorized users was not that you attested to the completion of training, it was you were attesting to competence, which we did not want to do.

If you are -- authorized users, in general, most of them are not teachers, do not provide this training, so there isn't any burden on

them. But I believe RRCs, and training programs, in general, if you accept the responsibility to provide the training, then I do not believe anyone doing so would see it as a burden to document the completion of training.

CHAIR MALMUD: Well, I think, Dr. Howe, as usual, is correct, and that we probably should put a small subcommittee together to come back with a recommendation. I think that the anxiety on my part is not with the change that has been recommended, because I have no problem with dropping "at a medical institution." My concern grew out of just thinking about well, if it's even part of a residency, and I'm sending the residents to a private clinic that's run by a clinical faculty person, how do I know that the resident is getting at the private clinic that which I know the resident is getting at the home institution, because of multiple oversight, which doesn't exist at the private clinic, or the satellite office, if you will, that might be run by someone who's income is totally independent of the academic institution, and who does this as a an adjunct to the academic institution. So, we just need some form of documentation that the individual truly received the experience. Not that he or she is competent, but that

he or she received the experience.

Then, the training program director seeing that, can feel quite comfortable in whatever his or her responsibilities are. So, I'm not opposed to the deletion of the prepositional phrase, "at a medical institution". I'm just concerned about the issue of oversight, once we get away from formal training program sites. So, we could set up a subcommittee to look at this issue, and actually approve your recommendation. The concern that I'm raising is not your proposal, Dr. Howe. It is really something that comes out of the proposal, which is an awareness on my part of something that might occur. Dr. Welsh.

MEMBER WELSH: I just have one point that was briefly mentioned by Dr. Guiberteau, and relevant to what you just said, Dr. Malmud; which is, the rigor of the training.

Medical institution phrase there is somewhat restrictive. I know that there are some training courses that are done outside of a medical institution, that actually do provide very serious dedicated instruction that allows someone who might not have had specific training in this particular area to get up to speed in terms of classroom, some of the radiation safety issues, and familiarity, so that when

they return to the clinic for the training with the patients, they are given a significant head start.

By having the words "medical institution" there, that might preclude such opportunity from being incorporated into the 500 hours. Yet, as you point out, experience at a private practice might not be nearly as valuable as training provided by a formal course, which might not be held within the medical institution. Thus, I'm not in favor of keeping the words "medical institution" there, because of that restriction.

CHAIR MALMUD: Thank you. Nor am I. I didn't suggest that we keep the wording. Dr. Suleiman.

MEMBER SULEIMAN: Let me share an experience. We have a situation right now at the Agency where the failure of a facility to adhere to the term "medical institution" has caused us to undergo some sort of major enforcement action. And it's precisely why I'm so agitated, because if we had allowed -- if the medical institution term had been enforced or interpreted correctly in the first place, we wouldn't be in the situation we're in. I can't go into any more detail, but you can create an environment. The environment of that facility clearly

is not a medical institution environment, which led to a whole bunch of other problems. So, maybe this is not going to happen here, but I'm just saying that the term was in there for a purpose, and to take it out completely, you could open the door for some scenarios to occur. That's my concern.

CHAIR MALMUD: Dr. Howe.

DR. HOWE: I would like to point out that if you form a subcommittee, that they focus on the training and experience requirements in here, because for the alternate pathway for 400 and 600, 490 and 690, you have 200 hours of classroom and laboratory training in certain topics. And then you have 500 hours of supervised work experience under an AU, and then you have a three-year residency in radiation oncology. So, those are not either/ors, those are ands.

Now, it's possible that the 200 hours, and the supervised work experience might be part of your residency program. And then there's a possibility that they may not be, if the residency program doesn't focus on our issues, and focuses more on linear accelerators, or things that are not within the NRC purview. So, those requirements are three, and they're ands. The Board Certification is just the

residency program, and then passing an examination.

CHAIR MALMUD: Thank you. Is there interest in having a subcommittee look at this? If there is none, we will just vote on this issue and move forward. There appears to be none. In that case, we will look at your recommendation, and vote in favor or against it. We'll regard your recommendation as a motion. Is there a second to the motion to delete the term "at a medical institution"?

MEMBER WELSH: Second.

CHAIR MALMUD: Seconded. Any further discussion of this motion? Dr. Suleiman.

MEMBER SULEIMAN: With all the discussion that's occurred, is the NRC still comfortable with your proposal, after what you've heard? If that's what you're recommending, I mean, I'm going to vote for -

MS. FLANNERY: Can I answer that?

CHAIR MALMUD: Yes.

MS. FLANNERY: When we discussed this among the staff, we've discovered the exact situation that Dr. Guiberteau described just a few minutes ago, that we found that medical institution, the definition, can be so broadly interpreted to include disciplines NRC doesn't even regulate. That doesn't

provide -- it doesn't address the concern that was expressed earlier about oversight.

CHAIR MALMUD: Right. We agree. All in favor?

(A show of hands.)

CHAIR MALMUD: Any opposed? Any abstentions? One abstention, no opposition. It carries.

DR. HOWE: Okay. Thank you.

Okay. Issue Number 2. In one of the medical events that I presented to you yesterday, there was a degree of frustration on our part. And once we realized that our written procedures in a number of cases, not only are inadequate to provide high confidence that administrations are in accordance with written directives, but also they may be inadequate in identifying medical events, and identifying them in a timely manner. And what I'd like to do is, I'd like to go over the case that, essentially, focuses on these issues.

We had a manual brachytherapy case in which none of the seeds were put into the prostate. There happened to be two CT scans done at different facilities. One was done by a radiologist, and he read the first scan, he recognized that none of the

seeds were in the prostate, and he notified the licensee's urologist immediately. Now, he didn't notify the AU.

The patient was due to get a second CT scan at the licensee's site within a day or two, so the second scan was performed three days later, and the AU read it immediately. And he identified that there was mispositioning of the seeds, and that external beam treatment was needed, so he clearly looked at the scans, recognized he had issues with it. And then he sent it on to the medical physicist with no note for the medical physicist to do a quick evaluation, or any other notes. So, the medical physicist put it in the pile, and a month later got around to reading it, and recognized that there were no seeds in the prostate. So, they identified it as a medical event only after the medical physicist read the images. But, in this particular case, it was clear all the way down the line that there was a problem with the administration. And we felt that the licensee had the knowledge, should have identified the medical event much earlier, and waited. So, we believe it should have been identified quicker, so we're looking at our requirements.

We don't have requirements that you do a

CT at a certain period of time that's a practice of medicine. We don't have a requirement that you pass on a CT in a period of time. That's, to some extent, the local choice. But we feel that medical events should be identified as quickly as possible, especially in these extreme cases. So, we searched for a place where we could maybe make a change that would be individual for the licensee, but would be effective in identifying things quickly. And what we came up with was the idea that 35.41, which is where you have a written program to insure that administrations are in accordance with the physician's written directive might be a good place to add a requirement that would capture the idea that medical events -- that errors in administration should be evaluated in a timely manner.

So, the next slide shows you the possible solution. And that would be to add a criteria that there be high confidence that the administration -- if the administration is not in accordance with the written directive, that a determination whether the administration resulted in a reportable medical event is made in a timely manner.

And the next slide shows just a suggested language, and you probably have to use the book,

because my pink coloring didn't show up very well. But it was to add a third item under the existing two items that says, "If the administration is not in accordance with the written directive, a determination of whether it resulted in a reportable medical event will be made in a timely manner." So, that seems to be a performance type of standard. It gives the licensee flexibility, but meets our concerns that these things are identified. And puts more emphasis on the fact that if physicians and physicists realize something is not in accordance with the written directive, that they need to think in terms of whether it's a reportable event, or not.

CHAIR MALMUD: Thank you. That's open for discussion. Dr. Eggli.

MEMBER EGGLI: I think I would support this change, but my comment would be that that would still not have picked it up until the fourth bullet. The first scan was ordered by the patient's urologist, not the authorized user. The radiologist's obligation, who read the CT scan, is to report that study back to the requesting physician, and would have no idea whether or not that information ever made it back to the authorized user, who actually treated the patient. So, it would certainly pick it up at

least one step earlier. But when a study which might identify that the treatment had not been successful is ordered by a physician not directly related to that treatment process, there is nothing that will guarantee that that result will get back to the AU, unless the urologist called him and said well, what the heck did you do? None of the seeds were in the prostate.

DR. HOWE: And I think we were looking at the AU should have recognized it, and started the ball rolling.

MEMBER EGGLI: Yes, at the time of the second scan. Okay. I've got no problem with that. Just to make it clear, though, that the first scan would not have started the process rolling.

CHAIR MALMUD: Dr. Howe, the definition of having administered in accordance with the written directive leaves a margin of the same percent that we discussed last time for the number of seeds that would not be necessarily in the prostate. Is it 20 percent?

DR. HOWE: I think so.

CHAIR MALMUD: So, there's no need to address the specifics, but there is some leeway, because I know that the radiation oncologist who was discussing this last time was very concerned about not

restricting the correctness of the dose any more than that at the time, if I remember correctly.

DR. HOWE: Right. And we understand that those that are close calls would take more evaluation. But some of these really obvious things, we'd just like them to think in terms of do you need to go another step further?

CHAIR MALMUD: Thank you. I would just ask the radiation oncologist, and radiation oncology physicists here if either of them has a comment regarding this.

MEMBER WELSH: This is Jim Welsh. I have a couple of comments. First, regarding the specific case, it's hard for me to understand why two CT scans were really performed. This really has got nothing to do with the matter at hand, just an editorial. But, in an era where we're trying to minimize the number of unnecessary scans, this is a glaring example of lack of communication resulting in unnecessary CT scan. Since the AU is going to do a post-implant dosimetry, and required a CT scan for that, it's not clear why the urologist would order a separate CT scan, and there was, obviously, lack of communication.

But the important points here are that post-implant dosimetry is recommended, but it's not

required. So, you would still have a number of situations where you might not pick things up with the change in the wording. In fact, unless it becomes required, rather than strongly recommended, it could be misconstrued as another way to get yourself in trouble. And, therefore, people might even start to shy away from doing post-implant dosimetry. I would recommend that it become a requirement.

The definition of timely is vague here, so the question at-large is, what is the ultimate purpose of all of this? It's to identify medical events, misadministrations. And does it really matter if it's picked up in a month, or in two months? It might not, but unless we specifically describe what we mean by timely, it could be open to interpretation and argument that a year later is still timely, a month later is not timely. So, I would recommend that if we change the wording, we have to be a little bit more specific. And to complicate things, it might be isotope-dependent, because the half lives are so very different.

CHAIR MALMUD: Thank you, Dr. Welsh. Dr. Thomadsen.

VICE CHAIR THOMADSEN: I agree with all the points that Dr. Welsh made. In addition, I'm not

sure that you need this to address the case as the example, and that once the authorized user saw the CT, it should have been quite clear that there was likely a medical event. And, at that point, they were obliged to report it. I think that it sounds like the authorized user did not execute his or her required duty at that point. I don't think he needed number three to do that.

If you do decide to write something like number three, I don't think it says what you want. It says, "if the administration is not in accordance with the written directive", which already meets the -- but if it is in accordance with the written directive, do you not need to do any further studies? Of course, you don't know that, so the wording of, "if it's not in accordance", you don't know whether it is, or isn't, so you don't want to write the rule dependent on something like that. I'm not sure that you need this. I think we already have the requirement to assess what's -- whether it's in accordance or not.

CHAIR MALMUD: Other comments? Rob.

MR. LEWIS: Just to clarify, you're saying that your logic is because an agent of the licensee knew a medical event existed, the licensee is then put on the clock to report the medical event? And,

therefore, the timeliness takes care of itself.

VICE CHAIR THOMADSEN: Yes. Right. Since it was the authorized user -- the first CT is completely irrelevant to the discussion, and to the case. But once the authorized user knew that there was a problem, the clock is already ticking.

CHAIR MALMUD: Dr. Malmud. I have a question. In the practice of radiation oncology, do I understand it's not necessary -- not a requirement to do a post-therapy CT scan? Is that right, Dr. Welsh?

MEMBER WELSH: I don't believe it's actually required. It's strongly recommended, American Brachytherapy Society, for example, has it in their recommendations, but I'm not sure it's in the regulations.

CHAIR MALMUD: So, that it's possible if a patient were to receive seed implantations that were all incorrectly placed, if the patient would not have been treated for the prostate cancer, there would be no record of this. And the patient could then theoretically go on to metastasize, have had a metastatic tumor, for lack of follow-up to the therapy.

MEMBER WELSH: That is correct. And that may have been the situation in the VA cases that we've

discussed recently, because of some difficulties with the post-implant dosimetry routine. So, it's not a mandatory step. I would, actually, recommend that it become so, because it would, perhaps, correct some of the concern that's being discussed right here, and why we would be changing the language in the first place. If it were a requirement, then much of this would go away.

CHAIR MALMUD: Would that requirement be a requirement of medical practice, or a requirement of the NRC, Dr. Howe?

DR. HOWE: The NRC requirement is performance-based. It says, "For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that", and then one of the items is, "each administration is in accordance with a written directive." That gives the licensee flexibility to determine what that program is. And Dr. Welsh's point is that he believes that licensees, if they're doing what they should be doing, in accordance with kind of the standards of care, would do post-implant CTs, but it would not be a specific NRC requirement to do post-implant CTs. It would be, they have to have some program to make sure the

administration is in accordance with the written directive, however they do that.

CHAIR MALMUD: I understand that. And that's what's raising my anxiety level of -- the incidents of microscopic prostate cancer in men is equal to their decade of life, as I recall. I don't know the incidents of significant prostate cancer is, but microscopic is equal to our decade of life. So, if it's something analogous to breast cancer, about one in seven of us will get it, if we live long enough.

The more I hear about the standards for the delivery of brachytherapy, the more I am convinced that it's a therapy I would not choose for myself. To have a therapy applied to me, and not to measure whether or not the therapy was effective, to me, is an indication that I, as a patient, and I as an individual who is concerned about the public well-being, would not choose this therapy. Is there anyone at this table who would under those circumstances, without any follow-up? You're shaking your head yes?

MEMBER MATTMULLER: I'm in agreement.

CHAIR MALMUD: You agree. I mean, I am made anxious, again. I used that term once before, and, unfortunately, it was quoted, but the anxiety

persists. This is very anxiety-provoking for me, as a potential patient. Dr. Suleiman.

MEMBER SULEIMAN: First off, I do disagree whether this is just a medical practice issue. I think it's also a safety issue. The NRC is responsible for the safe use of radioactive materials, so I clearly think that validating -- and I'd be afraid to just require a CT scan. Technology changes, there may be other imaging modalities. In other words, locking it into CT, maybe there are some other imaging modalities to validate. But I think validating that the seeds were -- these are cancer patients undergoing radioactive being inserted into them, so it's obvious that after this whole procedure is over, it should be validated, even from just a safety point of view. But, clearly, it's a medical issue, but it's also a safety issue. So, we're operating at the fringes that I had talked about. If society has already accepted validating after-the-fact, maybe it should be codified so that these fringe operators are required to do it.

DR. HOWE: This requirement is written for all things requiring written directives, not, necessarily, just the manual brachytherapy. So, it's stated in a very general manner.

CHAIR MALMUD: My concern was not about

the CT, specifically. It's just about the follow-up to the therapy to make certain that it was delivered, and not misdelivered, to validate it. We have a comment? Please identify yourself.

MS. VILLAMAR: Glenda Villamar with the NRC. I just wanted to share that some licensees read this regulation where they're actually -- they'll actually wait for a calculation to be performed before they report that a medical event has occurred. And they're not, necessarily, even though the authorized user might see it on the scan immediately that no seeds had made it into the prostate, they're still waiting for an actual number. That's just how licensees are reading this regulation.

CHAIR MALMUD: Yes, I understand that. But how would they know at all if there were no follow-up studies? They would not. Am I correct?

MS. VILLAMAR: Yes.

CHAIR MALMUD: That's what concerns me. I don't know whether that's a practice of medicine issue, which would be deferred to the radiation oncology specialists, or whether that's an issue for the NRC. But I do know that it's an issue.

I think there was a case recently in which it was decided that they weren't going to do them

within a certain time period, or at all, because the patients were traveling a great distance to get the therapy, and couldn't get the follow-up. Once again, if there's no follow-up, there's no knowledge. If there's no knowledge, not only is the patient denied the therapy, but the patient may suffer the consequences of the therapy, or the absence of it. Sue?

MEMBER LANGHORST: Sue Langhorst. In regard to the proposal of this Item 3, I want to go back to Dr. Thomadsen's comment, that I think it states the obvious. To me, if it isn't in accordance with the written directive, you evaluate whether you have a medical event. So, I think maybe if the NRC feels they need a stronger statement in regard to this, it might be better suited in a strong statement in the guidance documents that go along with this, rather than putting it in, an obvious thing like this in the regulations.

MEMBER FISHER: Darrell Fisher. It seems to me, from my limited knowledge, that Item 2 requires that each administration is in accordance with a written directive, if that's not the intent. And how does the NRC wish to regulate this matter? It would seem to me that the medical institution could not show

Item 2 without doing post-treatment imaging and dosimetry. How would the regulations work? I mean, is it only incumbent on the licensee to administer, or to both administer, and validate the administration as being in the target tissue?

DR. HOWE: I believe the requirements require a validation, because they have to have written -- develop, implement, and maintain procedures that show the administration is in accordance with the written directive.

MEMBER FISHER: Then it would seem that you have what you need without adding Number 3. One and two provide that assurance.

CHAIR MALMUD: Doctor -- oh.

MR. LEWIS: If I could, I think that the procedures wouldn't, necessarily, dictate a timely investigation. And I think that's what they were getting to. In this case, it was ultimately reported to us. We just didn't think that the licensee was particularly diligent in pursuing it as soon as they knew.

DR. HOWE: And we've also had other licensees that have indicated yes, we knew they had problems, but they never bothered to look to see if they had medical events.

MEMBER FISHER: Is timely 30 days, or 60 days, or is it a year, or two years, or five years?

CHAIR MALMUD: If I may -

DR. HOWE: Go ahead.

CHAIR MALMUD: If I may, that may be a medical question. There are couple of things coming up here, and I don't have the knowledge to address them. It seems to me that the college, the Governing College for Radiation Oncology, or the Board of Radiation of Oncology, must have standards which do require post-therapy follow-up. And they probably exist. I would assume they're not prescriptive, because technology changes, ultrasound versus CT, versus whatever else is coming down the pike. But they must exist. And I can't imagine anyone who is not doing post-therapy follow-up, so I would assume that that's there, but that's an assumption. And we have to determine that with the appropriate individuals. Can you speak for the Board, or the requirements?

MEMBER WELSH: This is Jim Welsh. I don't think that it's a Board requirement, but it is recommendation from the ABS, and it is something that is considered standard of care by most careful practitioners. But I don't think that it's an

absolute mandatory requirement. And, therefore, it is still possible, from what I see, that there could be sub-standard practices out there in which this set of recommendations that we're talking about here is not strictly adhered to, at all.

CHAIR MALMUD: So, as a radiation oncologist, and as a male, would you ever undergo brachytherapy without a follow-up of some sort?

MEMBER WELSH: I would make sure that the facility that was going to perform this adheres to the recommended standards, and has a good record.

CHAIR MALMUD: So, you would want the follow-up.

MEMBER WELSH: Absolutely.

CHAIR MALMUD: Right. So, that's a medical practice issue, is it not?

MEMBER WELSH: I think it's a medical practice issue, but as Dr. Suleiman pointed out, it's, perhaps, also a safety issue.

CHAIR MALMUD: And if it's a safety issue, then it comes back to, in essence, our responsibility to make certain that the appropriate board understands that we're concerned about the potential for a patient to have had radiation oncology brachytherapy, and did not have the follow-up, and not be aware of the

efficacy of the therapy. And that is something which we should not allow to occur, and which I assume they're not allowing to occur.

Debbie, you have your hand up.

MEMBER GILLEY: Yes, Debbie Gilley. I just wanted to reassure the NRC that as part of getting a radioactive materials license, they are required, the licensee is required to submit procedures. And in those procedures, there are some standard procedures that we use that they can adopt, or they can develop their own. But in the standard procedures for NRC, it does require them to do radiographs, or comparable images, such as computerized tomography, for the basis of verifying the position of the non-radioactive dummy sources, and calculating prior to, and then after. So, there are some procedures that are part of the license application that we hold the licensees accountable for in order to be able to do these procedures. So, it's not just the regulatory requirement, but also the procedures that they submit as part of their application.

DR. HOWE: Debbie, just to clarify NRC requirements, NRC does not require the licensee to provide their procedures to meet the requirements in

35.41, because these procedures came out of the Quality Management program. And the decision when we implemented the Quality Management program was that the procedures for that program should be flexible enough for the licensee to change at any time. And, therefore, were not submitted to the NRC, and are not tied down in the license condition.

The requirement is that they develop, implement, and maintain. They do not have to provide these procedures to the NRC. And, if they do provide them to the NRC, we state back in our cover letter that we have not evaluated them, and we do not consider them to be part of the license, because we do not want them to have to come in for a license amendment in order to change them. So, the fact that they have the procedures is a requirement. What the procedures say is not tied down in the license.

MEMBER GILLEY: Then I'd like to go on record saying that that is not true in some of the agreement states.

DR. HOWE: And that may be true, but for NRC, that is the way we license.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: Oh, I was just pointing to -

CHAIR MALMUD: Oh, a member of the public.

MS. FAIROBENT: Lynne Fairobent with AAPM. Donna Beth, however, whether or not the licensee submits the procedures, they are available for review, and I believe they're inspectible, if they're not being followed. So, they're still, whether they're a tied down specific license condition or not, they are still part of their license, and they are reviewable, and inspectible. If that's not the case, then please clarify.

DR. HOWE: They are inspectible, but they are not -- the procedures that are in effect when the licensee submits their application do not have to be the procedures that are in place when we do an inspection. They can be changed, and you don't have to seek an amendment, so NRC has not reviewed those procedures. The licensee is tied to having the procedures, and we do review them if we find that there is a reason to review them. One reason to review them would be if we think there is a medical event.

CHAIR MALMUD: Dr. Eggli.

MEMBER EGGLI: Part of the argument here has been that Number 3 is superfluous, that it should be obvious from the rest of the regulation. I never

cease to be amazed how often what is obvious to me isn't obvious to everybody. I'm a firm believe in the Will Rogers school of public speaking, which says you tell people what you're going to tell them, then you tell them what you're telling them, and then when you tell them what you told them. If there's a concern that what should be obvious, isn't behaving as obvious, I don't see the harm in adding an additional statement. And I would, with the exception that maybe timeliness probably should be tacked down, I see benefit, and no harm, in restating the obvious, because what's obvious to me, isn't always obvious to everybody else.

CHAIR MALMUD: That's a motion in favor.

MEMBER EGGLI: In favor.

CHAIR MALMUD: If Dr. Howe's proposal is a motion, you second it?

MEMBER EGGLI: Yes.

CHAIR MALMUD: Is there any further discussion of this motion? And then we can get back to the other issue. All in favor? Oh, excuse me.

VICE CHAIR THOMADSEN: Discussion.

THE WITNESS: Excuse me.

VICE CHAIR THOMADSEN: Regardless of the point that was just made by Dr. Eggli, I think the

wording, other than the timeliness, still remains to be cleaned up, because it's a conditional, which is unfortunate. And it shouldn't be written in that manner.

DR. HOWE: This is a potential change. If it becomes a proposed change, it will be -- it will go through a lot of review, and it won't, necessarily, look like this.

VICE CHAIR THOMADSEN: Yes.

CHAIR MALMUD: Dr. Thomadsen?

VICE CHAIR THOMADSEN: Also, I think that it is unnecessary, because we do have the timeliness of when you find something out. For permanent implants, for example, with the changes that we've made, you don't need to do dosimetry to know that there's been a medical event. You just have to look at where the seeds are, and count the seeds, so it's not a matter of even waiting for dosimetry to be done after the CT. All it has to do is to be looked at, in which case, I don't think that this is necessary. And I'm not in favor of redundancy in regulations, because inevitably, if you tell them what you're going to tell them, tell them, and then tell them what you told them, and have it three times in the regulation, you're going to have situations where you have

conflicts in the regulations that shouldn't be there. And regulations should only be telling things once, so you make sure that you have what you want said, and say it clearly once.

CHAIR MALMUD: Thank you, Dr. Thomadsen. Sue?

MEMBER LANGHORST: Sue Langhorst. I agree with that. And I think you can tell them in a different venue than in the regulations. I think information notice, regulatory issue, guidance document. I think you can tell them what you're going to tell them, tell them, and then tell them what you said in that venue. And I don't -- I agree, it should not be in the regulations.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: Jim Welsh. In this particular case that was discussed, the identification of the medical event not being within a timely fashion was, perhaps, due to the authorized user suspecting, based on what he saw with his own eyes, that there was a mistake, or a problem, but was reluctant to formally report it until it was quantified. So, rather than just a qualitative evaluation suggesting that the prostate was under-dosed, or the -- another organ was overdosed, he waited until the physicist did the

formal post-implant dosimetry to determine whether or not this was truly a medical event. And, in that sense, I think that this was understandable.

The point here, however, is that if the post-implant dosimetry was not ever performed, none of this would have ever been identified. And that would be a problem.

As written, with 1 and 2 there, Number 2 says, "Each administration is in accordance with the written directive." Implicit there is that there has to be some means of ascertaining whether or not the implant was done properly. And I would see in there that post-implant dosimetry is included. To me, that's obvious. But do we have to be a little bit more direct in that? That's a question for another debate, but I would say yes, because what's obvious to me, is not obvious to everybody. But I don't think that Number 3 is really mandatory. I think 1 and 2 say it all. If we expand Number 2 to say, "Each administration is in accordance with the written directive, and verified with post-implant dosimetry", would suffice.

CHAIR MALMUD: Dr. Welsh, are you proposing an amendment to the motion, which would add a phrase, "In accordance with post-implant dosimetry"?

Is that what you were suggesting?

MEMBER EGGLI: This is a generic rule that doesn't apply, necessarily, to brachytherapy, but all therapies for which a written directive is required. And, in many cases, a follow-up dosimetry would be inappropriate. For instance, the radioactive therapy for hyperthyroid disease, a follow-up dosimetry would be an inappropriate procedure. So, I don't think you can change the generic regulation to state that.

DR. HOWE: One issue we're also trying to get at, we've had a number of cases recently where it's come to our attention that the authorized users are not aware of what the definition of a medical event is. So, they know they have something that's not in accordance with administration, but they're not even thinking in terms of medical events. And part of this change would be to make it very clear that if it's not in accordance with your administration, then you need to think in terms of a medical event. And if you don't know what a medical event is, you need to find out what it is, because you need to make this determination.

CHAIR MALMUD: Good point. Dr. Thomadsen.

VICE CHAIR THOMADSEN: But I don't think that will make a difference. If they don't know what

a medical event is, adding another regulation here isn't going to make them know what a medical event is. We've got a different problem there, if they don't know what a medical event is. And we should solve that problem directly, as opposed to trying to solve indirectly by adding something else in a different part of the regulations.

CHAIR MALMUD: The motion remains before us. Any further discussion of the motion? All in favor of the motion?

MEMBER EGGLI: I remain stubbornly in favor.

CHAIR MALMUD: Oh, I beg your pardon. You're in favor.

MEMBER EGGLI: I am.

CHAIR MALMUD: Was it amended?

MEMBER EGGLI: It has not been amended.

CHAIR MALMUD: No, it is as it stands on the page in the book, which is legible. All in favor of the motion?

(A show of hands.)

CHAIR MALMUD: All opposed? All abstentions? The motion doesn't carry.

DR. HOWE: Please give the vote for the record.

CHAIR MALMUD: Okay. All in favor of the motion? Two. All opposed? Two, four, five. All abstentions? Two.

DR. HOWE: Thank you, Dr. Malmud.

CHAIR MALMUD: Thank you, Dr. Howe.

Having brought up something which may not be an issue, I'd like to resolve it, so that it isn't an issue. It appears that the standard of care is that following brachytherapy, some form of post-therapy evaluation is routine. Is that correct, Dr. Welsh?

MEMBER WELSH: It is.

CHAIR MALMUD: Therefore, the anxiety that I expressed is not relevant, since it is routine to do post-therapy dosimetry, a post-therapy evaluation of where the seeds are.

MEMBER WELSH: It is routine among those who are skilled, and knowledgeable in the procedure, and those who I would recommend a patient go to. But since it is not absolutely mandatory, I suspect that there are still those out there who might not adhere to these standards, since they are not absolute requirements.

CHAIR MALMUD: To the best of your knowledge, within the world of radiation oncologists,

does the Governing Board for Radiation Oncology have it as part of their standards that post-therapy brachytherapy evaluation should be done?

VICE CHAIR THOMADSEN: ACR?

CHAIR MALMUD: ACR?

VICE CHAIR THOMADSEN: ACR would be the only one with standards who practice -

CHAIR MALMUD: ACR.

VICE CHAIR THOMADSEN: They have guidelines in the AAPM, there's guidelines that coming on board, but they don't certify practice -

COURT REPORTER: Speak into the microphone.

VICE CHAIR THOMADSEN: I'm sorry. I was trying to ascertain the information rather than have a discussion with the group, because I do not know the answer to that question. But the information would be available. The only organization I can think of that would actually be relevant to this would be the American College of Radiology, which departments can be accredited by. There are standards, both by the ABS and the AAPM that would dictate after a permanent implant you do dose -- you do post-procedural evaluation. And there are guidances for what that would entail. But those are guidelines, they wouldn't

be part of an accreditation for a department.

I'm also not sure how big of a problem this is. I'm not aware of facilities that don't do any. But, then again, they may not be facilities with whom I would have any discussions.

DR. HOWE: Just as anecdotal data, we don't know what the situation is out there. But we do know, because we have had a chance to look extensively at the Department of Veterans Affairs and their manual brachytherapy program, that for a period of time their computer systems were not compatible at multiple locations. And in those locations, they tried to fix it with a work-around quickly, but in multiple locations, we had post-implant CTs that could not be evaluated with the treatment planning systems, because of incompatibility of the computer systems. And in the Department of Veterans Affairs at Philadelphia, they let it go on for a year and a half. In the other facilities, they got work-arounds in a much more timely fashion so that they could evaluate the post-implant CTs, but anecdotal data. We do know not everybody evaluates things in a timely fashion, for one reason or another.

MEMBER WELSH: That answers your question.

CHAIR MALMUD: Dr. Welsh says that you

have just answered my question, which is that it isn't always assured.

MEMBER WELSH: Not 100 percent are doing it. Maybe it's close, but I wouldn't be able to tell you exactly.

CHAIR MALMUD: Now, we come to my concern. Having tripped across the issue, though it's not the focus of what we were discussing, it would be remiss of us to ignore it. Someone has to deal with it, either the ACR, or the NRC, or both. Rob?

MR. LEWIS: Well, with the NRC, and part of our internal procedures, we have a Lessons Learned program. And we are currently chartering a Lesson Learned Group with respect to the Veterans Affairs event. And it's internally focused, so we'll be looking at what we require in licensing, and what we require in inspection. It's nothing about what VA did, or didn't do. It's about what we do. And part of the charter, I expect to be what we require by way of post-implant verification. So they will look into the issue. We'll bring the Lessons Learned, I can commit to you, before the Committee at a future meeting, so we can have that discussion.

CHAIR MALMUD: Thank you. Dr. Suleiman.

MEMBER SULEIMAN: Somebody once lectured

me and said if it's a safety-related issue that impacts on the public, don't be afraid of a regulation.

The professional practices, the societies, they take the lead. As Bruce had said earlier, you may not -- you don't know, what you don't know. That was another famous quote I remember. And, so, the people who may not be reporting these medical events may not be doing validation in a timely manner. So, maybe they're taking a picture, because they're saying oh, we have to do that several months downstream. And if it's an inappropriate isotope, by the time they take that image, it may no longer be relevant, because there's nothing they can do about it.

It would be nice if we had some data, whether this is a figment of our imagination, or these sort of things happen out there. But, the point is, I get a sense that if it is happening, nobody is going to know about it. So, I think some sort of high-confidence validation, or verification, which would clearly include a temporal, a time element in there, for brachytherapy sounds to me like it's obvious. I mean, it -

CHAIR MALMUD: It's obvious to me, but it may not be obvious. It's obvious to you. But Rob

indicates that he believes that their current investigation will result in a recommendation, and that recommendation will then come to us, and then it could be made applicable.

The way I tried to Chair this, at your request, is to always look at the questions from a position of naivete, which isn't difficult for me in many areas. But, the point is, the concern of everyone on this Committee is the safety and welfare of the public, including both people who work in radiation, and people who receive radiation.

I always remind myself that that's what we're here for, and that's why I should ask naive questions. The balance that we're trying to achieve is to maximize the access to therapeutic interventions for the public, and, at the same time, not restrict them by being overly prescriptive, and preventing physicians, or others, from providing those services. And that's what we're trying to weigh, all of us. It's quite obvious in these discussions. So, we all have the same goal.

The corollary to that is that sometimes we trip across things which are really not our turf. But we should, nevertheless, find some means of addressing them, if we trip across them, even though it may not

be technically in the NRC area. And this particular question, for me, is one that I think needs to be solved in two ways. One is by asking the people who are most knowledgeable, and they are the radiation oncologists, what they would like to see as an absolute standard. And the second one is for us to help enforce that standard, and to make certain that the public, and the radiation workers are safe. Dr. Welsh.

MEMBER WELSH: I'd just like to amplify those points, and conclude by saying that the issue is clearly a radiation safety issue, as well as medical practice issue. And, therefore, I think NRC does have a role in specifically stating how this should be standardized.

I was very pleased to hear what Rob Lewis just said about a formal statement about Lessons Learned, and I look forward to seeing what that shows.

CHAIR MALMUD: Thank you, Dr. Welsh. And I am pleased that you have volunteered to say that as a member of the radiation oncology world. That's very reassuring. Debbie?

MEMBER GILLEY: I just would like to bring up, since you're talking about Lessons Learned, that maybe we ought to be looking at performance-based

licensing versus the prescriptive way we do licensing. And maybe in certain instances, we do need to be more prescriptive, as in with what is required for brachytherapy.

CHAIR MALMUD: Thank you. I believe that -- does that complete your presentation, Dr. Howe?

DR. HOWE: Yes, it does.

CHAIR MALMUD: As always, thank you for a very stimulating presentation. I believe the next item on the agenda for which we are a bit late, is the Medical Uses of Radium-223, which Dr. Welsh is going to tackle for us. Do you want to do that now, or do you want to take a break now?

MS. COCKERHAM: Yes, you guys are scheduled for a break. You want to come back at like 10:15, or so.

CHAIR MALMUD: Okay. So, we'll reconvene -- it's 10:05. Can we reconvene at 10:20? Thank you.

(Whereupon, the proceedings went off the record at 10:02:04 a.m., and went back on the record at 10:24:31 a.m.)

CHAIR MALMUD: Ladies and gentlemen, if we may, we'll reconvene. We are running a little bit late, and as soon as we get together, we'll move on.

The next item on the agenda is a

presentation by Dr. Welsh regarding the Medical Uses of Radium-223. Dr. Welsh.

MEMBER WELSH: Thank you, Dr. Malmud.

Today I'm just going to talk briefly about new applications or Radium, specifically, Radium-223, which may become available in the United States for palliative therapy sometime in the near future, if all goes according to plan. I'm going to restrict my talk today to palliative therapy, but as many of you know, this isotope has potential very interesting applications that might go beyond palliation.

So, just in the way of background, Radium is the heaviest of the alkaline earth elements, and, therefore, the chemistry is very similar to Barium; thus, the famous experiments by Otto Hahn and Fritz Strassman, which they won the Nobel Prize for chemistry, in which they extracted Barium, when they were expecting Radium. It was discovered in 1898 by Bemont, and, of course, Pierre and Marie Curie. About 10 tons of pitchblende was used to isolate less than a gram of Radium. And then used pitchblende, which is an amorphous black pitchy form of the mineral Uraninite, Uranium Oxide, and this is one of the primary mineral auras of Uranium. It contains 50 to 80 percent of that element. But there were three

chemical elements that were first discovered in pitchblende. The first was way back in 1789, when Uranium was identified by Klaproth, and, of course, Polonium and Radium were also isolated from pitchblende.

In terms of basics, we're familiar with the concept of the curie, which one gram of Radium-226 undergoes 3.7 times 10 ten to the tenth disintegrations per second. I counted up 33 isotopes of Radium. Some texts say that there is a few less. All of them are radioactive. And, for the most part, their half-lives, with the exception of Radium-226, and Radium-228, which are measured in years, the rest are measured in much shorter time periods.

Radium occurs only as a disintegration product in the three natural extant radioactive decay series, specifically, the Thorium series, the 4n series, the Uranium series, the 4n+2 series, and the Actinium series, or 4n+3 series. Radium-226, the familiar form of Radium, is a member of the 4n+2 series. Uranium-226 is found in nature as a result of the continuous formation from Uranium-238 decay. And the parent is Thorium-230, daughters Radon-222.

Biological effects of Radium were identified very shortly after its discovery.

Becquerel only two years after the discovery of Radium, developed a skin ulcer after carrying a small ampule around in his pocket for a number of hours. Marie Curie developed a skin ulcer, also, after a few days following 10 hours direct contact with a small sample.

In 1903, the Radium craze began, and there were a number of absurd products that became available. The Cosmos Bag used for arthritis, so-called Liquid Sunshine, Radiathor, and all this ended with the sad case of steel magnate, Eben Byers' death in 1932. He consumed approximately 1,400 bottles of Radiathor, and the Wall Street Journal article says it all. "The Radium water worked fine until his jaw came off."

And then, as if that wasn't enough, we are all familiar with the story of the Radium Girls, the U.S. Radium Corporation. The luminous paint for watch dials contained a small amount of Radium, consisting of Radium Bromide and Zinc Sulfide. The Zinc Sulfide glows out to alpha radiation. Eight hundred employees -- of 800 employees, 48 developed radiation sickness, including a couple of cases of mandibular necrosis, and 18 of these people died, including cases of osteosarcoma.

So, how could there possibly be any interest in Radium today, after that wonderful background? Well, as I said, Radium-226 is part of the 4n+2 series, the Uranium series. The Thorium series, or the 4n series, has two Radium isotopes that are found naturally in some abundance in Monazite, but it's the fourth isotope that I'm going to talk about here, Radium-223, which occurs in the 4n+3 series.

So, Radium-223 is the isotope of interest. It has a number of radiological properties that make it well suited for radiopharmaceutical applications. And there is some compelling clinical data that is emerging, suggesting its got a potentially important role in the palliation of bone metastases.

Here's a table of some of the common isotopes of Radium. We see Radium-223 is an alpha emitter, which is not commonly used in radiation therapy, or nuclear medicine at this stage. It's got a half-life of 11.4 days, and decay energy approximately 6MeV. Here's where it sits in this decay scheme, with isotopes being horizontally arranged, and isobars being on the diagonal. Here's a more specific decay scheme of the Radium-223 ending in Lead-207 through a series of alpha and beta decays.

Radium-223 is a bone-seeking radioisotope,

similar to Strontium. Now studies have shown a bio distribution similar to Strontium-89, and that means that it accumulates in the skeletal matrix with retention in osteoblastic lesions. The first report on the use of Radium-223 goes back about 40 years, with a biokinetic bio distribution studies using tracer amounts for the purposes of establishing radiation safety assessments. Dose modeling suggests that a significant reduction in marrow irradiation might be possible with this isotope when compared to Strontium-89.

It is a bone-seeking isotope, similar to Strontium-89, and Samarium-153 EDTMP. And we know that these two beta emitters, MetaStron and Quadramet, their trade names, are effective, but their clinical use is hampered by myelosuppression. And they may be under-utilized because of this reputation of damaging the marrow. And, thereby, interfering with the ability to give additional chemotherapy.

Well, Radium-223 is an alpha emitter, which -- with an energy of 5.99 MeV is high LET. And, in principle, could be potentially more effective at killing tumor cells, as well as less myelosuppressive due to the relatively modest range of the alpha particles.

As I mentioned, it's got a half-life that is suitable for therapeutic applications. At 11.4 days, it rapidly decays into a stable form of Lead. And it does emit photons that might be suitable for imaging, 81 KeV at 15 percent, and 84 KeV at 25.6 percent.

I don't have the bone scan here to show you. Frankly, it's not a beautiful bone scan. I wouldn't say it compares with Technetium-99M and MVP, but you can see skeletal outline with this isotope.

Back in 2002, Hendriksen and colleagues showed an effective anti-tumor effect in a rodent model of metastatic breast cancer, and did not show much in the way of myelosuppression. At 67 days, two of the five animals treated with more than 100 kilobecquerel per kilogram survived, where none of the controls did. And then in a Phase I trial led by Nilsson and colleagues, published in 2005, a single IV administration with activities ranging from 50 to 250 kilobecquerel per kilogram was administered to 25 patients with bone metastases from breast or prostate cancer. Only three of them developed Grade 3 Leukopenia, and no patients had more than Grade 2 Thrombocytopenia, which compares favorably to what would be expected with the beta emitters. There was

improved pain scores at all doses. The alkaline phosphatase was also reduced at all doses administered, and 50 kilobecquerel per kilogram was the dose selected for further studies.

So, at Phase II, randomized multi-center placebo-controlled study was conducted, published in the Lancet Oncology by Nilsson and colleagues, 64 patients with hormone-refractory prostate cancer were treated, about 31 to 32 in both groups. And the dose was 50 kilobecquerel per kilogram every four weeks for four administrations.

The primary endpoints were bone alkaline phosphatase levels, skeletal-related events, and secondary endpoints were toxicity timed to PSA progression, and overall survival. There was a highly significant reduction in the median relative change in alkaline phosphatase. There was no difference in toxicity in two arms. Median time to PSA progression was also significantly altered. And the hazard ratio for overall survival proved to be significant, as well.

So, there have been other studies in which the biodistribution and tumor uptake of liposome-encapsulated Radium-223 in mice and human osteosarcoma, xenographs in dogs with spontaneous

osteosarcomas have been evaluated, and the results are promising in terms of the biodistribution in both species. And, collectively, the data suggests that there's an outstanding potential for Radium-223 as a therapeutic agent that might be beyond just palliation.

So, as far as future in the United States, there is now a Phase -- there's a Phase III placebo-controlled study that's ongoing in the United Kingdom. And Algeta, I think, has partnered with Bayer or sold their product, and how it's pronounced, Alpharadin.

(Off mic comment.)

MEMBER WELSH: Okay. That agent, is now with Bayer. And that means that there's possibility of it becoming available in the United States. And, I guess we'll have to keep our eyes and ears open for whether or not those clinical trials open here in the USA, and whether we can participate. And I know that while reviewing this subject, I came across a couple of papers that were co-authored by one of our ACMUI members, Dr. Fisher, so I would ask Dr. Fisher for any comments also on this topic that I might not have covered. Otherwise, thank you for your attention.

CHAIR MALMUD: Thank you, Dr. Welsh. Dr.

Fisher, you've been invited to make a comment.

MEMBER FISHER: Yes, thank you. I helped author the papers that you cited. My small role is dosimetry. And I think what's interesting about Radium is that it's also less expensive, and more available than the other alpha emitter choices for therapy. To use it in the broader context of a clinical setting, one needs to conjugate it to cell-directed targets, and that is being worked on at the present. So, while we see that the treatment of metastases from prostate, breast cancer, and lung cancer is the primary first use, I think other therapeutic applications are forthcoming.

One interesting one was the use of the parent, Thorium-227 chelated with Doda, conjugated to an antibody for targeting solid tumors, or even Leukemia, where Thorium-227 serves as an in vivo generator for Radium-223. There were at least eight papers on this at the S&M in Toronto, or various subcategories of the same concept. So, it looks like a very interesting therapeutic agent for not only bone cancer metastases, but also other forms of cancer in the future. And I thought you did a very nice job of giving an overview on this.

CHAIR MALMUD: Thank you, Dr. Fisher. Dr.

Howe.

DR. HOWE: I guess NRC has one overriding question, and that is, is it something we would regulate? If it's coming totally by natural products, raw material, we wouldn't regulate it. Is it something that you enhance its production through accelerators or anything?

CHAIR MALMUD: Dr. Fisher.

MEMBER FISHER: That's a really good question. I think it is regulatable, because the way you produce it for clinical use is you put Radium-226 in a nuclear reactor, and turn Radium-226 into Radium-227, and beta decay to Actinium-227, which decays to Thorium-227, and Radium-223, and then on down the chain. So, I suspect -- it is a natural existing material, but the Radium-223 that is used is created through reactor -- as a reactor byproduct.

DR. HOWE: Okay. Thank you.

CHAIR MALMUD: Dr. Eggli.

MEMBER EGGLI: Just sort of editorial comment on where I might see the use of this in a clinical practice. Given the short range of the alpha in tissue, this looks like it has potential as a treatment for micrometastases that are not otherwise yet clinically apparent. And, as we make steps

forward in the treatment of cancer, clearly, where we're going to have the biggest impact is in the treatment of non-clinically apparent micrometastases. As we deal with the big tumors, and remove them, and the patient has no evidence of disease, we always wonder about the micrometastases that we can't find. And this seems that this has great potential in the revolution of cancer treatment, if you can target an effective treatment to micrometastases. So, I hope the research continues.

CHAIR MALMUD: Thank you for your comment, Dr. Eggli. Are there other comments, or questions? If not, thank you for keeping us informed, Dr. Welsh. We look forward to hearing more about Radium-223 in the future.

Do I recall the reason that the Radium handlers developed bone cancer was that they were putting the tip of the brush on their tongues with the Radium Zinc Sulfide?

MEMBER WELSH: Yes, that's my recollection, as well. And I think, according to some accounts, it was quite obvious that they had very significant burden of Radium in their bodies, and in their skeletons. In some interpretations, this is viewed as evidence of a threshold for osteosarcoma.

Although, of course, that is highly debated, but it is often quoted as one tangible example.

CHAIR MALMUD: And what happened to all those Radium-painted wristwatches that we had as children in my generation?

MEMBER WELSH: Well, I know that some people have brought them to the Cancer Center and donated them to the radiation oncologist, but I can't account for all of them.

CHAIR MALMUD: Can the NRC account for them?

MR. LEWIS: Debbie could probably weigh in, but every -- well, once a year some old jeweler passes away, and their children inherit the family house, and we found out the basement is full of Radium. And it's an ongoing issue, well-known to NRC and the states.

CHAIR MALMUD: Dr. Eggli.

MEMBER EGGLI: In my department, we have a collection of naturally occurring radioactive objects that we use as training tools. The wristwatch with a Radium dial is the second most radioactive. The third most radioactive was a Thorium mantel from a Coleman lantern. And the very most radioactive was a plate of Fiesta Ware which was painted with orange Uranium

Oxide paint.

CHAIR MALMUD: Thank you very much. We'll move on to the next item on the agenda, and that is Dr. Suleiman, who will provide us with a brief overview of the Role of the FDA regarding Regulatory Responsibilities of the U.S. Food and Drug Administration. Dr. Suleiman.

MEMBER SULEIMAN: Yes. Thank you. I've been there for 30 years, and I'm still trying to figure out all our regulatory responsibilities.

Actually, I was going to mention the -- before I say "we", I'm very excited. Some of my colleagues at the Agency are very excited about alpha emitters. I've been hinting at it at this Advisory Committee for many years, that I think you can see in the pipeline, you can look in the literature. One of the benefits of Bexxar and Zevalin, which have been approved by the Agency a few years ago, they're, essentially, beta emitters, and they have much less side effects than conventional agents. And the alpha emitters would even have less side effects. And, obviously, dosimetry is a major, major challenge. And the drug is chemically very challengeable. And there are, clearly, radiation issues. And yes, Donna Beth, I think I can say pretty competently, it's going to be

regulated by the NRC, as well as us. So, we're excited, but let me give you an overview.

(Off the record comments.)

MEMBER SULEIMAN: Basically, back in 1906, the Food, Drug and Cosmetic Act was passed. There was a lot of media attention with foods, and the law has been amended many, many times. I mean, you can discuss this in great depth, but every few years, Congress comes up with another round of amendments to the FDA. And it incorporates a variety of laws that have been passed separately over a period of time.

Some of the ones that impact on radiation products is the Radiation Control for Health and Safety Act of `68, the Medical Device Law of `76, and since then we've had the more recent ones, FDA Modernization Act, we refer to as FDAMA, and FDA Authorization Act, which was passed in 2007.

There are several major centers in FDA. I currently work in the Center for Drug Evaluation and Research. They, primarily, regulate radiopharmaceuticals. We got involved with the medical isotope shortage issue, because we have a Drug Shortage Group, and we got plugged into that far more intensively than I had cared to get involved with.

CDRH, historically, has been involved with

the vast majority of radiation products, accelerators, brachytherapy sources, and so on. The Center for Biologics, blood and vaccines, actually, they approved the Bexxar and Zevalin products I had mentioned earlier. Since then, they've been moved over to the Drug Center, because those are monoclonal antibodies, which were regulated by CBER, but the therapeutic applications -- the cancer therapeutic applications have all been moved over to the Drug Center.

CDER has about two to three thousand people. We've undergone major expanse the last few years. CDRH has between one and two thousand. CBER has a couple of hundred people. CFSAN, Center for Food Safety and Nutrition regulates -- guarantees food safety. They regulate, also, food irradiators, but the other issue they get involved with is if the food were to be radioactively contaminated, the other federal agencies would come to us to declare whether it was, in fact, safe for human consumption. So, that's our big role in terms of emergency response.

There's a few smaller components, Center for Veterinary Medicine, National Center for Toxicological Research, which is actually located in Arkansas. Our two most significant components are the Office of Regulatory Affairs. That's our field

operation, numbers about 4,000 or so people throughout the country and the world. We just opened some international offices. And the Office of the Commissioner, which basically runs the Agency.

I'll briefly review some of the products, and some of the statutes. CDRH, as I said, has the -- regulates medical devices. The critical office in CDRH is an office known as Office of Device Evaluation. They do what we refer to as pre-market approval. We regulate the marketplace, so before anything is allowed to be sold, and they're making a medical claim, it has to be evaluated, cleared, reviewed by the Center. And the analogous office in the Center for Drugs is called Office of New Drugs. And some of the terminology changes, basically, nobody can make any medical product that makes a medical claim, has to be reviewed ahead of time.

Up until the early `60s, FDA basically had very limited pre-market, if any, regulatory authority. We, basically, chased after products that were making false and misleading claims. And it was only after the Thalidomide disaster that Congress gave us the authority to require pre-market review.

Radiation-emitting products cover cellular phones, microwave ovens, x-ray, a whole slew of

electronic products that emit radiation. That dates back to the `68 law, and that's in CDRH's Office of Communication, Education, and Radiation. And the Mammography Act, the MQSA, which was passed in `92, is also regulated by OCER. So, you have a broad range of products.

The three statutes, again, that affect CDRH were passed in `68, `76, and `92. One of the unique features of the Radiation Act is that it allows for mandatory performance standards. So, microwave ovens, any microwave oven that's sold in the country must meet - and if you look behind the console, you'll see it says complies with 21 CFR, such and such, and so and so. So, lasers have a whole slew of requirements. There are also performance standards for medical and security products.

I have to -- I want to dwell on this just a little bit, because there is a tremendous amount of confusion out there. And this is just for medical devices. I'll get over to the drug side in a few minutes. Basically, you hear this term "510-(k)". Basically, when the law was passed in 1976, any product that was already out there was, essentially, grandfathered in, so all a medical product manufacturer would have to do is say -- they'd have to

fill out this form, and it's called 510(k) because it is what -- is the part of the statute that addresses this. And say this product, an x-ray system. It was around before 1976, so it -- we just want to demonstrate that it's substantially equivalent. And they have to answer some basic questions. But it's, essentially, or used to be pretty much a rubber stamp-type procedure.

Also, we've classified products into three classes, I, II, and III. I, where you -- because tongue depressors, for example, come under -- are considered medical devices, where they minimal controls, where we really don't worry about them. Class II, special controls, and Class III are high-risk devices, and may require pre-market approval, which we call a PMA, and may require clinical trials. But it varies a lot, depending on the product when it originally was introduced into commerce. So, understanding these sometimes is very product-specific, and changes over time. So, the reason you don't always get a simple answer is because the questions are not always very obvious.

The MQSA Act, which really was the closest thing to regulating process, covered mammography, and it addresses quality control of equipment, periodic

testing. It addresses credentialing. Our other products don't address the user of the products. We trust the physicians, we trust the community that's using them, but with mammography, we actually require, for example, the interpreting physician must read 240 mammographs every six months, and RTs have qualifications, as do medical physicists. And the imaging equipment is actually assessed in terms of performance, so there's a phantom that addresses some imaging criteria, and addresses some dosimetry issues. So, it really covers the entire gamut.

And I'm going to use this as a soap box, because when I went over to Drugs -- well, with mammography we realized you needed to have a phantom, and this phantom on the right is one that we adopted, the ACR uses it in its accreditation program. And there are a bunch of test objects that have to be imaged. If the mammography equipment fulfills the task, and the radiation dose, it's also dosimetry phantom. If the radiation dose meets a certain amount, then it's okay. It passes. And you can't use people because human anatomy varies over time, and whatever.

When I got involved with the drug trials, I went over to the Center for Drugs, and I got

involved with imaging-based drug trials, and I thought I was dealing with the best and the brightest. So, where you're trying to see cancer efficacy, and you're trying to measure tumor size over a period of time, and an awful lot of other imaging endpoints, what I discovered was that a lot of the trials were fundamentally flawed.

I was at a drug meeting, and some of the - they call them CROs, Contract Research Organizations that do all the heavy lifting for the drug companies, and I said what kind of phantoms do you use? This was an imaging-based CRO, so I thought I'd talk some shop with them. And they said we don't use phantoms, we use patients. So, how can you demonstrate that these changes over time are, in fact, due to the effect of the drug? So, I've been on a personal crusade internally, and it's gained some traction. And pharma is a very different beast than the other industries we interact with, so it's been fascinating. They're eager to learn, but they're also eager to tell you how it ought to be done. So, there's been some benefit there.

This is just something I had put together a while ago. Early in the `70s and `80s, we knew that radiation doses from mammography were pretty high, and

so there was a big public effort by the professional societies, industry, film companies, to reduce the doses. These doses were, basically, a direct film dose, and doses were on the order of 1400 millirads. And they came down, as the community shifted to faster, or lower radiation dose technologies, film screens, xerox, and now you're seeing a lot of digital imaging.

And this was the image quality. We learned earlier with mammography, you couldn't just reduce the dose. At some point, the image quality, the efficacy was a critical part, so we had a metric that we tracked, and was very important in the overall program. And in `92 is when, essentially, all these forces -- this is where a lot of people were doing it right. The American College of Radiology had a voluntary accreditation program. It was a very good program. It was voluntary. And, eventually, Congress, advocate groups came together and people said why don't you apply this to other imaging technologies? Well, it's not our decision, it was Congress', and Congress passed the MQSA Act. And it was embraced pretty much across the board. But it's not something that's been really applied to other modalities.

Shifting back over to the Drug Center, most radiopharmaceuticals are either drugs, or biologics. The vast majority of the radiopharmaceuticals now are regulated by CDER.

Now, the point I wanted to focus on here is what does it take to get a drug approved? There are two hats that FDA wears, and people don't ever appreciate the first one. The first one, we're supposed to protect human research subjects. You cannot conduct any sort of research on any people in the United States unless you -- if it's a drug, unless you do it under and investigation of a new drug application. And you always hear the terms Phase I, Phase II, Phase III. And, basically, a Phase I is a safety trial. And it doesn't apply much to radiopharmaceuticals, imaging pharmaceuticals, but it does apply to therapeutic pharmaceuticals.

But, basically, you want to know how much is too much. So, you basically escalate the dose, and you determine how much is safe. And then you worry about efficacy until you get into the Phase II trials, which usually require a few hundred human subjects. That's where you want to demonstrate that this product actually has some sort of benefit medically. And the end of Phase II trials, we have a big meeting with the

sponsors, usually the drug companies, and they present their Phase III protocols. And these are large-scale studies that address risk, that address dosing. And, usually, these are completed in a few years. Contrary to all the business about it takes eons to get a drug approved, a lot of the pre-clinical, a lot of the animal research, and a lot of the early research takes sometimes five, ten years, when they come to us, it usually doesn't take but a couple of years to get the product researched and approved, or not approved.

Now, the other thing that people are never aware of is, we're also focused on manufacturing. And this raises a lot of anxiety, because once the product is approved, we want to be sure that it's manufactured in a consistent and safe way. So, what I call quality control for devices, I call CMC, Chemistry Manufacturing Control on the drug side. So, we're pretty -- we can be pretty picky on these issues. And it's our field operations, they go in and it's -- they take manufacturing very, very seriously.

Now, I had mentioned pre-market approval for medical devices. For drugs, you do the research, you collect it. You can take forever as far as we're concerned. Then you decide you're going to apply for a new drug application. Now, right now, I think the

application for a NDA is over $1 million, and you can get exempted if it's what's called an orphan product, where it's used on a much smaller population. But, basically -- and we have to, from the time the application is submitted, and we -- there's usually a short period of time we have to tell the applicant that it's of quality to be considered or not. But then we have to make a decision within six months. Sometimes that could drag out to nine months, depending on whether the quality of the submission is appropriate. But once they submit to the NDA, it's got to be resolved relatively quickly.

And another area I've been very much involved, again, is the research phase. We actually realized a few years ago that radiopharmaceuticals don't all, necessarily, require an investigation and new drug application. They do it under what we call this Radioactive Drug Research Committee. And it allows research to be done by these committees at medical institutions. If the research is basic, meaning it's not for development as a diagnostic or a therapeutic agent, if the Committee approves the protocol, we don't, necessarily, want to look at the protocol. And there's no -- there are certain radiation dose limits that are met, and this involves

organ dose calculations, and they're capable of doing this. And there's no clinically detectible pharmacological effect from the drug itself, you're administering such a small quantity of the drug that, basically, there's no safety issue with that. So, as long as they meet these criteria, and there's other requirements, administrative and record keeping requirements, as long as they meet those, we sort of keep our hands off, and allow these committees to operate independently, with strong oversight. We do review their annual reports. We review their annual reports on an annual basis, and we can go in and inspect, and do other things to keep them honest.

So, manufacturing responsibility for medical products are isotopes, I threw these up here just for reference purposes. For pharmaceuticals, we have what's called Good Manufacturing Process. The PET CGMPs are going to be in Parts 212. I know Steve is excited about those, not as much as we are. That's a tragic example of regulatory slowness. It involves a Supreme Court ruling, it involves some other issues, and for a variety of issues, we don't -- and the community is eager for PET drugs. The Agency looks on PET production, even though it's very local, as manufacturing, so they're subject to manufacturing

regulations.

An aside, I don't know how many of you would appreciate this, because I learned this. I didn't understand the difference between compounding, which the pharmacist does, and manufacturing. And one of my pharmacist friends said if people are -- the physicians are requesting so many drugs, we'll prepare for them. Sometimes you may anticipate a lot more, so you'll prepare for them. When a pharmacist starts compounding lots and lots of dosages, and starts selling them, or soliciting them, at some point you cross that threshold. Well, the GMP -- the manufacturing regulations are much more stringent. So, that's where there's been some issues, and concerns. For whatever reasons, the Agency looks on PET drugs, despite their short-lived nature, as manufacturing. So, we're promised these regulations, and we're waiting for them, as well as you are. They have to clear the upper echelons of the government.

Medical device, also quality -- what they call our Quality Systems Regulations. These are all very similar; record keeping, periodic testing on various components in the manufacturing cycle. And we also have an office called Office of Combination Products, that now when you have products that both

have a device or a drug nature to them, they have to be registered, and the lead agency identified.

And I threw -- this slide is really more for my FDA colleagues, but I decided to leave it in here, because the term "licensing" comes up. FDA does not license radioactive materials. Obviously, the NRC and the agreement states do. However, FDA does license some products. It's licenses biological products. Just like the pre-market approval for devices, and the New Drug Application for drugs, biological products, like the vaccines that we all should be getting, have to be approved under a biological licensing application. So, that's it.

I could have gone into an awful lot of more detail on any of those subjects, but I figured I'd finish early, and answer questions, as they come.

I did have a slide that I couldn't project here on the CT exposure, so if you have any questions, that has made the news recently, but it's something that's, apparently, still under investigation. But the only thing I can say is, you never know, what you hear initially may not always be what happens when the whole thing is investigated, lying the flying saucer balloon. So, I'd wait until the investigation is completed, but I think it's 206 patients were started,

who were being treated with CT brain profusion study, started to show hair loss. And that adverse event, we don't call them medical events, we call them adverse events, was actually reported, and the whole thing unraveled. So, like I said, that's been in the news. Anyway, any questions?

CHAIR MALMUD: Are there any questions for Dr. Suleiman? If not, we thank you for a very informative presentation regarding the FDA. The FDA and the NRC complement each other.

MEMBER MATTMULLER: If I could make a comment, said the Staff at the NRC, if ever you think you're being picked on for slow response, you can always hold up FDAMA 1997 as an example of how quickly the FDA operates, because the PET CGMPs were supposed to be in place by 1999, I believe. So, you're pretty close.

MEMBER SULEIMAN: It's not the first mandatory deadline we haven't met.

(Laughter.)

MEMBER SULEIMAN: And it probably won't be the last.

CHAIR MALMUD: All right. If we may, we'll move on to our deadline with Item 17. Oh, is there another comment? I'm sorry.

COURT REPORTER: Speak into the microphone.

CHAIR MALMUD: Oh, thank you. We'll move on with our own deadlines, and hear the next presentation from Dr. Eggli, who will give us a few final words about his experience on the ACMUI.

MEMBER EGGLI: Thank you, Mr. Chairman.

When I was first appointed to this Committee, I had absolutely no idea what I was getting myself into. Ashley asked me if I wanted to use slides today, and I said no, but what I probably should have said is I don't think anything I'm going to say is memorable enough to be rendered to slides. But, joining ACMUI seven years ago, I made several new friends. And that's one of the things that this Committee does, is cement some lifelong friendships.

In that time, not one of those people I started with is still here. But I've made new friends in the last seven years that I will take with for the rest of my life. I think it takes a while to learn the regulatory process. For new people on the Committee, although you may have opinions to share relative to your expertise, unless you have a strong regulatory background, it's going to take a while to learn the process, at least it took me a while to

learn the process. The regulatory process, I think, is both slow, and complex. It has a unique set of rules, and its own vocabulary, which doesn't translate into ordinary English. So, it takes a while to learn that, and to make more than just a technical contribution, but make a contribution to the regulatory process.

At my first ACMUI meeting, I think I learned that this not the place to fight a turf battle. Turf battles are won and lost on a completely different playing field. In my everyday clinical practice, I fight, and either win, or lose turf battles, but this Committee is not the place to fight turf battles. Turf cannot be protected for any significant period of time via regulation. It just doesn't happen.

So, what I think we do here is, we bring our expertise to bear on questions of public interest. Our professional experiences inform the discussion, and each one of us, in theory, comes from a different professional background, so we each bring something different to the discussion, which informs that discussion, and, hopefully, then provides a better quality recommendation to NRC Staff.

However, even though Dr. Fisher is the

official patient advocate, I see our primary responsibility here in this Committee, each and every one of us, as patient advocate. Our task is to make sure that materials-based diagnostic and therapeutic procedures are widely available to support public health, and well-being. And this should be done in an environment that protects safety both of the patient, and the public. And that's where the balance has to be created, and that's where all of -- a big chunk of the discussion revolves.

NRC, again, strives to create risk-informed regulation. Part of our task is to help NRC understand where the diagnostic procedures, or therapeutic procedures that employ radioactive materials fit in the risk versus benefit spectrum. Everything has a risk, everything has a benefit, somewhere there's a tipping point where the benefit is no longer supported by the risk. And there's also a tipping point where below a certain level of risk, the benefit is obvious. And that's what, I think, we help to inform the discussion. Lower risk procedures, obviously, require less regulation. In my background as a clinical nuclear medicine physician, I sit at the low end of the risk spectrum, and that probably colors my opinion of the risk benefit discussions.

I think we are most effective when we work collaboratively, and develop a consensus. I won't hold up the last vote that we had as an example of consensus, but I think that's when we're most effective. A Supreme Court decision of 9-0 sets a clear precedent. A Supreme Court ruling of 5-4 says the issue is unresolved, and it's going to be back again another day.

I think the same is true for our ACMUI recommendations. A variety of opinions and points of views are critical to inform the discussion. But, at the end, we need to close ranks, and make a consensus recommendation that is in the interest of patients, and good healthcare.

It is difficult to argue that the expense and time to change a rule should be undertaken on a split recommendation. Because what that, to me, says is that we really don't have a uniform opinion, and why spend millions of dollars, and two or three years worth of time to implement a rule on something that we haven't agreed upon, just to have it changed at a later date. So, I think that the more -- as Chris and Rob say at the beginning of every meeting, our goal should be to arrive at a consensus.

All of us are probably impatient by

nature. I know that I am. But progress if often incremental, and I think that it's wise to accept what you can accomplish now, and come back to discuss and debate another day. It may be another rulemaking cycle before the process is done, or it may be two or three rulemaking cycles before you end up at an endpoint. But incremental progress is still progress, and I think should be viewed with a sense of accomplishment.

The other thing is, we have to make our case. I watch politics all the time. I'm a political junkie. And I listen to a politician make a beautiful and elegant speech, occasionally they do, and then I listen to the press afterwards saying they haven't made their case. And I say, what do you mean they haven't made their case? Look at this. Well, I think the question is, the definition of making your case. It is one thing to make an elegant intellectual argument and support it with fact. It is another situation all together to create a high level of comfort that what you're doing is the right thing. And I think that's a key part of making your case, is making everyone comfortable with the pathway you're embarking upon. And that's why I think after a beautiful intellectual argument laid out, the press

will often say well, he hasn't made his case yet. So, our job in making our case is not to just present the arguments, but present them in a way that the regulatory agency can be comfortable with the approach that we're advocating. And that's what I think making your case is.

The staff have to be comfortable. And, ultimately, the Commissioners have to be comfortable that we're taking a reasonable and appropriate path. So, making our case means making people comfortable that we're heading down the right path.

Over the last few years, NRC has developed an emphasis on the concept of a culture of safety. And Leon touched on some of this earlier, and stole a little bit of my thunder here. And if I could have reached under the table, I would have kicked his leg and say don't -- this is what I'm going to talk about later. But, a culture of safety has the airline industry as its primo model. The culture is desirable, and should be both encouraged and rewarded. A culture of safety really assumes that almost all problems are system problems, that there aren't really human errors, but that if the system were improved, the errors would go away.

However, there are still airplanes that

crash due to pilot error. There is no system that is perfect, but there are systems that can improve. Just yesterday we heard about medical events that cry out for a better system. Yet, we can't bring the error rate to zero with systems alone. There will always be a few human errors. One of the things I was told once is, nothing can be made foolproof, because fools are truly ingenuous people. So, nothing can really be foolproof.

In the medical events arena, Dr. Howe presented that in I-131 treatments, there were four medical events last year. If you look at the denominator for administrations of doses greater than 30 microcuries, I don't have good data, but the N on the denominator is in the at least tens of thousands, so the error rate is very small. And as you look at systems approaches, you have to determine whether a very small number is simply noise in the system, or if a systems approach can really improve that.

If a systems approach is created that is perceived as complex, or onerous, people will find a work-around. And as a result of that work-around, more errors will occur. So, you reach a point in systems approaches where you can actually create more errors, than you reduce, because the system you have

created is either perceived as too difficult, or too onerous to comply with. So, part of, again, what the Committee needs to do in looking at medical events is achieve that balance between a clear-cut case, where an improved system would make improvements, and the case where we're at the point where you can't get any better than you're at. And, unfortunately, we've had several airline tragedies this year, that were human error in an industry where systems are about as sophisticated as they could be made. So, human error will continue to occur, and I encourage people to remember that even with a systems approach, human errors will still occur. And part of our role as ACMUI, is to help describe and understand the balance between the improvements that can obtained through systems approaches, and the human errors, which are going to exist at the margin, and that you can't just get by.

Finally, over the last seven years, I've seen the relationship between ACMUI and the Staff evolve from probably something grudging, and a bit distrusting, and intermittently confrontational, to a very collegial and collaborative environment. The list of ACMUI recommendations that actually reviewed yesterday demonstrates the overwhelming favorable

response by Staff to ACMUI recommendations. Did we get 100 percent? No. Did we do good? Yes, we did good. And sometimes perfect is the enemy of good. And you can't struggle for that perfection, because you and undo the good. And in the relationship that I think the Committee now has with Staff, it is good, and we'll never get 100 percent of what we want. I think we can all bask in the light of the good results that have been achieved through the input of this Committee.

Finally, I'm grateful for the opportunity to have participated, and wish you all good fortune moving forward. And I'm sure that collectively, you will help to create that good fortune.

(Applause.)

CHAIR MALMUD: Thank you very much, Doug. I speak for the whole Committee when I say that it's been a pleasure working with you, and gaining from your insights, knowledge, and opinions, as we try to achieve the goals and the purposes of this Committee. You've been a wonderful colleague, and we will miss your presence. And we wish you the very best in everything else that you're doing outside of this Committee, and will continue to do.

MEMBER EGGLI: Thank you.

MR. LEWIS: Now, I would just, on behalf of the NRC Staff, add to the appreciation that Charlie already expressed, and the Chairman expressed in writing, and we know the Committee is losing one of its more vocal members, and someone who remembers the history of the Committee debates, and often interjects that history, and it's very valuable. So, that will be tough to replace, I mean, we have no choice but to go on. But I was -- it's tough to focus all day long, to be honest. But when Dr. Eggli speaks up, I can hear him, because I think that he offers advice to us that is really pragmatic, and really about how this regulatory process that we have down here in the halls of the ivory towers in White Flint really hits the road at the licensee sites. And that is really invaluable, and that's really the epitome of why we have this Committee. So, really appreciate all of your contributions over the years, to me, in particular.

MEMBER EGGLI: Thank you.

CHAIR MALMUD: Any other comments? If not, we'll move on to Ashley.

MS. COCKERHAM: Okay. I'm going to pass around the new 2009 recommendation sheets. We have three new recommendations from this meeting.

CHAIR MALMUD: You want the extras?

MS. COCKERHAM: Okay. So, if you'll look at Recommendation 9, Dr. Malmud added three temporary members to the Medical Event Subcommittee, and the new members include Dr. Welsh as the Chair, Dr. Langhorst, Mr. Mattmuller, and the existing Subcommittee members still include Debbie Gilley, Orhan Suleiman, and Bruce Thomadsen.

For Item 10, the ACMUI recommended deletion of the phrase, "at a medical institution", from 10 CFR 35.490(b)(1)(ii), and 35.690(b)(1)(ii). I could tell you this recommendation will be accepted. Any questions on that?

CHAIR MALMUD: I see that.

MS. COCKERHAM: Okay. I have a question for Dr. Malmud. Did you vote on that one?

CHAIR MALMUD: Yes.

MS. COCKERHAM: Was it in favor?

CHAIR MALMUD: Yes.

MS. COCKERHAM: Okay. Thank you. So, I had nine in favor, and one opposed. I'm sorry, one abstained.

VICE CHAIR THOMADSEN: Ten. Yes.

MS. COCKERHAM: I had one abstention.

VICE CHAIR THOMADSEN: I thought it was --

I didn't think that was unanimous. Was that one unanimous at all? I thought it was quite a split decision.

MS. COCKERHAM: No, that was the next one.

VICE CHAIR THOMADSEN: Oh, that was 11. That's next.

MS. COCKERHAM: The next one is 2-5-2. Yes, so this one was nine in favor, and one abstained.

Okay. For Item 11, ACMUI recommends revising 10 CFR 35.41(a) by adding Number 3, "If the administration is not in accordance with the written directive, a determination of whether it resulted in a reportable medical event will be made in a timely manner." And this motion did not pass. There were two in favor, which I have Dr. Malmud, and Dr. Eggli, there were five opposed, I have Dr. Thomadsen, Dr. Fisher, Ms. Gilley, Dr. Langhorst, and Mr. Mattmuller, and I have two abstentions, Dr. Welsh, and Dr. Suleiman.

CHAIR MALMUD: That is correct.

MS. COCKERHAM: Okay. So, those are the only recommendations. Any other comments on these?

CHAIR MALMUD: Are there any comments from any members of the Committee regarding these issues? I see none.

MS. COCKERHAM: Okay. The next item is just a reminder that your travel vouchers will need to be submitted when we leave the meeting. Shayla will email you those, and she'll send examples, just like I always have. If you took the train, or if you flew, or if you bought your own flight, how to fill out that form, so you'll mail those back to Shayla, and she'll process those for you.

MEMBER EGGLI: Is the deadline for that this Friday, or next Friday? Where are we in the cycle?

MS. COCKERHAM: It's not time. Travel vouchers aren't due by time. I would typically give you 10 business days to complete your travel vouchers.

MR. LEWIS: I'm sorry.

CHAIR MALMUD: Rob?

MR. LEWIS: On the action items, was there an action to -- for the Committee to submit a letter to NRC with respect to the ICRP 103 Subgroup work? There was not? Okay.

VICE CHAIR THOMADSEN: There was no action on that.

CHAIR MALMUD: You're correct. The Vice Chairman is correct.

MS. COCKERHAM: Okay. That takes care of

travel. The next thing is your time, which is what Dr. Eggli was referring to. And time -- this is the end of the pay period. Correct? This week?

MR. EINBERG: Yes.

MS. COCKERHAM: Yes, this is the second week, so your time will be due to Shayla. You could email it to her Wednesday or Thursday, that would be appreciated. We are going to try a new system. We need to include other secretaries on the emails, and the way the form is set up right now, when you hit send email, it just sends it directly to Shayla. And if Shayla is not there, it needs to go to her backups. And there's no way to get it to her backups, unless you send it to her backup. So, I created a new email for Shayla to send to you that says to send all of your time to her, and to two other secretaries. And your hours can just be a text email of here's the date, so 10/19/2009, eight hours ACMUI meeting; 10/20/2009, eight hours ACMUI meeting. And that email goes to all three secretaries, and that's it for email space. So, as soon as they receive that email, they can immediately input your time into the system, and we won't have any late time.

Then you still need to fill out the form. And you can either type in the form. It's still

typable, and savable, or you can handwrite it and mail that form to Shayla, as you've always done.

MR. LEWIS: Please bear with us as we try to make the process better. I know time and attendance is -- it eats away at me, as well. But the Agency is a fee-recoverable Agency, so the timing of all of the staff getting their time in directly effects the bills that are sent to licensees, and the corporate support offices, necessarily, have very tight schedules, and strict systems. And we're trying to work with them, particularly, the Committee and the Medical Consultants, because it's always been a hard process.

MS. COCKERHAM: So, I think this will, hopefully, be the easiest way. It's a simple text email to three people. Okay?

And the last thing I have, if you'll turn to Tab 18 in your binders, we need to choose a new meeting date. We've had a chance to look at the calendars. There are eight dates that I've already circled in April and May, and those are the dates that the auditorium is available. And I've already reserved the auditorium, so we cannot be bumped, moved, or shifted in any way, shape, or form. So, if we could pick from these dates, are there any dates,

in particular, that don't work for anyone?

MR. LEWIS: Could I make a comment, too, that Ashley doesn't know about yet?

MS. COCKERHAM: That the ACRS room will be ready?

MR. LEWIS: Well, no, that -- I just heard this yesterday, but one of the things that the Commission is considering for the next ACMUI meeting is to conduct it concurrent to the FSME Program Office briefing. So, once a year, FSME goes and tells the Commission about all the stuff that we've done for the year, and some Commissioners would like the ACMUI meeting to be a second panel on that meeting, so that we all hear everything. And that will be a Commission decision, so it's outside of our control.

The current plan for the FSME briefing is in June, so we can pick a date here for a tentative, but if that plan comes to fruition, we're going to have to re-engage you about the spring meeting.

MS. COCKERHAM: I have a question. Will we consider what we did last time, where we flew the members who were giving presentations back -

MR. LEWIS: That would be an alternative.

MS. COCKERHAM: Okay.

MR. LEWIS: Yes, that would be an

alternative.

MS. COCKERHAM: Okay. So, the preference would be for the full ACMUI meeting to coincide with the Commission briefing, if the Commission chooses for ACMUI to participate in that. The other option would be what we did last time, when the two meetings didn't coincide. We flew back the members who were giving presentations to the Commission separately in June, even though we had our full ACMUI meeting in May.

CHAIR MALMUD: I noticed, Ashley, that the fourth is Easter Sunday. That would mean that if the meeting were on Monday and Tuesday, that some people's holiday would be interrupted by their having to travel on Sunday. So, should we consider as a first choice the 8th and 9th?

MS. COCKERHAM: Sure, or we can look at dates, either one.

CHAIR MALMUD: Jim.

MEMBER WELSH: The American Radium Society meeting is May 2nd through 5th, and I, for one, was planning to attend that. So, I don't know if anybody else was, but that's not my first choice.

CHAIR MALMUD: Radium-223?

MS. COCKERHAM: So, Dr. Welsh, would even the 8th and 9th be pushing it for you for travel,

getting from one meeting -

mEMBER WELSH: I was talking about May.

MS. COCKERHAM: That's in May.

DR. HOWE: So, he's eliminating May 3rd and 4th.

MS. COCKERHAM: Okay. So, it looks like either April 8th and 9th, or May 24th and 25th. Is there a preference for one over the other, April first, or May first?

CHAIR MALMUD: Does anyone have a preference?

MEMBER GILLEY: I like May 24th and 25th, but I -

MS. COCKERHAM: Okay.

CHAIR MALMUD: You like the 24th -

MEMBER GILLEY: I like to travel on Sunday.

CHAIR MALMUD: All right.

MEMBER GILLEY: It keeps me out of the office just two days.

(Off the record comments.)

CHAIR MALMUD: Debbie expressed a preference for traveling on Sunday, rather than during the week. That would make it May 24th and 25th. Is that acceptable to everyone else? It is a conflict

for anyone? Excuse me? I hear a voice behind me.

(Off the record comments.)

CHAIR MALMUD: A member of the public indicates that the American College of Medical Physics will have a conflicting meeting with the 24th and 25th of May.

MS. COCKERHAM: Is anyone planning on attending that meeting?

CHAIR MALMUD: There is no indication that a member of the Committee will have a conflict.

MS. COCKERHAM: Okay. So, we'll write down May 24th and 25th as the first preference?

CHAIR MALMUD: Yes.

MS. COCKERHAM: With April 8th and 9th as the second.

CHAIR MALMUD: April -- yes.

MS. COCKERHAM: And all of that will pend the Commission's decision.

CHAIR MALMUD: We understand that that's tentative, pending the Commission's decision, yes.

MS. COCKERHAM: Okay.

MEMBER SULEIMAN: Now, in June the SNM meets, and that may take a number of people away from here.

CHAIR MALMUD: Yes.

MEMBER SULEIMAN: I forget when that is.

CHAIR MALMUD: I've forgotten which days it is.

(Off the record comments.)

CHAIR MALMUD: Mickey, do you know what days the SNM meets in June?

DR. GUIBERTEAU: Yes. The Committee meetings start on the third Thursday, the 3rd, and will go to Wednesday, the 9th.

CHAIR MALMUD: So, that's a concern for us.

MS. COCKERHAM: And I know normally when I make these calendars, I go look at CRCPD, OAS, SNM, ASTRO, ACR, you name it, so that's why there are only eight dates. And I tried to avoid holidays, but I missed Easter on there, so that's Sunday travel.

CHAIR MALMUD: Very good. Thank you.

MS. COCKERHAM: I will keep that in mind for the Commission.

DR. GUIBERTEAU: The 24th and 25th of May are the ABR examinations, if anyone is planning to examine there.

VICE CHAIR THOMADSEN: What was that?

CHAIR MALMUD: Dr. Guiberteau said -

DR. GUIBERTEAU: May 24th and 25th are the

ABR examinations for radiation oncology, and diagnostic radiology, if anyone -

VICE CHAIR THOMADSEN: I have an exam for the physics, which is the same time.

CHAIR MALMUD: So, the preferences are as stated?

MS. COCKERHAM: Does that change the preferences for you, or Dr. Thomadsen?

DR. GUIBERTEAU: Well, I'm a trustee, so I will be examining, but I could probably get away for the two days, since it's a large group examining. And I make up the schedule, so -

VICE CHAIR THOMADSEN: If I'm examining, I can't get away. They don't allow a break in -

MS. COCKERHAM: So, should we change the preferences to be April 8th and 9th as the first preference then?

CHAIR MALMUD: Is the Committee, therefore, in favor of April 8th and 9th? All right. April 8th and 9th, that's a Thursday and Friday. First choice.

MS. COCKERHAM: Okay. That's all I have. Thank you everyone for coming.

CHAIR MALMUD: Thank you. And thank all the members of the Committee. Appreciate your time.

Wish you a safe trip back home. There are some members of the Committee who will remain for their random drug testing.

MR. EINBERG: For those members that were selected, if we could -- Ashley, did you have any thoughts on that, the drug testing is at 1:00. We could meet, perhaps, at a few minutes beforehand in the lobby of Two White Flint, and we could all go up as a group.

CHAIR MALMUD: Is there a shuttle?

MR. LEWIS: The shuttle is at 12:10, I believe.

CHAIR MALMUD: Is there a shuttle from here to White Flint?

MR. LEWIS: There is a shuttle to White Flint. It's the shuttle that has been out here every 40 minutes, or so. But the shuttle takes a break for lunch, and none of us are familiar enough to know.

MS. COCKERHAM: Yes. We can check the shuttle schedule. It's right here on the board.

MR. LEWIS: The next one is 12:10.

CHAIR MALMUD: 12:30?

MR. LEWIS: 12:10 to 12:30.

CHAIR MALMUD: Right. I'll take the 12:30 shuttle. It stops right in front here?

MS. COCKERHAM: Yes.

MR. LEWIS: Yes, right there.

MS. COCKERHAM: So, we can take the 12:30 shuttle, and meet in the Two White Flint lobby.

CHAIR MALMUD: I have some bags to take with me.

MR. LEWIS: It's a white shuttle, and just ask the person if they're going to White Flint, because there's another NRC building they might go to first.

CHAIR MALMUD: Thank you.

(Whereupon, the proceedings went off the record at 11:38 a.m.)

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