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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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WEDNESDAY,

OCTOBER 26, 2005

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The meeting was convened in Room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:19 a.m.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., ACMUI Chairman

EDGAR D. BAILEY Member

DAVID A. DIAMOND, M.D., Member

RALPH P. LEITO Member

SUBIR NAG, M.D. Member

SALLY WAGNER SCHWARZ, Rph, Member

ORHAN SULEIMAN, Ph.D Member

WILLIAM VAN DECKER, M.D., Member

RICHARD J. VETTER, Ph.D, Member

JEFFREY F. WILLIAMSON, Ph.D, Member

SPEAKERS AND PARTICIPATING NRC STAFF:

RICHARD BLANTON	NMSS/IMNS
TERENCE BEVEN, M.D.	Society of Nuclear Medicine
THOMAS H. ESSIG	NMSS/IMNS/MSIB
CINDY M. FLANNERY	NMSS/IMNS/MSIB
ROBERT L. GALLAGHAR	State of Massachusetts
PATRICIA K. HOLAHAN, Ph.D,	NMSS/IMNS/MSIB
DONNA-BETH HOWE, Ph.D	NMSS/IMNS/MSIB
ANGELA R. MCINTOSH	NMSS/IMNS/MSIB
MOHAMMAD SABA	NMSS/IMNS/MSIB
RONALD E. ZELAC	NMSS/IMNS/MSIB

ALSO PRESENT:

CHARLES L. MILLER, Ph.D

LYNNE A. FAIROBENT

I-N-D-E-X

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

8:06 a.m.

CHAIRMAN MALMUD: On the record. We have a full schedule today. The schedule for today has been amended so that Item 14, just to remind you what was discussed yesterday, will go from 8:00 a.m. until 10:00 a.m. Item 15 will from 10:00 a.m. to 11:15 a.m. Excuse me. There will be a break at 10:00 a.m. and then 10:15 a.m. to 11:15 a.m. is Item 15. Item 16 has been removed from the schedule and then we'll resume with Item 17.

The first item on this morning's agenda is a discussion of the Congressional Energy Bill, the NRC Regulation of Accelerator Produced Isotopes and Nuclear Medicine Perspective, the NRC Regulation of Accelerator Produced Isotopes open session. Mr. Blanton will discuss portions of the Energy Policy Act of 2005 which was signed into law by President Bush in early August.

Mr. Blanton's presentation will focus on Section 170H, Radiation Sources Protection. He will focus on the NRC's newly acquired regulatory authority over naturally occurring and accelerator produced radioactive material and this is called NARM. Mr. Blanton.

MR. BLANTON: Good morning. I'm Richard Blanton. I'm Health Physicist with the Office of State and Travel Programs NRC and currently on assignment to the Energy Policy Act Task Force to implement the new provisions of the Energy Policy Act of 2005. I'm filling in today for Douglas Broaddus who is in France.

The Energy Policy Act was enacted on August 8th. The Act is a significant legislative act that indirectly affects Nuclear Regulatory Commission. It also contains specific requirements which directly affect the NRC. One of the many provisions is that it gave the NRC for the first time regulatory authority and jurisdiction over certain accelerator produced materials and certain naturally occurring radioactive materials. In response to this provision, the Commission initiated two activities. One, we formed a rulemaking working group and second, we formed the Implementation Task Force which of I am a member.

Section 651(e) of the Energy Policy Act amended the definition of byproduct materials (Inaudible.) for the detection of (Inaudible.) of the Atomic Energy Act. The definition now includes certain naturally occurring and accelerator produced radioactive materials. Specifically the definition of

byproduct material now includes accelerator produced materials such as sodium-22, cobalt-57, gallium-67 and fluorine-18. It also includes discreet sources of radium-226. The third new form is discreet sources of naturally occurring radioactive materials other than radium-226 which the Commission determines in consultation with the Environmental Protection Agency, the Department of Energy, the Department of Homeland Security and any other appropriate Federal agencies to pose a threat similar to radium-226.

(Inaudible.) form other than radium-226. Just one note that the definition only applies to the accelerator materials produced for use in commercial, medical or research activity. The definition of discreet source is not specified in the Act. The Act instead specifies that NRC must establish the definition by rulemaking.

In order to avoid a gap in the regulation of NARM during this transition period from the previous regulating scheme to the new one, the Act allowed the Commission to grant a waiver that allows current users and current state regulatory programs to continue using and regulatory the certain NARM for up to four years through August 7, 2009. Unless terminated earlier by (Inaudible) and the Commission

required by the Act to terminate the waiver in case of an agreement state, if the governor certifies that the agreement program covers this new NARM material as defined in the Act; and the state program is adequate to protect public health and safety with respect to this new material. The Commission issued the waiver on August 25th. It was published in the *Federal Register* on August 31st.

The definition of byproduct material, as amended by the Act applies to this certain NARM regardless of when it was produced, extracted or converted after extraction. However, the materials, as I noted before must be for use in commercial, medical or research activity. And, as an example, the Legislation does not give NRC authority over NARM, such as radium-226 that might be filtered out of water during drinking water or waste treatment processes.

The Act specifically excludes NARM from the definition of low-level radioactive waste. The Act does not give NRC regulatory authority over the accelerators themselves, only over the material that they produce. Now this is different from the case of reactor produced material because reactors are licensed by NRC. So we have the case of the material being produced in those reactors going essentially

from one license to another. Here since we don't license and will not license the accelerators, we're having unlicensed material all of a sudden becoming licensable and defining exactly where that authority begins is one of the things we're going to have to address in rulemaking. Again, the Act does not give NRC regulatory authority over any naturally occurring material other than radium-226 or any material that we determine poses a threat similar to radium-226.

Section 274(b) of the Atomic Energy Act is one under which the agreement state program operates. It was amended to include the expanded definition of byproduct materials. There is a transition plan required that we have to create in order to transition the authority from the states and back to the states and we're working on that.

The Act requires NRC to consider as part of this the impact of the availability of radiopharmaceuticals to physicians and patients from promulgating our regulations and our programmatic changes. Now there are other provisions of the Act which address radiopharmaceuticals, but those provisions are outside the charter of this task force. So I'm not going to address them any further.

The Act requires NRC to consult with

states and other stakeholders on its NARM regulations. Now in this line, NRC will hold a public meeting here at headquarters on November 9th. The agenda for that meeting is expected to be posted on the NRC website shortly.

The working group for the NARM rulemaking include representatives from NRC's headquarters and regions and also from the states. The Act requires the final NRC regulations to be in place 18 months after the effective date of the Act which works out to be February 7, 2007. This schedule for accomplishing this is currently in the process of being approved by the Commission but at this time. It is estimated that the proposed rule will be published in April of 2006 and the final rule will be published no later than February 7, 2007. Now those of you who have been involved in Federal rulemaking probably realize that is a very tight schedule.

The Energy Policy Act 2005 contains a multitude of significant activities like the new rulemaking for the redefinition of byproduct material, activities which require significant NRC and state cooperation in order to accomplish. Recognizing that the close association of these activities, the NRC established a multi-organizational task force under

the direction of the Director of the Division of Industrial and Medical Nuclear Safety within the Office of the Nuclear Material, Safety and Safeguards and that is the task force that I am assigned to.

The task force has been charged to develop a framework under which the activities will be planned, managed and implemented. The task force within one year is expected to develop and perform the activities that insure timely complete implementation of the Act and the transition plan.

Various actions will take place and will be completed by the task force over the next year. Significant activities of the task force applicable to the NARM legislation include: preparation of the technical basis of the NARM rulemaking, this is an explanation of why we think the rules that we're going to pose will be the correct ones, this should be then sometime early in November; development of a definition and description of discreet source, (We're very much engaged in that and again we hope to have something by early November); development of the Section 651(e)(4) transition plan to allow orderly transition of the regulatory responsibility from the old format with the states being primarily responsible to the new format with NRC being primarily

responsible. (Again we hope to have that completed by September of `06); development of Commission policy regarding new state agreements that govern NARM only. (We thought that this might be very straightforward, but it turns out there's some language in the Act that we're going to have to look closely at, but we will expect to have something in the final decision by September of `06); development of the NARM rule guidance in areas of inspection, licensing and enforcement, (This will be done concurrently with the NARM rule and should be available for people to look at by the time the rule is final); and finally, identification of other NRC regulatory program changes that need to be made, this would include things like changes to the Nuclear Materials Events database to incorporate NARM events and regulations of the sealed source and device registry system, training for nonagreement states and any modifications that might be necessary to the general license tracking system.

That's pretty much concludes my prepared comments. If there are any questions, I'm not sure if we're going to take them now or hold them for later.

CHAIRMAN MALMUD: Thank you, Mr. Blanton. I think that if you'll entertain questions we'll open the floor to questions. Is that acceptable, Dr.

Miller?

DR. MILLER: Sure.

CHAIRMAN MALMUD: Are there any questions from the floor? Dr. Williamson.

MEMBER WILLIAMSON: What is your plan in the medical use area? Are you going to change, amend or revise Part 35, section by section to include the new sources; or would you create a new part for medical use of NARM that would be parallel to Part 35 for byproduct material?

DR. MILLER: Jeff, as we develop regulations, we'll make the appropriate changes to whatever portions of our regulations that we feel we need to do so. Right now, we're very much in the intake mode. Congress has given us this task and has given us a short time to do it.

What everyone has to recognize is this is not an area that NRC has regulated before. However, the states have. So the states have a lot more experience in the regulation of this than we do and Congress in its wisdom wants to make sure that the NRC to the maximum extent possible uses the states' regulatory structure that has been developed. So we're to receive that in. So we're trying to evaluate that.

Maybe Mr. Bailey can address it from a California perspective on where have medical regulations that you have to be compatible with but yet you've regulated NARM and we haven't. How do you deal with that within a state structure? Do you see a need for Part 35 to potentially be changed from your perspective, Ed? We don't know yet the answer.

MEMBER BAILEY: Yes, because I believe there are certain isotopes mentioned in 35 and so you have to take a look at them. The states don't typically mention the isotopes. They just say radioactive material. So it's a much easier fix for us.

DR. MILLER: Since Congress has redefined byproduct material, we're trying to see where we can get the regulations changed with as a minimal disruption as possible. We're very much in an intake mode trying to hear from all stakeholders on their views. That's one of the reasons why we're holding a public meeting in November. We want to get input and get various stakeholders' views. To the extent that the medical community wants to have input to this, I encourage them to please give us their views.

CHAIRMAN MALMUD: Mr. Bailey.

MEMBER BAILEY: After I woke up, I think

the biggest challenge --

DR. MILLER: I'm sorry to put you on the spot.

MEMBER BAILEY: I had to get a new badge and everything. The biggest challenge will be in the area of PET and at what point in the PET production process will NRC say that they are now regulating? It was mentioned the discreet sources; and I've sat in on a couple of those phone calls discussing discreet sources. It sounds on the surface like a very easy thing to say. I know what something discreet is. It has boundaries and all. But that will be the challenge.

Where will NRC start regulating it? Will it be immediately after the targets are taken out of the accelerator? Will it be somewhere down the process route? Or where? That's going to be the big issue because the Act, I believe (and kick me if I'm wrong) did not give them the authority to actually regulate the production accelerator.

DR. MILLER: That's correct.

CHAIRMAN MALMUD: Excuse me. I just wanted to ask a question first if I may. How many states currently have accelerators producing these kinds of radioisotopes?

DR. MILLER: Do you know? I don't know off the top of my head.

MEMBER BAILEY: I'm not sure how many states have them but it's a large number of the 33. Certainly, California, Texas, Florida, on and on. I would be surprised if any " major", I shouldn't say that, any of the "larger" states with larger populations with larger medical communities do not have a PET production facility; and, probably if they have VA hospital, they probably have a PET production facility.

CHAIRMAN MALMUD: The reason that I ask the question is that we obviously already have a database and that is, as you alluded to the states currently regulating this to some degree or another. And it would be most interesting if we could obtain the regulations of each of the states that we currently at least overseeing the production of these isotopes so that a spreadsheet could be developed. A large one obviously, if 33 states are doing it currently!

DR. MILLER: Actually, it could potentially be all 50 states. It's not just agreement states. It's non agreement states also. So we have to interface.

CHAIRMAN MALMUD: An even larger spreadsheet.

DR. MILLER: Yes, United States.

CHAIRMAN MALMUD: So that the regulations that are developed are in recognition of methods that have already been tried, tested and implemented and also are encouraging of, rather than unintentionally suppressing, medical research and the application of these isotopes to the provision of diagnostic healthcare.

I think this committee would be most interested to assist in the process, since we will require education ourselves in formulating a national policy which would encourage the continued production of the use of these isotopes and encourage it in a way which would advance the healthcare needs of the nation without undue regulation and without undue restrictions on isotopes simply because they're isotopes. By that what I'm alluding to is that some of these isotopes have half lives of seconds. So even if large amounts are produced, they have a potentially inconsequential effect on the health and welfare of the public in terms of their short half life . Perhaps regulatory methods could be developed which would differentiate that with a potential risk versus that

which does not present a potential risk so that there would be logic to the restrictions and rules governing the use of these isotopes. Dr. Suleiman.

MEMBER SULEIMAN: FDA has proposed draft guidance on the radiopharmaceutical manufacturing of positron drugs. It's currently out for comment right now. Of course, FDA is concerned more about the radiopharmaceutical medicinal aspects of it but I think that clearly would help out somewhat and I think they're just not interested obviously in the PET drugs. But I also think that most states, I don't have that number, but we're pushing 50 and I think that information is readily available.

CHAIRMAN MALMUD: Dr. Vetter.

MEMBER VETTER: Just to reassure anyone who might be concerned about lack of control of PET production, if for example the NRC does not regulate the emissions from the production of PET radiopharmaceuticals, the state still does. So it's not that it's not going to end up not being regulated. It's just a matter of who is going to regulate what part of it.

The question I have relates to the waiver. I assume from your comments that NRC granted a waiver for all agreement states. Is that what this says, a

waiver granted August 25th?

MR. BLANTON: I believe that's correct. There's a waiver. It was published in the *Federal Register* and then I did personally work on development of that waiver and as I recall, it was intended to allow basically the status quo as of the date the bill was signed to continue until we have the new regulatory scheme in place.

MEMBER VETTER: Does anyone know at this time what happens at the end of that four year period? And will agreement state, still have their regulatory structures.

DR. MILLER: If you look at the schedule that Congress put us on, they put us on a pretty fast track to conduct rulemaking with the knowledge of that once the rulemaking is promulgated, the states have three years to implement it. I think that's how they came up with the four years, a little more than a year to promulgate a rule and then three years to get it implemented in the states. Dr. Malmud, may I respond to your query?

CHAIRMAN MALMUD: Please do.

DR. MILLER: Okay. First I want to say that I agree with you. We need the maximum intelligence from what the states are doing. I have

been assigned the leadership for this task. The task force reports to me so I have a very large stake in this.

What we have done to try to gain that is we've worked with the Organization of Agreement States and we've worked with the CRCPD, the Conference of Radiation Control Program Directors, so that we capture all 50 states, and, we have solicited participation from the states in that respect. The states have assigned basically, or have been willing to strike an agreement with us, to have an individual come here and work full-time with the NRC to be the liaison back to the states. In addition, the Organization of Agreement States has assigned an individual that will come up here on a periodic basis to work with us.

We're going to try to use them to the maximum extent possible for lack of a better word to "pick the brains" of the states for how we do it. It's a fully dedicated task force to get this done. This is all they're working on.

I have a question for the committee. You raised the concern about not promulgating a regulatory requirement that would inhibit the medical practices and patient care. Does the committee have a view on

the current status quo? In other words, it's regulated by the states. Do you believe that there are any state regulations that currently do that? I recognize that puts you on the spot; but what we're looking for is a practical regulatory scheme here that's going to work. So we need to know what's working and what isn't as a starting point.

CHAIRMAN MALMUD: I don't feel competent to answer your question with respect to the production of PET radiopharmaceuticals. But there are members of the nuclear medicine community, both physicians and scientists, who have vast experience over decades in the production of and application of PET pharmaceuticals to research and clinical care. It would seem to me that in the course of collecting data from the states we should also invite for their opinions those leaders in this nation who are easily identified who have had a vast experience and who can give us their views on how their individual states have interacted with them in the encouragement of the research and at the same time, maintaining public safety.

DR. MILLER: Because I do not believe that it was Congress's intent to inhibit the process. I think they just determined that they wanted the NRC to

pick up this regulatory function for whatever reason.

CHAIRMAN MALMUD: I think that the members of the medical community are certain that it was not the intent of Congress to inhibit. What always concerns us with new regulations whether they be federal, state, local or institutional is the concept of unintended consequences.

DR. MILLER: Understand.

CHAIRMAN MALMUD: And therefore it's my belief and I think I speak for the members of the committee who are practicing physicians and scientists in medical care, that we come up with a policy that will protect the public safety and at the same time not discourage research or application, by undue regulation and undue expenses entailed in documenting the regulation.

So it would be interesting to see how each of the states has managed this. Some states I'm certain have done better in some areas than others. In addition to get the perspective not only of the state regulatory agencies, but the leading individuals in research institutions who could attest to their views with regard to current regulations in their own states, so that we see both sides of the picture. There may be only one side. In other words, there may

be agreement between the investigators and the physicians and the state. On the other hand, there may be a difference. If we simply poll the state, we may miss that important input.

DR. MILLER: Thank you.

CHAIRMAN MALMUD: Do I speak for the members of the committee? Dr. Diamond?

MEMBER DIAMOND: Yes, I would actually say that it may be very interesting. We may find that there is a wide disparity in how these materials are handled among the agreement states and this may be actually a very nice opportunity for us to develop some common sense pragmatic regulations that will be useful for all parties, given the explosion in the use, for example, of PET and other modalities.

My question is I'm actually just reviewing this document from the Society of Nuclear Medicine and within the document, there is some common sense language in which there's a recommendation that certain very short-lived radioisotopes that have very low threat concerns (and they would include some of the PET isotopes) that within this document there's a recommendation that actually these particular radioisotopes be exempted because of the very low risk. And the question I would pose is within the

rubric of your mandate from Congress in which they ask you to now oversee the materials, can you then in turn say yes, we accept this responsibility but for these particular materials there's no need for a specific regulation because the threat is so low? Is that a potential within the framework of the Act?

DR. MOORE: Dr. Malmud, I could answer that. This is Scott Moore over here.

CHAIRMAN MALMUD: I'm sorry. Go ahead.

DR. MOORE: Hi. I'm Scott Moore. I'm chief of the Rulemaking Guidance branch in Dr. Miller's division. I'm Tom Essig's colleague. Anything's on the table. At the November 9th roundtable discussion, we can discuss any possibilities. I would say that the Legislation gave us, the NRC, authority and jurisdiction over all accelerator produced material. But we could discuss any regulatory scheme.

If the ACMUI or if any individuals in the round table discussion wanted to bring any regulatory framework or thoughts up for discussion, then that would certainly be open for discussion and we could consider any framework and especially if the states are doing that now, then that would be a model that we could consider. But the Legislation gave us authority

over all accelerator produced material.

I would add a few other things to this discussion that's been going on. The roundtable discussion on November 9th is in fact a roundtable discussion that we're inviting key players that we feel have stakes in the outcome of the regulation. They include the states, the OAS, the CRCPD and individual states, SNM, CORAR, Double APM, HPS, the waste industries, NEI, other industries that we feel are of particular interest and Dr. Malmud has identified another one that maybe we need to think of, individuals in the research community that we need to consider.

So if you have suggestions, we'd like to know that. We need to know who we ought to consider inviting. Chip Cameron is going to facilitate that meeting. We will be inviting and maybe Chip has already gotten in touch with you, the ACMUI, to sit in in the roundtable discussion as a member of the roundtable. So the ACMUI will be asked to be represented in the roundtable discussion.

There's a very fast time schedule for production as Mr. Blanton mentioned. We will be putting a proposed rule to the agreement states and you will see your copy in the ACMUI in the January

time frame. So you'll get a copy of the proposed rule before it goes out to the Commission and to the public. So this would be a predecisional copy in the January time frame to review. This is a single opportunity to get input and we have not made any decisions yet on the kinds of questions you're asking, Dr. Diamond.

CHAIRMAN MALMUD: Thank you. Dr. Williamson.

MEMBER WILLIAMSON: Maybe this gets to the definition of discreet source but what is your plan to respect to radionuclides that are produced inadvertently as a result of accelerated producing radiation via accelerators. For example, high energy medical Linax will produce certain quantities of very short-lived radionuclides, oxygen-15, which is essentially a level of contamination.

DR. MILLER: You're getting into a level of detail that we haven't developed yet. But that's the kind of input that we need to make sure that we think about all aspects.

CHAIRMAN MALMUD: Dr. Williamson, it may be early for that kind of consideration, but I'm certain that it will be considered and I suspect that the states themselves have recognized this issue in

the past. But it will come forward. Right now, we're in a first step and if I may, it would seem to me the most important is the one that -- Is it Dr. Mower? I couldn't hear your name clearly when you spoke?

DR. MOORE: I'm sorry. I'm Dr. Scott Moore.

CHAIRMAN MALMUD: Scott Moore. Excuse me. That Dr. Moore indicated that there will be a meeting at which all interested parties could have a voice in beginning this process. That would seem to me to be the most important element that we deal with right now, and that there be broad representation from each part of the medical community, and scientific community so that we have a process in which all interested parties have a voice and expressed their concerns. I think that might be the first step, Jeff, and then what you are alluding to-being a physicist, as you are will eventuate and I'm sure be addressed.

DR. MOORE: That's correct. I can answer Dr. Williamson's question. The discreet definition only applies to the naturally occurring materials. The accelerator produced materials in the legislation do not have the discreet attached to them. So the legislation applies to all accelerator produced materials. However, the legislation also only applies

to materials for commercial, research and medical use; and so we will have figure out how it applies to material for commercial, research and medical use.

CHAIRMAN MALMUD: Thank you. Other questions? Dr. Suleiman.

MEMBER SULEIMAN: I just want to add for the record not to forget the science, but I think PET Nuclides are very energetic and even though they're low quantities, they give some of the highest doses in medical diagnostic procedures. Separate from that though, the radiation safety issues are not going to go away. They're probably more significant for PET nuclides than they are. People think they're so quick that you don't have to worry about them. Well, you'll get the dose very quickly and you may not be able to measure them. So there are some real technical challenges there. But the safety issues I think we're all concerned and, Ed, doesn't the CRCPD have model bylaws for PET or not?

MEMBER BAILEY: May I respond to that?

CHAIRMAN MALMUD: Yes. Mr. Bailey.

MEMBER BAILEY: Not entirely and I was just glancing through Part 35. There's very little that I can see that would be changed in Part 35. The challenge I think has been to the regulators the first

time they get one of these cyclotrons. It's a black box that you put inert material in and get radioactive material out.

There's always a tendency to want to try to reinvent the wheel and I think the states do not have a suggested state reg at this time on it, but there has been enough interchange because we do go to our colleagues in the other states and say what did you do when it occurred. It's just an extension of health physics. It's higher energy and that's the difference. You're going to have to look at shielding. You're going to have to look at personnel exposure. All of those things have to be increased or are increased.

So I don't see that as a real big challenge to coming up with brand new regulations. The difficulty will be carving up of the norm portion what's not a discreet source and what you're not going to regulate.

MEMBER SULEIMAN: I think the anxiety here is really among the facilities that were not regulated by the NRC, that now will have to be regulated by the NRC, because I think the agreement states they're already under agreement state oversight.

MEMBER BAILEY: Right. And there are some

other pharmaceuticals or other radionuclides other than just the PET radiopharmaceuticals that will come into play, the gallium and the iodine-123 and so forth. But those should not cause much of a perturbation. They will have to look at exemptions under the Biomedical Waste Rule. They'll have to look for the quantity that can be distributed in in vitro kits as exempt and on and on. But that should not be a big deal because the states have already added that in for the most part.

DR. MILLER: Dr. Malmud, one thing I want to make clear is that while the NRC has been given authority for this, it would be our intent, once the regulations are promulgated, to enter into agreements with the states so that the regulation of this material would revert back to any state who so signs an agreement with us in that regard. That's the reason for the waiver period and the transition period and all of that so that all of that activity can take place.

CHAIRMAN MALMUD: Thank you. Dr. Williamson.

MEMBER WILLIAMSON: I guess I'll try to ask a very general question. What is the intent of this legislation? Obviously Congress thought

something was broken and needed to be fixed. So what's broken?

MR. ESSIG: May I speak to that?

CHAIRMAN MALMUD: Mr. Essig.

MR. ESSIG: Having been involved in some of the early discussions of the Legislation, this is a bill we had asked for and we received. But it's been through several Congresses and it finally made it to the point where it was passed. One of the concerns that we had or the questions that was raised is we have the IAEA Code of Conduct which speaks to a certain list of radionuclides and it focuses on the safety and security of those with a focus on the potential consequences of malevolent use of the material. That is some organization or individual taking material and either dispersing it via radiological dispersion device or taking the source and putting it in a public place and exposing members of the public overtly.

The question was raised. We have this list of radionuclides. The NRC has certain regulatory authority in the Atomic Energy Act which doesn't include all of the radionuclides and radium-226 came out in that discussion. So the question was raised. Since we have applied additional security measures to

these radionuclides that we regulate and if radium-226 if it's present in that same quantity would pose the same risk of some of the radionuclides that are on the list that we do regulate such as some of the alpha-emitters like curium-244 and californium-252 and plutonium-239 and so one, so the idea was that we would add radium-226 recognizing of course that it's not in the widespread use that it once was.

As part of that same discussion it was raised what about accelerator produced radioactive materials and this speaks somewhat to Dr. Diamond's question. The impetus for adding accelerator produced materials, at least the initial focus, was on those materials that could be used in a similar manner that would pose a similar risk and it was mentioned that sodium-22 for example. That's a good gamma-emitter, 511 KEV photon and two and a half year half-life and if I had a source of sodium-22, obviously sodium is normally the chloride form, very soluble, could be used, might be attractive as a material for malevolent use.

So the thinking was that we would focus on that type of material and originally the word "discreet" was in the legislation for the accelerator produced material. But along the way, the word

"discreet" was removed by Congress. So I think our going-in position was to regulate these materials so that we level the playing field from a security point of view so that we had some materials out there that we regulated. If they posed the same risk of malevolent use for the same consequence of malevolent use, that they would be regulated much in the same way.

So the point that Dr. Diamond was raising about the very short-lived radionuclide such as fluorine-18, certainly we have to decide how to regulate that and the radionuclides that you mentioned that are produced as byproducts from Linax certainly are obviously present and we'll have to decide. That will be one of the considerations that we'll have as part of the rulemaking effort to decide. The reason we wanted it because of this and now we have this large authority that we asked for and we have to sort out what regulatory emphasis would be placed on that. So it will be a major challenge, that rulemaking.

MR. MOORE: In addition, I think Health Physics Society and the CRCPD jointly approached Congress and pointed out that radioactive material produced in different manners but of similar risks and then in some cases even in greater occupation risks

are regulated in entirely different schemes and suggested that they be regulated in the same manner. So the CRCPD and HPS are due some credit in pushing it through Congress. OAS instead of CRCPD.

CHAIRMAN MALMUD: So in summary, Mr. Essig, the stimulus for this was national security.

MR. ESSIG: Yes.

DR. MILLER: Dr. Malmud, if you read the Energy Act which has many parts of which we're only talking about one portion, it has a very security bed to it in other aspects of the national security also.

CHAIRMAN MALMUD: So Dr. Williamson's question could be answered in a phrase with "national security" was the concern. That being the concern, there is still obviously an opportunity that some of the shorter half-lived pharmaceuticals, which have very little potential use by terrorists for lack of a better term, may be of disinterest with regard to the reason for the legislation. So we'll see how this evolves as the policy develops.

MR. ESSIG: And one more point I would add and that when the IAEA Code of Conduct was developed, I was a participant in more or less the final meeting that brought it fruition. One of the considerations that we made in coming up with a list that's in the

table that's appended to the Code of Conduct was the going-in position was that there were some shorter-lived radionuclides that were in a tech doc 1344 that provided the categorization scheme that the IAEA uses and some of those, there was a summary table and we made a conscious decision, we the members who were present at this meeting in July 2003, to not transfer from that table to the Code of Conduct some of the very shorter-lived radionuclides such as tech-99m. Gold-198 was another one that was on the list that didn't get transferred and so forth. So that flavor has already been captured in the Code of Conduct, that thinking.

CHAIRMAN MALMUD: Thank you. So the next step in the process is the meeting to be held on November 9th and may other interested parties in the public request a presence there and to whom would they make the request?

MS. KERR: Yes. All members of the public can attend the meeting and there will be different times during the day when we will ask for public comments or questions. If they go to the NRC's public meeting website, there is a meeting notice that gives all the information. The meeting is also available via teleconference for those who can't attend in

person.

CHAIRMAN MALMUD: Thank you.

MR. ESSIG: Leslie, you should mention your name.

DR. MOORE: Leslie Kerr is the project manager for the rulemaking itself and the public meeting as I mentioned is a roundtable discussion. The meeting announcement, has it been run in the *Federal Register*? Is it being run? Okay, it's about to be run in the *Federal Register*. We'll give information about how people can get in touch with the facilitator for attendance at the public meeting.

CHAIRMAN MALMUD: Thank you, Dr. Moore.

MEMBER SULEIMAN: Dr. Malmud.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I would like to make one suggestion. I had a chance to look at the Energy Bill. It's 500 some odd pages; but the sections that are relevant to this are only a few pages or a few paragraphs. So I would encourage anybody who is going to participate in this at least as a minimum read that and get an appreciation for what it actually says.

CHAIRMAN MALMUD: Do you recall which pages?

MEMBER SULEIMAN: I can actually get you

that information but Tom Essig got me that.

MR. ESSIG: It's a 550 page document and I think it starts --

MEMBER SULEIMAN: Took me as long to find it as to read the small sections.

CHAIRMAN MALMUD: That's why I asked which pages.

MEMBER SULEIMAN: It depends on what format. Probably the paragraph number is more accurate.

DR. MOORE: Dr. Malmud, we can post that on the website when we post the meeting notice on NRC's website.

CHAIRMAN MALMUD: Thank you. That would be very helpful since I believe the average individual may not have the time to find that.

MR. ESSIG: That would be the section that Mr. Blanton referred in his presentation, Section 170H.

CHAIRMAN MALMUD: One seventy H.

MR. BLANTON: That's the section of the Atomic Energy Act that was amended. The section of the Energy Policy Act I believe is Section 651.

CHAIRMAN MALMUD: That's Section 651. Thank you. That's now in the minutes.

MEMBER WILLIAMSON: Could you distribute that to the Committee?

CHAIRMAN MALMUD: Dr. Williamson asked if those pages could be distributed to the members of the committee.

MR. ESSIG: I have it right in my office and we can get it copied.

CHAIRMAN MALMUD: Can we get that done today?

MR. ESSIG: Yes.

CHAIRMAN MALMUD: Thank you. Mr. Leito.

MEMBER LEITO: Just a question. When you talked about the definition,it was not applicable to low-level radioactive waste. Could you expand on that little bit? It sounds like it's the reverse of the accelerator situation at the production. But once you declare its waste, it's not applicable. That's almost what it sounds like in here. But I'm sure this might be abbreviated.

MR. ESSIG: I'll start the discussion. Maybe others can add to it as they see fit. But I know one of the unintended consequences of the early version of the legislation which was called to the attention of the Congress was the fact that if it was enacted as worded it would prevent radium-226 from

being disposed of at the U.S. Ecology site in Richland, Washington which,now accepts the waste nationwide, and unless it was excluded it would be contrary to the Low-Level Waste Policy Amendments Act of 1985. So it was an unintended consequence which was fixed. So the radium-226 can continue to be disposed at the U.S. Ecology site across the U.S. as it currently happens.

MEMBER LEITO: So the issue really only addresses radium.

MR. ESSIG: As I understand it. That was the driver.

CHAIRMAN MALMUD: Dr. Bailey.

MEMBER BAILEY: Thank you for the promotion.

CHAIRMAN MALMUD: You're welcome.

MEMBER BAILEY: It was not only radium. Because of the odd quirks of the compact system, Richland, Washington was able to accept any naturally occurring material from wherever it occurred or was produced anywhere in the United States. It was not restricted to that compact area because low-level waste was only AEA regulated material. So any naturally occurring material that was radioactive could go there. There was a great desire not to have

that disposal option cut off and so that was identified early on by the states as one of the unintended consequences of the early language.

CHAIRMAN MALMUD: Any other questions from members of the panel? From other attendees here? If not, Dr. Williamson.

MEMBER WILLIAMSON: Has anyone from this committee been invited to participate in the November 9th meeting?

MS. KERR: I believe Chip Cameron has contacted Dr. Malmud and we're in the process of getting someone from ACMUI to participate.

DR. MILLER: Is that accurate, Dr. Malmud? Did you receive a call from Chip yet?

CHAIRMAN MALMUD: I have not received a call. No.

DR. MILLER: Okay. By virtue of this meeting, I am formally inviting ACMUI to participate if a member wants to represent the committee or more than one member. If the whole committee wants to come, that's fine also. I recognize everyone's busy schedules.

MR. ESSIG: But I think, Charlie, there would only be a seat for one at the table.

DR. MILLER: Yes, since it's a round table

discussion we're going to try to have key representatives from all stakeholders in the roundtable for the discussions and then at various points in the day, any member of the public can get up and make comments, statements, whatever it is they want.

CHAIRMAN MALMUD: We will produce a member of the ACMUI to attend the meeting on the 9th.

DR. MOORE: The meeting's going to be held here in this room.

CHAIRMAN MALMUD: So the environment will be familiar. I believe that that ends the questions for you, Mr. Blanton. We thank you for having presented the material on rather short notice and it was a very stimulating presentation in terms of the discussion that was generated and I'm certain it will be an ongoing topic of interest to this committee and the public at large for the next several years. Thank you for kicking it off for us.

We are now ahead of our agenda. We now have Roy Brown, Senior Director of Federal Affairs, Council on Radionuclides and Radiopharmaceuticals. Before you begin, Mr. Brown, it will be necessary for me to leave this meeting at 9:15 a.m. for a period of time at which time Dr. Vetter has agreed to continue

chairing the committee. I make the statement in advance so that you will recognize that my departure is not related to your presentation.

MR. BROWN: I understand. Good morning and first of all, let me thank the committee and NRC staff for CORAR to come to the meeting this morning and present our views on the NRC's new jurisdiction over NARM, as I call ARM, accelerator produced radioactive material.

Let me start off with a little bit of background about CORAR, who we are and what we do. CORAR is the Council on Radionuclides and Radiopharmaceuticals. It is the North American Trade Association for the manufacturers and distributors of radionuclides and radiopharmaceuticals. All the major manufacturers are members of CORAR. These include companies like GE Healthcare, Bristol Myers Squibb, Tyco Healthcare Malinckrodt, Nordion, Cardinal Health and others. The members of CORAR utilized radionuclides to produce radiopharmaceuticals for medical diagnosis and therapy as well as radionuclides for medical and life science research.

Let me skip over this. We already heard about a background about the Energy Policy Act of 2005. But let me do point out that CORAR has been

very supportive of adding ARM to Atomic Energy Act for several years and in my presentation, you'll understand why we've had concerns for the last several years. There's been some inconsistencies in regulations of accelerator produced materials from state to state, more from a licensing standpoint than a clinical use standpoint and that's why CORAR has been supportive of amending the Atomic Energy Act to include NARM products.

One of our main focuses has been CORAR is seeking uniformity in the regulation between byproduct material and ARM material and this is really the focus of my presentation this morning.

Let me spend a few minutes talking about problems we've seen with the states. I made a very similar presentation of this to the OAS meeting last month in San Diego. So several of you at the table today were present at that meeting. So I appreciate your indulgence in hearing pretty much the same speech over again.

We've had trouble. One of the major problems CORAR has had over the years has been getting new radiopharmaceuticals licensed by the states. As you know the process, first of all, the manufacturers go to FDA and get the radiopharmaceutical approved by

FDA. Then in the case of what works for a NARM product or accelerator produced product, we have to go then state by state to the individual states and say what does this take to get this product into your state. For an old definition byproduct material, it's very easy. You go to the NRC, amend your license and then you're good for all 50 states. In the case of an accelerator produced new radiopharmaceutical, you have to go state by state and say what does it take to get it into California, into Texas, into Oregon, into North Dakota, Montana and in most cases, the agreement states are very good and very capable of bringing new radiopharmaceuticals in. But in the case of the nonagreement states, we've had troubles sometimes getting approval in that individual state.

What that's resulted in delays of getting new radiopharmaceuticals into some states where for example as soon as it's FDA approved and it's approved by many agreement states, they can go for sale in many states. But there are other states that are not sure how they want to approve it or what they need, whether they need a copy of the package insert and the labeling or the material safety data sheet. They're not really sure what they want and consequently that causes some delays and in some cases we've had new

radiopharmaceuticals being introduced in many states after FDA approval and then taking another three, four, five, six or eight months to get into all 50 states. And we don't see that as a very good public policy and this is one of the main reasons CORAR has been supportive of amending the Atomic Energy Act to include NARM products.

One of the other problems we've had, as I mentioned before was, nonuniformity in the agreement state regs and in some cases, the NRC states not having the expertise to approve. The agreement states we've had very good experience with but I'm talking about the nonagreement states and those states that are NRC states that may not have a very strong radiation protection program and I really don't want to mention states we've had troubles with.

We've also had problems with operational difficulties in individual states and I have some examples here and once again, I won't name any names to embarrass any states. But we've had problems in some cases where we have an RSO at a nuclear pharmacy and one state may have a requirement for an RSO and that nuclear pharmacist has been an RSO for that nuclear pharmacy in that state for many years. If the company chooses to transfer him to another company-

owned nuclear pharmacy in another state, all of a sudden he may not be qualified to be an RSO even though he may have been RSO for many years in another identical pharmacy in another state.

Some states require that an RSO have a Bachelors of Science in Health Physics or Radiological Health and other states may not have that requirement. It's the disparity. It's the nonuniformity that we've had troubles with.

Also we've had troubles with states changing requirements for facility decommissioning. We've had some nuclear pharmacy try to be decommissioned. You get the decommissioning permit and then as you start that decommissioning process the state comes back and says wait a minute. We've changed the requirement. We want you to do things differently and that's required us to go back and refile an new application for a decommissioning plan and that's very costly and sometimes very time consuming as well.

We've also run into problems with state specific product approval and labeling requirements. I've already talked to you about the product approval requirements we've had. We also have had some very specific state labeling requirements. Some states for

example only recognize SI units on product labels where other states can take kinds of units. So in some cases, we have had to relabel products and package inserts going to some states and that creates other problems with the FDA for example where labeling is very critical.

We've also had issues with state specific protocols for reciprocity and in many cases, this deals with going in and servicing sealed sources in different states. Different states have different requirements if you have to go in and perform some emergency service. Some states require preapproval before the technician goes in and does repair work on a source. Other states don't. So once again, you have to go in and say what state am I going into, what's that state requirement today, for this week and this month and sometimes it's very difficult to stay on top of this.

Also we run into problems with differing approaches to the level of detail for sealed sources and sealed source registry and device registries. In some cases if a sealed source or a device is registered in one state, another state may not necessarily recognize that. If the NRC recognizes it, usually states will recognize it and in some cases,

the state will recognize it and the NRC won't. So there's once again a disparity in sealed sources and device registry that we would like to see more uniformity rather than just consistency.

One more example, we have one state in our country that before the Atomic Energy Act was amended actually defined byproduct material to include chlorine-18, nitrogen-13 and carbon-11. So we have one state that defines some of these PET isotopes as byproduct material and you can imagine the licensing problems they created for the manufacturers.

Some more problems. What this has led to is when states have different regulations, the manufacturers have to stay current with all these regulations as they change. That requires us to stay current with the state activities, what they're doing to change the regulations, the rulemaking, what they're doing with radioactive waste and it's very time consuming and very expensive for the manufacturers to do this.

Also our concern with the states' handling technology differently and handling regulations handling, when new technologies come along, sometimes we've seen them being handled differently by different states. Once again, this is very frustrating and very

time consuming.

Also some of these problems, some of this disparity from one state to another has created competitive advantages and disadvantages doing business in one state versus another. If you're in a nonagreement state and trying to get a new radiopharmaceutical approved, it's very difficult sometimes and sometimes you have to go an agreement state to work with them even though the facility and the manufacturing is done in a nonagreement state. So this is a very bizarre regulatory scheme and it's really created some problems for the manufacturers.

Also a lot of times customers were call the manufacturer looking for licensing help. They ask a question about what does it take to get your product into my facility, things like that, and it's very difficult. The manufacturers' customer service people have to stay on top of all 50 states and the regulations. If the agreement state program was more uniform and the regulations were identical state to state, it would be very easy to do. But with this nonuniformity, it creates a situation where we have to stay current with 50 states making an easy question that comes into your customer service department very difficult to answer sometimes.

This nonuniformity in regulations, we have some recommendations or some consequences from this that I would like to discuss as well. As I've talked about before, some of the disparity in labeling is very difficult to cope with and in some cases, you have to have different versions of products and different labeling to comply with different regulations.

This is very similar to what the manufacturers have seen working with the EC for example in Europe where you're trying to distribute products in Europe where one country wants their local language but another country wants it in French and English. So this is very difficult to deal with at a state level where we have different states having different regulations.

We feel that the regulations should focus on generally accepted safety standards and protection standards. We feel this is very important and really needs to be considered in this new rulemaking.

Also establishing one set of comprehensive regulations, we feel will conserve the NRC's limited agency resources and also licensee resources for dealing with this issue.

And lastly, states with uniform

regulations are better able to be compatible with new requirements that come from NRC. So we're pushing very hard for not just consistency which we know CRCPD and OAS very often goes for. We want to see uniformity from state to state.

Let me talk for a few minutes about what we understand NRC's plan to be with the implementation of the NARM rulemaking. It appears that NRC staff is looking at a fast track program for new states to become agreement states and for new states to be able to regulate ARM products. We're afraid that the creation of more agreement states, new agreement states, will actually lead to more nonuniformity than less nonuniformity. If we have new agreement states coming online very quickly, we're afraid that they're going to have more nonuniform regulations and this is going to exacerbate the problem rather than fix the problem and remember going back to my initial statement, CORAR in the past has been very supportive of including NARM products in the Atomic Energy Act. So once again, we're looking for uniformity and we're afraid a fast track problem may create more nonuniformity.

Also the new fast track agreement state program may create NRC state ARM regulations versus

agreement state ARM regulations and there may be a disparity in that. Once again, we would like to have NRC staff look at this very closely and have uniformity across the board with NRC states, agreement states, nonagreement states, everyone. We would like to see uniform regulations across the board. Once again, CORAR is pushing for uniformity rather than just consistency between the states.

I originally had a slide in here about the Society of Nuclear Medicine. I'm going to jump over this slide because SNM will follow my presentation. But I do want to say that CORAR has been very supportive of SNM's position on this and SNM will elaborate on that in the next presentation. What CORAR's concern is we want to make sure that nuclear medicine, both diagnostic and therapeutic nuclear medicine, is available to physicians, nuclear pharmacists and the patients and that really needs to be considered in this rulemaking and we have been very supportive and we will continue to be supportive of SNM's position on this.

Let me talk about an imperative regulatory matrix that I discussed, I brought up at the OAS meeting last month. Once again, CORAR's biggest concern with this rulemaking process is

inconsistencies between state regulations. What CORAR is doing is we're encouraging OAS and CRCPD to develop a matrix in which specific regulations for different states are compared against NRC regulations. For example, we can look at labeling regulations. We can look at licensing regulations. We really think these states should be compared regulation by regulation to see where the discrepancies are and to try to get these resolved in the new rulemaking.

By developing this matrix, we think important differences in regs could be identified and addressed in the rulemaking. Once again, I'll make this offer to NRC and to ACMUI. CORAR is very ready to work with OAS, CRCPD and NRC on the development of this regulatory matrix.

Just in summary, CORAR would like to continue to work with NRC, OAS and CRCPD on the implementation of these new regulations. CORAR will continue to push for uniformity over just consistency. Once again, we would like to see these new regulations implemented without hurting physicians and patients in the use of PET radiopharmaceuticals which has been a great success in this country. We would like to push for a comparative regulation matrix comparing state regulations with the NRC regs. Lastly, we have been

invited and we will participate in the November 9th meeting and we think it's a very good idea to have the stakeholders present there and to have this type of workshop. The NRC has been very successful with these in our opinion in the past and we're very encouraged by that. But we don't think this is enough. We would like to see continued stakeholder involvement beyond that process.

Thank you. I'll be glad to take any questions at this time.

CHAIRMAN MALMUD: Thank you. Are there questions? Dr. Williamson.

MEMBER WILLIAMSON: My impression is that the existence of Part 35 NRC regulations for byproduct material has not resulted in a great deal of uniformity among the states because so many of the components of Part 35 are at a very low level of compatibility. So what assurance is there that this expansion of NRC authority will have a good effect on that in the NARM area?

MR. BROWN: Are you asking me or NRC?

CHAIRMAN MALMUD: To whom was your question addressed?

MEMBER WILLIAMSON: I'm asking you I guess. Do you think your expectation is realistic and

I'm asking NRC to comment.

MR. BROWN: Yes, I would share that concern.

MEMBER DIAMOND: If I could just speak to that, that was the whole point of my statement a little while ago to Charlie. This is a really good opportunity as we're looking at all these different methodologies that the states use to perhaps relook at this issue, come up with some new guidance or new regulation and perhaps some of those will be implemented in a more uniform and logical fashion throughout the country.

CHAIRMAN MALMUD: Thank you, Dr. Diamond. That was Dr. Diamond. Other comments? Mr. Leito.

MEMBER LEITO: A couple of observations and a comment. It seems like your statement here is a little inconsistent with the purpose of your presentation. You say you don't want any more new agreement states but you want consistency of the regulations. It seems like if you're going to have this group of nonagreement states or states that are still NRC states so to speak and yet you're going to have this larger group of agreement states because they're not going away, that it seems a little inconsistent there in terms of what you're trying to

achieve here.

I do agree with your statement about the workshop on November 9th. I was going to mention this earlier. I think the fact that this has not even been announced to the general public and you have probably less than two weeks before, probably on the order of maybe a week notice, I think it's not going to facilitate attendance by stakeholders who may be interested and want to attend on such short notice.

One question I had was I'm a little confused. What do you mean by the difference between consistencies and uniformity?

MR. BROWN: Let me address your first point first. CORAR doesn't really care whether there's more agreement states or less agreement states. We're just looking for consistency. We're looking for uniformity and maybe I ought to explain at least the difference between the two. We've always seen in the past CRCPD and OAS looking for consistency. They've been calling for consistency in the regulations and I guess what we've seen from that so-called consistency is nonuniformity where they may be compatible with NRC or they meet a minimum set of NRC requirements but they're not uniform from one state to another. So they may be compatible meaning

the compatibility rule but they're not really consistent because they're different from one state to another. That's why we coined or started using the word uniformity where they are really uniform from state to state.

MEMBER LEITO: I'm still confused.

MR. BROWN: Let me maybe expand on that. Some of the examples I cited when an RSO can't even move from one state to another, he's qualified in one state but not qualified in another state just because he crosses the border, that's inconsistent.

MEMBER LEITO: I also think it nonuniform too. But my other concern, I don't know if it's a question or a comment, this comparative regulation matrix, is this something that CORAR has already started to put together or are you asking ACMUI or NRC to put this together? Who are you directly that to or is it a statement of your organization?

MR. BROWN: It's a statement of a wish to do it. We'd be glad to do it if OAS or NRC asked for it or ACMUI asked for it. We'd be glad to do it. We have reams of examples of inconsistencies that we can deal with.

MEMBER LEITO: I would consider or I would ,recommend to you that considering the short time

track that this regulation is on' that if you have something already in a developmental state, I would greatly encourage you including naming states to present this at the stakeholders meeting because they, they being the NRC, can use this as somewhat of a template to address some of these issues.

I agree with you. You definitely want this reciprocity between states of RSOs and I would think also nuclear pharmacists it might apply to also in commercial nuclear pharmacies. Again, I greatly encourage to have that and present it and let the chips fall where they may as far as the states are concerned. Don't be offended by that.

MR. BROWN: That's one thing we'd be glad to do,but what our fear was is we could turn that over NRC and NRC would say there are inconsistencies; but it's compatible with NRC regs and we can't tell the states what to do. So if the states want to do more or do something different, we can't control it and then all that effort would be for nothing. I guess that's why we haven't done it to date.

MEMBER VETTER: Dr. Nag.

MEMBER NAG: A clarification. You had mentioned about the agreement states, the NRC states and the nonagreement states. Would you tell me what

the difference is? I thought all the NRC states were the nonagreement states. Are they one and the same or not?

MR. BROWN: Yes. I believe they're one and the same. I was thinking of examples like the State of Texas. The State of Texas and the State of California are agreement states and then you have a state like Missouri that I would consider an NRC state because they're not an agreement state. Then there's another category of states that shall remain nameless that really don't have a very strong program. So the program for the NARM products is really not very well developed.

MEMBER NAG: Yes, but all the nonagreement states are licensed by the NRC. Right?

MR. BROWN: That's correct.

MEMBER VETTER: Other questions? Dr. Schwarz.

MEMBER SCHWARZ: I don't know a question. Maybe just a comment. I think this whole undertaking seems huge to accomplish in this short period of time to me realizing that you're dealing with all of these agreement states who certainly are strong states. The nonagreement states probably being the weak group of states at varying levels and I'm sitting in one of

those nonagreement states, Missouri. So for my practice and I'm in PETs, I'm managing a clinical production of PET radiopharmaceuticals, certainly all of this is of concern to me because obviously what happens will happen in our State of Missouri. So it's just a concern.

Certainly Missouri, I believe, acts kind of like the agreement states in that essentially a lot of materials are managed similar to NRC regulation for accelerator produced materials. But it's just, I think, an overwhelming task to take on and as a user, I am concerned that this whole field of PET will get caught and that the patients will be the ones that will end up at the disadvantaged end.

I think certainly what Dr. Diamond suggested in terms of exemption potentially for these short-of-life materials might be something to consider at least for an interim period of time until some of them, maybe the organizational structure is better defined or defined.

MR. BROWN: We certainly share your concerns.

MEMBER VETTER: Dr. Nag.

MEMBER NAG: For the byproduct materials, the agreement state has up to three years to comply.

For NARM material since the NRC is taking over new and the agreement states are already relating it, how is that? Will NRC now have three years or the nonagreement state have three years to comply with whatever the NRC comes up with?

DR. MILLER: I think our expectation is yes that's true. As I mentioned earlier, Congress put the rulemaking on a very fast track so that after four years, I think what they were thinking about was getting a rulemaking done in a little over a year and then that allows three years for the states to become compatible with the rulemaking.

MEMBER NAG: Yes, but in this phase, the states already have most of the rules and NRC now has to catch up with the agreement states.

DR. MILLER: Absolutely correct. But what it would mean in that period is for the states to become, during the period by which the states would become compatible, the existing regulations in those states would get transitioned over those three years to the NRC requirements whatever the compatibility level is determined to be. CORAR is asking for the highest compatibility level. We have to go through all of that and the Commission makes the decisions on the compatibility level. It's a real challenge.

MEMBER VETTER: Mr. Bailey.

MEMBER BAILEY: I think one of the things that might not be obvious to people who haven't been involved in this is NRC is showing a great deal of concern not about what the agreement state program is for regulating these materials but also taking into account existing NARM programs in the nonagreement states and it's a delicate balance there because there are some states that have programs and they may not look like agreement state programs and how NRC is going to interface with those programs. I have to commend them from what I've seen. They're really seeking to get that information about what the differences are in these nonagreement state programs.

MEMBER VETTER: Dr. Suleiman.

MEMBER SULEIMAN: Yes, I empathize with your concerns but sometimes it's Civics 101. I mean the states have quite a lot of rights. So I think the states how they control, how they license their practitioners, how they license their healthcare people, it's going to differ. Maybe you'll see, I use the word harmonize where regulations are not incompatible with each other though they may not be the same. But I don't see how you're ever going to avoid differences from one place to another. But I

think the overall premise here is radiation safety and standards which really ignore the source.

In this case, you happen to have some vary, the way the sources are generated. But in terms of how health physics has operated over the years, I think where you're going should be easy. It's the legal, regulatory issues that are going to have to resolve and work it out in a simple way. But I don't see it all that difficult except for your legal issues in terms of defining what's what. The safety issues are going to be there.

MEMBER VETTER: Dr. Moore.

MR. MOORE: Dr. Suleiman makes a good point. The legislation requires us to consult and cooperate with the states and to use model state standards to the extent possible. The states are a key stakeholder in the rulemaking process and Ed Bailey's on the ACMUI but the states would tell you, we just had the OAS meeting, that the only way to get uniformity in the regulations is to have a compatibility level B and by and large, the states object to compatibility level B in most cases. We'll hear from the states at the November 9th stakeholders meeting but I would expect that the states would not be in favor of compatibility level B on these

regulations since they already have in place regulations themselves for accelerator produced radioactive materials.

MEMBER VETTER: Mr. Brown, we thank you very much for taking the time to share with us today the position of CORAR and we're happy to hear that you'll be participating in that November 9th workshop. Thank you very much.

MR. BROWN: Thank you.

MEMBER VETTER: We now have a presentation from Dr. Terence Bevin speaking on behalf of the Society of Nuclear Medicine and the American College of Nuclear Physicians. He will present on the Nuclear Medicine community's desire to work cooperatively with the NRC to insure the public safety from unnecessary exposure to radiation while simultaneously protecting medical and scientific accessibility to short-lived accelerator produced radionuclides.

DR. BEVEN: Thank you very much for the opportunity to present SNM's views this morning. The Society is an international scientific and professional organization with over 16,000 members dedicated to promoting the science, technology and practical application of nuclear. The Society supports regulations which would insure public safety

from unnecessary exposure to radiation while simultaneously protecting medical and scientific accessibility to short-lived accelerator produced materials for nuclear medicine procedures and research. To achieve this common goal, SNM will work cooperatively with the NRC staff, the states and fellow medical associations throughout the public rulemaking process.

I think the NARM language has been covered; but just to reiterate the section D of 170H, in promulgating regulations under subparagraph A, the Commission shall consider the impact on the availability of radiopharmaceuticals to physicians and patients, the medical treatment of which relies on radiopharmaceuticals. Of course, in our view, we put the patients as number one and the physicians would be number two.

Our recommendations are to fulfill the requirements outlined in subparagraph D. SNM recommends that the NRC offer exemptions for isotopes with short half-lives and for isotopes with low levels of radioactivity. These accelerator produced products pose no conceivable threat to the public. Additionally, SNM recommends a full threat assessment of each medically-used isotope included within the

NARM regulations.

This is a list of the isotopes which we feel generally fit into this category. I won't read the whole laundry list and certainly some of them like fluorine-18 and a few others are in general use and others are being used in various experimental protocols. Additionally, other radionuclides such as gallium-66, Zr-89, Cobalt-55, may be used for medical applications in future years. Therefore, any list of exempted isotopes cannot be considered exclusive, but must evolve along side with scientific innovation.

In conclusion, SNM asks the members of the ACMUI to endorse exemptions for medical use isotopes with short half-lives and isotopes with low levels of radioactivity in adherence to subparagraph D of section 170H of the Energy Policy Act of 2005. If the exemptions are not offered for these products, the regulations could have an unintended but highly detrimental impact on American patients, indeed on access to life-saving diagnostic and therapeutic nuclear medicine procedures. I'll be happy to answer any questions.

MEMBER VETTER: Questions from members of the committee? Dr. Williamson.

MEMBER WILLIAMSON: To what extent is your

proposal consistent with the suggested state regulations which must already address this issue?

DR. BEVEN: We have not, the SNM task force has not, had the opportunity to look at the existing state regulations to see whether they accomplish this purpose in part or entirely.

MEMBER VETTER: Mr. Bailey.

MEMBER BAILEY: Yes, I was going to, before the question was asked. I was going to respond to Scott. If these exemptions were put in and it was a category B, I think most of the agreement states would object to that being a category B and the reason is that they are not exempted now and we don't see that there's any problem with their not being exempted. Quite frankly, we don't see a lot of any of these. So we don't see they've being regulated in name is a real problem. They're just like any other radioactive material to us and there would be exempt concentration and exempt quantities and on and on. But to exempt them simply because they happen to be that radionuclide doesn't fit into our normal scheme of like even byproduct material which they're not isotopes by name exempted.

MEMBER WILLIAMSON: Carbon-11 is one I saw. That is used in imaging procedures. Carbon

acetate is experimental. That's a pharmaceutical.

MEMBER BAILEY: Right. I'm just saying this whole list, we don't see very many coppers for instance. I was just commenting in general on the list.

MEMBER VETTER: Yes, fluorine-18 is used, for example, very commonly. Dr. Nag.

MEMBER NAG: I saw palladium-103 on your list. Now palladium-103 is used very commonly for the 400 level brachytherapy as a substitute for I-125 brachytherapy, probably one of the most common isotopes being used for radioactive implant. Why did you have palladium-103 there? It has a half-life of 17 days, a reasonably long half-life, not a short half-life, the Energy 21 KEV.

DR. BEVEN: I cannot answer that question because this list was compiled by a number of individuals engaged in the research and that particular one I just have no explanation for.

MEMBER SULEIMAN: Again, it's the question I said before. I briefly looked at what you passed out but there's another section in the Energy Act that describes radiopharmaceutical to include all the product materials. So whatever applies to conventional radiopharmaceutical would apply to the

PET nuclides and from a terrorist's point of view, the PET nuclides are trivial obviously. But from the medical side of it, you may want to use very large quantities in terms of medical doses just to get the imaging even. So again without going into the details of the science and the dosimetry, PET nuclides give the highest doses of all medical pharmaceuticals out there and the beauty of this authority is that now you don't have to worry about breaking out the different nuclides, just assess them basically in terms of their hazard, what's acceptable and that way you have a uniform playing field in terms of the radiation safety assessment and not worry about the activity. Because then you're going to need the decay characteristics and go through the whole exercise.

DR. BEVEN: I would only observe that when you are working with short-lived radionuclides there are regulations imposed that would delay the delivery of these nuclides to the target individuals, the patients that would be a concern.

MEMBER SULEIMAN: I think that's a valid concern, but by exempting them doesn't solve the problem. You may create safety hazards if you exempt them completely.

MEMBER VETTER: Dr. Miller, you want to

comment.

DR. MILLER: Yes. I like Mr. Bailey. I'm an engineer. I need some help from a practical application. I've heard a lot of concern about the short-lived radionuclides and possible unintended consequences. Can anyone give me an example of where an unintended consequence might occur? You talk about the delivery. How might that happen? How might an inappropriate regulation from your perspective cost something unintended to happen? Can anyone think of an example to help me understand it better?

MEMBER VETTER: Dr. Schwarz.

MEMBER SCHWARZ: I don't know that it's -- I guess what I'm thinking in terms of for specifically states that are nonagreement states, essentially NRC states. I'm not speaking in terms of the agreement states. I think they do have a program that essentially accommodates all of the isotopes. So for us, I think the situation in terms of needing possible exemption of these products will be just that in this interim period where regulations are being written and everything is being defined, it just might be a time frame that if there is regulation and an institution has to accommodate all the regulations and how everything is supposed to be addressed. So it seems

that maybe it's a year-long period time that regulations are getting written and we're trying to come on board and fit in place.

It may be easier not to include these particular isotopes in the beginning until there's framework for this regulation in place than to take on the short-lived isotopes because I think we're managing at this point in time without this new regulation and your focus was essentially the terrorist's activities. These isotopes really are not prime concern for the terrorist's activities but for medical purposes.

So just thinking in terms of a facility that's going to have to accommodate to new regulations and new ways of doing things not necessarily totally different, but just in an interim period, it might be wise.

MEMBER VETTER: Dr. Miller, this is just purely speculative. But some hospitals get their fluorine-18 from a PET production facility. They don't make it onsite. If, for example, the new regulation required some onerous security requirements for the transportation of that material that would delay the delivery of the material, that would be problematic. That's purely speculative. I don't know

what your regulation will require. I think there was a member of the public. Mr. Brown.

MR. BROWN: Roy Brown with CORAR. One of the concerns we have is the transition that's going to have to happen in the NRC or the nonagreement states. For example, there are a couple of states out there now that don't even license these accelerator produced materials like thallium and indium and I-123. There's no license required. There's no registration. There's virtually nothing.

So to have them go from that status to regulating all these products by 2007, they have to go through their state legislature to get funding to hire people to get expertise and we're concerned that's just too much to happen too fast and we're concerned that they're going to from nothing to going 100 miles an hour in a short period of time. That's an unintended consequence or that's a concern we have that they have to go so far in such a short period of time.

MEMBER VETTER: Dr. Suleiman.

MEMBER SULEIMAN: Yes, I was going to say the same thing. Let me hazard my concerns. Yes, you're going to have facilities that now are going to have to go through the whole licensing process and the

fear, the anxiety, we're back to anxiety here, but I think the anxiety there is that all of a sudden they will not be able to get licensed in time and, therefore, they won't be able to do their medical practice. I think that's the underlying fear here. So I think the NRC has to be very sensitive to that in terms of the transition and accommodate them as much as possible.

MEMBER VETTER: Dr. Williamson.

MEMBER WILLIAMSON: I stepped out of the room and maybe I missed something. But is the focus of your statement current agreement states and the assumption that there are agreement states which regulate only the byproduct materials and ignore all the non-byproduct materials? Is there such a state or do you apply uniformly byproduct type of regulations?

MEMBER VETTER: Mr. Bailey.

MEMBER BAILEY: Yes, to the best of my knowledge, and I think NRC's Office of State and Travel Programs can verify this, there's not a single agreement state that does not already regulate NARM and ARM in the same manner that they regulate the traditional byproduct material. In fact, during IMPEP reviews of agreement state programs, that is looked at. Generally, the agreement states, and I think 100

percent of them, if they are doing sealed source and device review, are using the same criteria and are putting it in the sealed source and device registry, just as if it were the traditional byproduct material.

MEMBER WILLIAMSON: So why is there a concern about the nonagreement states, because what would happen is NRC would simply expand their already existing authority to just cover these new facilities the same? I'm a little confused.

MR. ESSIG: If I could comment.

MEMBER VETTER: Yes, Mr. Essig.

MR. ESSIG: The fast track authority that Mr. Brown referenced before that's referenced in the Energy Policy Act is I believe really directed at those states, the 33 who are currently agreement states to get them on board. It's a letter from the governor basically firming that they have a program that would give them authority to put in place as an agreement state this new material using their current suite of existing regulations. We then have in parallel a regulatory process where we're going to be developing regulations and depending on the capability level that ends up in each section of the regulations, those states that have entered into that fast track agreement may have to make adjustments to their

regulations based on however the compatibility level comes out.

The other 17 states who are currently what we've labeled nonagreement states can come in and express interest to become agreement states for the new material, the entire suite of byproduct material. Personal speculation is that --

DR. MILLER: Can I correct you on that?

MR. ESSIG: Go ahead.

DR. MILLER: That's going to be a Commission policy decision. One of the things that we're working is getting a paper before the Commission on a policy decision concerning nonagreement states and whether the Commission will allow a nonagreement state to enter into an agreement for this aspect only or whether they have to enter into an agreement for the whole suite of issues that an agreement state has to meet in order to become an agreement state. That will be a Commission policy issue.

MR. ESSIG: Good point. But the only thing I wanted to suggest there, it's possible that we could have a large number of additional agreement states. Of those pool of 17 that are currently nonagreement states, many of them could, to the extent that some of them are already, regulating accelerated

produced material they may see it as attractive. I have to sign up now to become an agreement state for this government produced material. I might just then decide to regulate all of the byproduct materials. So we could end up with a number of additional states and there may be a few states, some of the lesser populated states, that we were referring to in kinder terms that may not ever want to become an agreement state for anything. Some of the western states for example may not want to.

MEMBER VETTER: Mr. Blanton.

MR. BLANTON: Just to follow-up on what Mr. Bailey said. The agreement states to the best of our knowledge in the Office of State Programs, they generally regulate radioactive materials which they define to include byproduct, source, small amounts of special nuclear material and the naturally occurring materials and accelerator produced materials, all lumped together. So they basically don't distinguish the way NRC does.

MEMBER VETTER: Other questions? Dr. Miller.

DR. MILLER: Maybe if I could just recap to make sure I understand. I think what I'm hearing is anxiety over the potential to put regulations in

place that would inhibit the practice of medicine and patient care that currently exists or delay patients from being able to receive these kinds of treatments and to make sure that when the regulations are put in place that there's an implementation. It's the implementation period that I think that we're talking about such that an implementation period doesn't create that unintended consequence.

One comment that I would make listening to the whole discussion is while we recognize that the Energy legislation was aimed a lot at security and building on Dr. Suleiman's comments earlier on some of these short-lived radionuclides, when the NRC inherited this authority we didn't just inherit the security aspects of it. We got it all. So we got all the health and safety aspects of all of this also.

Inheriting that we have to put a program into place that's going to insure that aspect of the things that we inherited under the byproduct material safety for that. So we have to consider all of this and balance it all as we go forward.

MEMBER VETTER: Right and that thought needs to be carried forward to that November 9 meeting so that everyone hears that. Dr. Suleiman.

MEMBER SULEIMAN: Yes, I wanted to

clarify. Don't confuse the negligible terrorist threat associated with short-lived nuclides with the real radiation safety issues associated with them. Those are two separate issues and that's it.

MEMBER VETTER: In that regard, is it possible to consider exempting short-lived radionuclides from security provisions without exempting them from all of the other safety regulations?

DR. MILLER: Like we do with safety, we have to look at it from a security perspective of what is the risk and obviously since they're short-lived radionuclides, that contributes to the overall risk factor. So we have to evaluate all of that. And what's appropriate? Given the nature of the beast, what is the appropriate security that needs to be put in place. And I don't want to get too hung up on the word security because a lot of what you do for public health and safety and the control of materials also gives you security of these materials.

You're doing it for a duel purpose; not just to protect it from terrorists, but to protect the public health and safety from unintended consequences and coming into contact with the material that's not controlled. That's a public health and safety

concern.

MEMBER VETTER: Right. I'm not sure anyone here is concerned about the current requirements for Department of Transportation, Security, that level of security. It's the unknown, the anxiety as Dr. Suleiman said, about what sort of security requirements might be implemented as a result of this Act that would become onerous and result in a patient not getting a dose of fluorine-18 for example. That's a real serious concern for us.

DR. MILLER: And that's where you have to balance the risk. What's the greater risk, the overall? And we have to evaluate all of that. Is the risk the patient not getting the intended treatment more consequential than the risk of a terrorist activity and the reality of it all? I mean all of that has to get put together. There's a common sense that has to get put to it, at least, from my perspective.

MEMBER VETTER: Dr. Schwarz.

MEMBER SCHWARZ: Just one other comment too is to just keep remembering these states that are not agreement states and don't have personnel involved in the states enough to be able to take on all this new regulation in a very quick period of time.

DR. MILLER: One of the reasons that we were so aggressive in trying to seek state support for this and we sought it from not only the OAS, from the agreement states, but from the CRCPD. The CRCPD represents the nonagreement states also. So we want to make sure that we have the picture for all 50 states, not just the agreement states.

That's why we felt that it was important to have represent from both groups recognizing that many of the people, the functions of many of the people in the agreement states, are also very acted in the CRCPD not to mention any names like Ed Bailey. But we want to make sure that the whole family of states is captured and we don't miss something.

MEMBER VETTER: We appreciate that.

DR. BEVEN: I would like to thank the members of the committee for their questions and I think this is a good beginning to our discussions.

MEMBER VETTER: Great. Any other questions? Yes, Mr. Essig.

MR. ESSIG: Just to follow on Charlie Miller's comment, I think, Sally, maybe I was reading something. I just want to understand the nature of your concern. I had the impression that you were offering that the State of Missouri was going to be

forced to become an agreement state in very short order.

MEMBER SCHWARZ: No.

MR. ESSIG: That's what I read into your comment.

MEMBER SCHWARZ: Not forced to become an agreement state.

MR. ESSIG: That's a state decision as to whether or not they want to become an agreement state.

MEMBER SCHWARZ: Correct, but I'm just thinking in terms of administering new policies and things like this that will become reality and that it does take time for these regulations and people to get on board and that the enduser can be the person.

DR. MILLER: If I looked at your concern, I think you have someone in an agreement state who currently is allowed to do this and if we put a regulation in place such that they didn't have a license in place to do it and they had to stop that activity, that would interfere with patient care.

MEMBER VETTER: Mr. Bailey, did you have a comment?

MEMBER BAILEY: Yes. What you just said brought up something to me. Luckily I think in the licensing process that we use now, we talk about uses,

100, 200, so forth. The authorization will already be there basically to use these radioactive materials for those processes. So there should be very little that has to be done in the way of amending licenses to allow the people to do it and the same goes with the broad scope licenses. Broad scope licenses which are now three to 83 but you really didn't regulate some of them before. So I don't think it's a big deal for existing facilities that have an NRC license or in most cases, an agreement state license.

MEMBER VETTER: Other questions from members of the committee or the public or the staff? Yes.

DR. MILLER: If there are no more questions, I'll make a closing remark if it's okay. I think from the staff's perspective, from myself and my staff who is represented throughout the room, I think the discussion today was an extremely good forum because I think it allowed some of the stakeholder issues to be put on the table and that's what we're seeking. So from my perspective, I felt the discussions were a huge success. I appreciate the committee's willingness and interest in discussing this matter today. Thank you.

MEMBER VETTER: Dr. Beven, thank you very

much for taking time out of your schedule to present this material for us. We are five minutes ahead. Mr. Essig, is it okay if we take a 20 minute coffee break to get back on schedule to start sharply at 10:15 a.m.? Thank you. Off the record.

(Whereupon, the foregoing matter went off the record at 9:56 a.m. and went back on the record at 10:16 a.m.)

DR. VETTER: The next item on our agenda is the presentation by Cynthia Flannery on recognition of foreign trained physicians and physicists as authorized users or authorized medical physicists.

Cynthia.

MS. FLANNERY: Thank you.

The discussion this morning will be on the recognition of physicists and physicians who are seeking approval under the alternate pathway as AMPs and AUs.

The requirements for physicists to get recognition as AMPs in 10 CFR 35-51 are listed here. That individual must hold a Master's or a Doctor's degree in one of the listed degrees. That individual must also have one year full-time training in medical physics, one year full-time work experience under the supervision of an AMP, and written attestations signed

by a preceptor AMP.

So what about approval for physicists and physicians who receive their training outside of the U.S.? There are three questions that were considered by staff.

May NRC or a broad scope licensee accept foreign degrees?

May NRC or a broad scope licensees accept a degree not specifically mentioned in the regulations if that degree can be shown to be equivalent to the degrees listed in 35-51, in the first bullet here?

And may NRC or a broad scope licensee rely on a preceptor statement from a foreign physician?

And the reason why broad scope licensees are listed in these questions is because the broad scope licensees have the authority to approve AUs -- I'm sorry -- approve physicians and physicists as AUs and AMPs internally through the Radiation Safety Committee.

So the first question: may NRC for broad scope licensees accept foreign degrees?

NRC staff did not identify any prohibition against the acceptance of foreign degrees, and the same thing with degrees not specifically mentioned in the regulations because the physicists are the only

ones that have degree requirements in Part 35.

So, again, here there's no prohibition against the acceptance of a degree found to be equivalent to those listed in 35-51.

And may NRC or broad scope licensees rely on preceptor statements from foreign physicians? Again, there's no prohibition against a preceptor statement from a foreign born or a foreign trained physician. However, the definition of an authorized user in 35-2 states that that individual must be licensed in the U.S.

So although foreign training of a preceptor AU may be acceptable, that individual must also hold a U.S. license.

DR. NAG: Excuse me. Are you talking now only about the AU or the AMP and AU? The two have slight different connotations.

MS. FLANNERY: Here I'm talking about the physician.

DR. NAG: Okay. After you finish I will have some comments about the physicians.

MR. BAILEY: Cindy, did you mean both the applicant and the preceptor must have U.S. licenses?

MS. FLANNERY: No. The preceptor.

(Participant speaking from an unmicked

location.)

MS. FLANNERY: Yes, yes, both, but the question is having to do with the preceptor, yeah.

MR. BAILEY: And the answer wasn't. The preceptor must be licensed in the U.S.

MS. FLANNERY: Yes. when the regions receive request for approval of physicians and physicists with foreign training, the current practice is for the regions to submit a technical assistance request to the headquarters to present the technical assistance request or this case to the Advisory Committee. And they are reviewed on a case-by-case basis.

And in an effort to have consistency among the regions and the broad scope licensees, what NRC is proposing is to allow the same authority between the broad scope licensees as well as the regions in terms of approving the training and experience requirements of foreign trained physicians and physicists.

Because currently the broad scope licensees have an authority of reviewing the training experience and approving these individuals that regions currently are presenting to the ACMUI. So in an effort to have this consistency among the regions and the broad scope licensees, NRC's staff is

requesting that the regions have the same authority as the broad scope licensees and being able to review the training and experience of physicists and physicians and approving these individuals as AMPs and AUs.

Now, having said that, if there are circumstances that warrant a further review, say, for example, there's a question on the validity of the degree that was received overseas, for example, or outside the U.S., the regions could still submit a technical assistance request and present it to the Advisory Committee for review and approval, and the other consideration is that only attestations by a preceptor licensed in the U.S. will be accepted.

So under no circumstances will a non-U.S. licensed preceptor be acceptable.

That concludes my discussion. I wanted to open it up.

DR. VETTER: Dr. Nag.

DR. NAG: I would probably like to decouple the AMP from the AU because, first of all, I have more detailed knowledge about the physician's training requirement, and I have less with the foreign trained physician requirements.

Irrespective of the NRC license, any foreign trained physician would be allowed to practice

in the U.S. only after extensive retraining in the U.S. So that the M.D. degree, the basic degree is recognized, but the residency requirement, et cetera, will have to be redone all over again.

So that even if someone is a practicing radiation oncologist outside the country, when they come into this country, they will have to fulfill again the four years of retraining before they can be granted or before they can practice radiation oncology in this country.

So, therefore, you really do not have to depend on any of the foreign training. They will be retained in this country. So they will still have that four years of training in this country. They will still have preceptor statements from this country.

So I think as far as the AUs are concerned, that should not be a problem for the NRC. I'm not fully aware about the AMP, you know, what their training requirements are.

DR. DIAMOND: I would just like to make a clarification.

DR. VETTER: Sure, Dr. Diamond.

DR. DIAMOND: There are a few exceptions to that. For example, I believe physicians that are

trained in Canada --

DR. NAG: Right.

DR. DIAMOND: -- do not necessarily need to go through that, but, for example, if you had, for example, a radiation oncologist who was licensed to practice radiation oncology in the nation of Germany and that individual wanted to practice radiation oncology in the United States, that physician would come to the United States. He would recognize his or her medical doctor degree, but if he wanted to practice radiation oncology, he would have to go through the entire radiation oncology training program again.

DR. NAG: Right. That's what I mentioned, that the M.D. degree will be recognized, which is the basic medical degree, but the specialty degree, whether it's radiation oncology or medicine or surgery would have to be retained all over.

DR. VETTER: Dr. Miller.

DR. MILLER: I need to ask a question of the medical doctors. Just prompted something in my mind.

So if someone were a practicing physician in a foreign country, even if they were the world's foremost expert in something, they could not come here

and perform a procedure without going through the residency program?

DR. DIAMOND: To answer your question --

DR. MILLER: Yes.

DR. DIAMOND: -- with the exception of, for example, Canada, we have had examples in the State of Florida where we have had a world famous subspecialist surgeons who wanted to relocate to the State of Florida. Let's say I know of the example of a physician, a surgeon from Venezuela who had to leave because of the civil unrest there, and the only way this individual could practice his subspecialty of surgery is he had to go and join the faculty of one of the state medical schools and the state legislature had to pass an exemption for him to be able to practice surgery without going through the entire training process even though most of the individuals that would have trained him he had trained himself.

DR. MILLER: How about an individual who like is there ever a situation where someone is flown in on a one time basis because of their expertise, you know, to perform one special kind of procedure?

DR. NAG: I can address that. I mean, I'm in a university setting. I have this happening all the time. I do have people who visit us who are well

recognized all over the world for their expertise, but they cannot touch a patient. So they can see me perform an implant or they can probably, if you are not an expert, they can probably look over your shoulder, but they cannot touch the patient.

DR. VETTER: Dr. Williamson -- I'm sorry. Were you finished? Yeah. Dr. Williamson.

DR. WILLIAMSON: Yeah, I have a question for either Dr. Diamond or Dr. Nag. I guess I would like to know the mechanism by which foreign trained radiation oncologists, for example, can't practice. I am aware that the American Board of Radiology will not accept a foreign residency except Canadian residency as eligibility for sitting for the boards, but I'm not aware that the state per se licenses radiation oncologists directly. It only licenses physicians in general.

So what is the mechanism that precludes a foreign physician from practicing?

DR. NAG: First of all, they will not be able to get a specialty board. So they will not be board certified, and a hospital would not accept them because they are not board certified or board eligible. It will be if that person was only an M.D. with no training in radiation oncology.

Now, if he uses to practice on his or her own, he will not have the credentialing process of a radiation oncologist. He'll have the credentialing process of only an M.D., but he will still need an approved intership before he could even practice medicine at a family practice level.

PARTICIPANT: Who controls that?

DR. DIAMOND: So, for example, world famous doctor from another country other than Canada comes to the United States because of civil unrest in his home. That individual needs to at least complete an internship, and after that one-year internship can practice basic medicine in, for example, a clinical setting, but that individual until he or she becomes board eligible or board certified, would not be able to get hospital privileges, would not be able to get state credentials to practice in that subspecialty.

So for example, there are some individuals of this ilk that practice general medicine in communities but really can't do anything beyond that.

DR. VETTER: So the control of all of this actually is over and above or lies outside the NRC rules and regulations. It's over and above that.

DR. WILLIAMSON: It lies outside the state, too, because it's a function of the hospital.

DR. NAG: A statement requirement, because you cannot get a state license without your internship or without any other training.

DR. WILLIAMSON: But who licenses private practice radiation on free standing radiation oncologists who have the internship in basic medical license? What prevents them from practicing?

What legal barrier prevents a foreign trained radiation oncologist with a U.S. license to practice medicine from practicing in a free standing facility?

DR. NAG: Well, first of all, I think that person would not be allowed to call himself a radiation oncologist by the state. Okay? He can --

DR. WILLIAMSON: I don't think the state licenses subspecialties.

DR. NAG: Yeah, but that is to practice medicine. You know, he can practice medicine, but first of all, none of the hospitals will give him any privilege.

DR. WILLIAMSON: Free standing.

DR. NAG: I don't know anyone who is that -- malpractice, he will not be on my malpractice, definitely.

DR. VETTER: I think in terms of trying to

relate it to the discussion here, is there a nuclear medicine physician or radiation oncologist who is foreign trained who could open up a practice in a lesser populated state, a free standing practice.

DR. NAG: Not that MOA.

DR. VETTER: So they would be able to do that?

DR. NAG: I don't think os.

DR. VETTER: And what precludes them from doing that? Mr. Bailey?

MR. BAILEY: I can tell you that we do have free standing therapy facilities where the radiation oncologists or whatever you want to call them are not board certified, and in a couple of cases are not using radioactive material probably for that very reason. They're going with accelerators.

DR. NAG: Yeah, but they are board eligible. You are not board certified.

DR. DIAMOND: Not necessarily, not necessarily. For example, I know of circumstances as Mr. Bailey does of individuals who train in the United States, never passed their examinations in the American Board of Radiology. So they completed the residency program, but by virtue of not passing their boards or not board certified and then after a period

of time if you have not passed your boards you no longer are board eligible. So they are not board eligible radiation oncologists, but they are practicing radiation oncology, but they are not able to use the byproduct material.

I don't know, to answer your question, Dr. Williamson, I don't know exactly the mechanism that would prevent a foreign trained radiation oncologist who, let's say, completed a medical internship in the United States and, therefore, has a valid state medical license of practicing radiation oncology. I just am not familiar enough with the state regulations.

I myself am not familiar with any circumstance of that happening. I can tell you that from a practical point of view that person would never be able to see a patient in a hospital and also would basically not be able to get on any of the insurance plans, and that perhaps is the most important factor of all, isn't it?

So the question is if you ran your own private, for cash clinic, I just don't know. I'm sorry.

DR. WILLIAMSON: I thought there was provision. Why I asked the question is that I thought

academic institutions had the option of credentialing on a short-term, sort of supervised basis foreign trained radiation oncologists and that the issue might be relevant here.

DR. DIAMOND: Again, Dr. Williamson, like I said, there are examples. In the State of Florida, my home state we have had very prominent physicians that foreign nationals come, and then based upon their expertise, the actual statute is written. Legislation is passed through our state legislature that exempts them as individuals, and those are generally at state hospitals or teaching hospitals.

DR. VETTER: Well, a broad scope license, is it not true that they could require this foreign trained physician to practice under the direction of an authorized user for a period of time, and that authorized user, knowing about the background and training that this foreign physician had obtained could as the preceptor verify that the training had occurred and, in fact, then they have their one-year of experience under the direction of that authorized user.

Couldn't that authorized user sign the preceptor statement? They're simply verifying that the training had occurred, and they have personal

knowledge that it did. They have transcripts and so forth.

DR. WILLIAMSON: I guess there is the Canadian trained physicists and physicians, you know, who are allowed to practice by other practice mechanisms in this country that it would seem to me would be reasonable for the regulations not to punish.

DR. VETTER: But without focusing on any country, just foreign trained, if an authorized user on a broad scope license in this country has verification that the individual completed the training in the foreign country comes and practices for a year under the direction of that authorized user, why can't the authorized user act as the preceptor?

MS. FLANNERY: Well, in the case of -- and let me just give you a little history on how this came up. This really applied to a physicist rather than a physician.

DR. VETTER: Okay. If it's only physicists, let's take that later. We're just focusing on physicians now, and we'll try and separate the two.

DR. NAG: That is why I said we should decouple the physician from the physicist because the

physician requirements to practice in this country are so strict that they are more strict than the NRC regulations. I felt that for the physician that would not be a problem.

To answer the question about the academic radiation oncologist, there is a provision that if you are an academic radiation oncologist outside this country and you are coming here at the academic appointment, you could be on the faculty for four years and the you can apply for a board certification without doing a residency, but then you would have to be on the faculty of the university.

DR. VETTER: Mr. Bailey had a comment.

MR. BAILEY: I'm sorry. I don't remember whether it was oncology or just diagnostic, but I do know that we had a physician come in, foreign trained. His partner wanted to be his preceptor, and we basically said, no, that for a preceptor it really should be someone from a teaching institution and suggested that they make some arrangements for someone at a teaching institution rather than simply having which, with all due respect for cardiologists, we had the same problem where a cardiologist wanted to be the preceptor for his partner, and we sort of frowned on that and said, "Hey, you should get some independent

training or get some training from a facility that is in the business of education."

So it can occur. I mean, it does occur

DR. VETTER: I think it can occur. It's unusual. These are unusual, and the impact on a patient receiving care from one of these or from a foreign trained physician who perhaps can't practice in a lesser populated state because of the lack if ability to get the additional training, I think that's remote. In most cases they'll be able to go to a broad scope licensee or somewhere to get that training under an authorized user.

So the question was can -- the NRC is interested in allowing regions to make that determination for physicians as well as physicists; is that correct?

MS. FLANNERY: Yes, that is correct.

DR. VETTER: So now the physicist. We have kind of --

DR. WILLIAMSON: Have we settled the issue of the physician though, the Canadian physician who does the Canadian residency, can become ABR certified, can have all privileges of a radiation oncologist now, except, I guess, being able to use byproduct materials?

I think it would seem to me it would be reasonable for such an individual to have some route for becoming an authorized user.

DR. NAG: I think for all practical purposes that group, the Canadian physician who is trained in Canada and came to the U.S., that would be the only group that you will have to think about because any other group of physicians will have to do their residency of four years of training all over again.

And I think for the group from Canada who are coming here and, therefore, are board certified, I think you could have a provision that they practice one year under a preceptor to get the license.

MS. FLANNERY: And I would like to clarify that the request that's being made is really going to be for the physicists.

DR. VETTER: Okay. So you were about to answer a question asked earlier, if you will recall, to explain what the issue was with that physicist.

MS. FLANNERY: Yes. The reason why this came up is there was a physicist who received a degree in Dublin and that degree was not one of the listed degrees in 35-51. So that was what brought up one of the questions.

And also this individual got their degree in Dublin rather than here; also did their one-year training overseas, and then came here for the work experience, and this was for a broad scope licensee, you know. This individual did meet all of the criteria. I don't think it was questionable in any way, but the issue is if that same situation had happened for, say, a non-broad scope licensee, specific licensee, that would have been, you know, submitted to headquarters as a technical assistance request and presented to the ACMUI for approval.

DR. VETTER: Okay, and currently that can't go to the regions. Is that --

DR. WILLIAMSON: What's the question you have?

DR. VETTER: Yeah, I'm not sure what the question is.

DR. MILLER: What happens in those situations is the regions do the reviews, but in certain unique cases the regions will write what she has referred to as a technical assistance request to headquarters for guidance on what they should do, and then we do a review, and part of that review would include -- correct me if I'm wrong -- giving the committee's views on the matter, and then we respond

back to the region with regard to what action we recommended.

DR. VETTER: So that's the current standard operating procedure.

DR. MILLER: Yes.

DR. VETTER: And you'd like our input on whether or not it would be appropriate to simply allow the regions to make that determination.

MS. FLANNERY: Correct.

DR. VETTER: Okay. Thank you.

Mr. Leito.

MR. LEITO: Right now the current policy is ACMUI looks at these on a case by case; is that correct?

MS. FLANNERY: Correct.

MR. LEITO: Okay. I'm kind of sitting on the fence on this one because I think if you have ACMUI doing it, you've got a consistency whether it happens in Region I, Region II, Region III, and so forth.

Right now I don't think there's any specific guidance that is actually out there that is a written document that the regions go by, and if you're also having all the broad scopes develop their own criteria to some degree as to what they're going

to accept, you get this variation that once this person, this AMP or AU is on a broad scope license, okay, the assumption is that they've met all of the criteria that would have been the same as if they went to the region, and I don't think that's a fair and accurate conclusion.

So my initial feeling is I would not have an objection if the regions or a broad scope license were given that ability, providing they are all following the same guidance in terms of what they needed to do, you know, to look at these credentials.

One of the questions that Cynthia had in her third slide here -- actually the first two bullets I think we could group together -- was can the region or the broad scope licensee accept a foreign degree or degree not specifically mentioned in the regulations.

The consensus I have from the committee is that, yes, that would be acceptable. The second bullet, I don't think we really reached a conclusion on regarding the preceptor statement, and I think that might need some further discussion, but again, I think it's still going to go to if the committee is recommending that this responsibility that currently is ours is now going to be delegated to the regions and broad scopes, then I think if we're going to

delegate that, we need to delegate it with guidance.

DR. VETTER: Dr. Malmud.

CHAIRMAN MALMUD: I have a question, and that is we recognize that the ACMUI is made up of specialists from varying areas. Do the regions have that breadth of talent available to them to make those decisions on a standing basis?

DR. MILLER: Obviously the regions don't have the talent that's at this table, given the fact that the regions do not necessarily have physicians on their staff. They have people who are knowledgeable about all of that, as we do in headquarters. Part of the purpose of this committee is obviously to bring that talent to bear to help us with our regulatory process.

CHAIRMAN MALMUD: That's part one of my question.

Part two, if there were a means of expediting the process whereby it could come to this committee even with an E-mail review and then a -- would a public meeting be required to review this? No, I would assume not.

PARTICIPANT: No.

CHAIRMAN MALMUD: So if this could be done expeditiously through the ACMUI communicating with us

by E-mail, we could review it and have a telephone conference call, probably do it more quickly than the region with a greater breadth of talent to review the CV of the individual.

For example, I'd be hesitant to judge the qualifications of a physicist, but I'm certain that Mr. Leito and Dr. Williamson would not be the least bit hesitant, and similarly for a nuclear physicians or radiation oncologist.

So I think this committee has a breadth of talent, breadth of talent which could address these issues. They don't arise very often, do they?

MS. FLANNERY: No.

CHAIRMAN MALMUD: About how many a year?

MS. FLANNERY: I couldn't tell you. I think we may have seen one case in the last year.

CHAIRMAN MALMUD: So one or two a year. It would seem to me it wouldn't be particularly burdensome, and since people's careers and their ability to move forward depends upon the decision, I would recommend that we review it.

DR. VETTER: Dr. Williamson.

DR. WILLIAMSON: Yeah, I just have a question of clarification. I'm unclear what the question is you're asking us. Is the question whether

all foreign degrees should be reviewed by the ACMUI, the office via a TAR or be reviewed independently by the rod scope or the license or the licensee or the region? Is it the one year of training that needs to be addressed?

So are you asking about the mechanism of approval for alternative training types? And are you also asking our opinion on the issue of non-United States license preceptor?

There are so many questions I'm really not clear which one you're asking us.

MS. FLANNERY: We are trying to have consistency among the regions and the broad scope licensees. So this is really geared more towards the physicist rather than the physicians. So the question is, you know, would it be acceptable for the regions to be able to exercise the authority or reviewing the training and experience of these physicists without having to submit a technical assistance request and presenting it to the ACMUI in more clear-cut circumstances?

And as I mentioned in my last slide, certainly in unusual ones, and I used the example like questioning the validity of a degree, we certainly would still do that, but in this case, like I

mentioned, this physicist who received their degree in training in Dublin, it seemed pretty clear cut that that would have, if it had not been a broad scope licensee, that would have been a case that we would have presented to the ACMUI.

DR. VETTER: Ms. Fairobent.

MS. FAIROBENT: Yeah, Lynne Fairobent with AAPM.

A couple of comments because we're getting questions at AAPM obviously on this. One, I think the number of instances for a physicist is going to be on the rise, and the reason I say that is because we have not had physicists on licenses before. We've not required a preceptor statement.

In the four states that license physicists, okay, in order to be licensed you have to be board certified. There's nothing to say that you have to have studied or performed a clinical rotation to my knowledge in the U.S. So that a foreign trained physicist who does his clinical fellowship or rotation outside of the U.S. comes and is eligible for board certification by ABR or ABMP because they do an equivalency on the degree in the program, sits for the exam and passes, can't be licensed, for example, in the State of Florida or Texas or New York or Hawaii,

and yet they would not, without doing what I'm hearing -- and I'm asking for clarification -- without doing another year under an AMP be able to be an AMP if byproduct material was in use.

I do think this is going to be an increase problem, and I do think you're going to see more circumstances.

I know, for example, when I spoke a year ago at the Florida chapter, I had five people come up to me to ask me what their situation would be under the new regulation.

We have an awful lot that are trained in South America that practice in the southern state areas. I don't think it's a problem for the Canadians so much up in New York, but it is going to be a problem in California, Texas, Florida, where many of these folks come in and practice. And we have not had this situation before.

DR. VETTER: Point of clarification, if I may. So if a licensee in a region needs clarification or needs approval to license a physicist on a license, they would currently request that through their region.

If the region, if it isn't real straightforward, they need to apply for a technical

assistance request, which then would come to headquarters and might involve us. So there's an additional lag there. Even if we handled this by conference call, there would be a lag that would delay approval of a physicist. We don't know if that would be a problem for the licensee or not, but it could be, I guess.

MS. FLANNERY: Yes, that is correct.

DR. VETTER: Okay. Dr. Suleiman.

DR. SULEIMAN: I'm going to share my own personal thoughts. I'm a little troubled that the ACMUI would even review or approve specific physicists, but that's just how I feel.

I think you should be able to have internal criteria for the regions that say if it's an outside university, international university, it would probably have a list of universities that are accredited or qualified or whatever. Otherwise, how do you -- you know, so the number one criteria would have to be a university or college that is legitimate.

Number two, obviously, if the degree doesn't meet what you want, you'd have to go through the transcript and see that they meet so many hours of physics or whatever. So you could be prescriptive.

I think if they meet those criteria, then

we shouldn't be bothered, you know, with it. I think at that point you could come here for clarification on maybe new policy, but you have to have some structure to this whole review process.

DR. VETTER: Mr. Bailey.

MR. BAILEY: I hate to further complicate this, but there are states such as California that do have a list of, for lack of a better word, approved physicists, and at this point we would tend to put them on as authorized users if they were requested to be put on because we do have some knowledge of them, and they have filled out essentially a registration form and so forth.

Probably even more unsettling, if you're looking for uniformity and consistency is you've got 33 states to deal with, and depending upon the local state situation, that physicist may be approved with credentials that you would not approve.

So it's going to be a while before there's uniformity and consistency, particularly among physicists. And many of us don't have as much difficulty making a decision about whether we think a physicist is qualified, as we do, making a decision about whether a doctor is qualified.

DR. VETTER: Dr. Williamson.

DR. WILLIAMSON: I think the reason the ACMUI is involved and the TAR is involved is because it's sometimes very difficult to lay down hard and fast criteria or policy as to why a variance should be given from a regulation. So I think basically Ralph is right. If you want to institutionalize or somehow codify the range of allowed options that broad scope licensees and individual regions have, you know, you are then going to have to sit down and create some kind of guidance document for them to follow or it won't be very consistent.

Because right now what you do is you bring many of them to the full committee. Sometimes I'm aware you just may ask the specialist or the one or two individuals on the committee what their opinion is of a particular question rather than bringing it before the committee, but this system allows you to proceed with this what may be growing but still relatively small number of cases without having to go through the trouble of creating a more formal guidance document.

So that would be, I guess, one issue you would have to decide. I would be concerned that many qualified physicists could be unnecessarily rejected by the fact that the regions, who are not specialists

or do not have representation from our field to judge these credentials, or on the other hand, they might let some individuals through that, you know, we think couldn't pass successfully through our board certification process.

That would basically, I think, be the criteria we would use, is could this person, if they did sit for our examination process, pass it.

DR. VETTER: Dr. Miller.

DR. MILLER: Yes, just a couple of other points to think about, embellishing some of Ed Bailey's comments. For the 33 agreement states, when they encounter such a situation, that doesn't come into the process to the committee. The decision is made in the states.

So for the majority of licensees, that's not the case. That being said, also, you know, if you look at the provisions of the regulations, people could be on an agreement state license and move to another jurisdiction, whether it be an agreement state or NRC jurisdiction, but because they remained on that license, that's an avenue for being put on a license in an NRC or another agreement state. That wouldn't come to the committee.

So all of these factors weigh in also to

the fact that the committee itself doesn't get to see all of the applications nationally, and it's just food for thought.

DR. VETTER: Mr. Leito.

MR. BAILEY: As we have to try to wrestle through this.

MR. LEITO: A couple of questions. I guess this would be mostly for Cindy. Are these applications almost at least for the physicist, are they being applications under the alternate pathway, and is that a fair assumption that these all come --

MS. FLANNERY: Yes, it is.

MR. LEITO: And for the broad scope approvals, the NRC still has to be notified regarding the AMPs being put on the license, correct?

MS. FLANNERY: No, they do not.

MR. LEITO: Okay. So how is NRC --

MS. FLANNERY: That may be reviewed during, say, an inspection.

MR. LEITO: So you don't have necessarily a sense of how many broad scope reviews are now -- well, for AMPs occur.

MS. FLANNERY: No.

MR. LEITO: All right.

DR. VETTER: I can comment from personal

experience that when our broad scope license is inspected, the inspector always pulls a few authorized users somewhat at random. I would suggest if it were a foreign trained physicist, it probably wouldn't be at random, and we would have to defend the process by which we approved that AMP. That's broad scope.

Dr. Nag.

DR. NAG: Yeah. I think from what we've heard, I think the present requirement is not a problem because the safeguards and the training requirement for qualification is so tight that you are very, very unlikely to cause anyone who would maybe got the license and practicing not in a hospital, but maybe on his own in a free standing place. So that's really, really there.

So I think you should concentrate on the physicist and the only group from the medical field which we know who are trained in Canada and has their full training in Canada and is now coming here, whether you need one year extra for that person to be under a preceptor or not. I think those are the two questions you need to look at.

And I guess those who are coming from Canada in some of the licensing requirement and handling requirements may be different in the two

countries even though the magical pot is one thing that's equivalent. I suggest that those who thought they -- those reports certified in Canada and after coming here and, therefore, certify you have a one-year receptor who would want them.

DR. VETTER: Ms. Fairobent.

MS. FAIROBENT: Yeah, Lynne Fairobent, AAPM.

Just another question because let's talk about an AMP who's already on the license for, say, one modality, and a new modality comes along and we have the provision of requiring vendor training, and what has brought this up to mind is I know in the past, several of our physicists have gone to a foreign country where the vendor-manufacturer lives in his house, maybe the first use in the U.S., gets their vendor training overseas. The preceptor would have to be somebody from that institution. There is nobody in the U.S.

Is that going to be accepted since you said no foreign preceptors?

PARTICIPANT: That's a very good question.

MS. FAIROBENT: And I don't think that's an uncommon practice.

DR. WILLIAMSON: And it does say here that

the device specific training can be supplied by a vendor, and so when the vendor is not an authorized user, you know, you have a contradiction because then you say the preceptor who must be an authorized user has to attest to Part C.

DR. VETTER: Yes, Cynthia.

MS. FLANNERY: Well, I would think that that would fall under one of those unusual circumstances.

DR. WILLIAMSON: It's very routine, and in fact, say, a nucletron representative gives the training, devices specific training, Part C. You know, the logical person to sign off that that training was delivered is, in fact, the vendor and not some authorized user who had nothing to do with it.

DR. NAG: But then I think that --

DR. HOWE: Excuse me. If I could just add.

DR. VETTER: Dr. Howe.

DR. HOWE: The regulations do not require the preceptor to have provided the training. The preceptor has to verify, and so if the preceptor verifies that the individual received the training from the vendor and knows what the vendor is providing, then the preceptor can be the authorized

use or the authorized medical physicist, whatever the requirement is.

DR. VETTER: I think that answers that question.

DR. WILLIAMSON: Okay. I think so.

DR. MILLER: Yes. I actually agree with that. I think that works.

DR. VETTER: Yes. Now, relative to the -- yes, Dr. Miller.

DR. MILLER: Another scenario, this is something I've been wrestling with personally and mentally, and maybe I just don't understand. Can anyone postulate a scenario whereby somehow someone could find themselves on an NRC or agreement state license as an authorized user or an AMP, but yet not be licensed to practice in that state. In other words the way I think about it is if you're not licensed to practice medicine in the state, even if you found your way somehow on an NRC license, from a practical perspective it would never happen. Is that true or is that a problem or --

DR. VETTER: Dr. Malmud.

CHAIRMAN MALMUD: Yes. That could occur. For example, let's say that I am an authorized user and I move to Florida where I'm not licensed to

practice medicine, but you see there I'd be prevented from practicing medicine because the credentialing process in Florida would exclude me from the practice of medicine. Hence my authorized user status is irrelevant because in the practice of medicine there's a credentialing process.

Now, I can't speak to an analogous situation for physics because I'm not familiar with it -- for physicists.

DR. VETTER: Mr. Bailey.

MR. BAILEY: Yeah, I think that occurs all the time. We have many physicians practicing at VA and military facilities in California who are not licensed to practice medicine in California. They're not required to be.

Similarly, with pharmacists and one of the large pharmacies wanted us to recognize the NRC license which named 20 or 30 pharmacists. They were a little miffed at us when we asked that they provide us with information that all of those people were licensed to practice pharmacy in the State of California. So that occurs all the time.

DR. VETTER: Dr. Howe?

DR. HOWE: My comment or my response is very similar to what Ed Bailey has said about the

physicians at the federal facilities. You're not required to have a license for the state in which you're living because you may move around.

For the pharmacy issue, I was involved in the development of the radiopharmacy rule, and we actually assumed that there would be cases in which there might be two pharmacists required, one licensed in the state to meet the state pharmacy requirements, and he would act as a supervisor for a nuclear pharmacist that would meet our requirements but couldn't practice in that state. So he would act as not a pharmacist under the state license, but for the NRC he's acting as a pharmacist, but he wouldn't.

So we had assumed that there would be some pharmacists that wouldn't be licensed, but they would have to operate more as pharmacy techs under state rules.

DR. VETTER: And, Dr. Miller, relative to physicists, most states do not require the licensure of physicists.

DR. MILLER: My primary concern was as authorized users, you know, is problematic.

DR. VETTER: Dr. Williamson.

DR. WILLIAMSON: Well, it sounds like in the physicist case if we divide it into -- if physics

boards become recognized as they hopefully will the board certified route and the alternative pathway route. So it sounds like for the board certified route, they still have to have a preceptor's statement, but the preceptor's statement would be essentially one of verifying that the training, wherever it was received, that constituted the grounds for sitting for the boards was appropriate, and that would be that. So there doesn't seem to be a problem at the local level, at any level for a board certified physicist.

So I think the question comes in the alternative pathway, where it says clearly both the practical training and year of supervised experience has to be done under the supervision of an authorized user or medical physicist, which presumes, you know, a United States practitioner.

So there would have to be, I think, a system or some approach for exemptions, I think, from some or part of that process in the case that a foreign trained medical physicist came to the United States that wasn't board certified.

DR. VETTER: Ms. Fairobent.

MS. FAIROBENT: Yeah, Lynne Fairobent.

Just to follow up on Donna-Beth's answer

on the vendor training, in order to be a preceptor, yes, you only have to verify that the training occurred, but you have to be an AMP preceptor for that modality of which you're verifying the training. So I don't think that is a solution if you are the first user of a modality and are trained in a foreign vendor.

There may not be a preceptor on a license who could serve to verify your training by virtue of being an AMP in that modality.

DR. HOWE: I just want to make a quick comment, and that is we consider modalities in a very broad definition. So if you're talking about a new HDR unit, then the preceptor could be an HDR authorized user or medical physicist. He may not be approved on that new HDR unit, and if you're talking about a brand new modality, then we're in 35-1000 space. In 35-1000 space we don't have specific training and experience requirements that require a preceptor statement because we recognize there is at some point a first, and if there's a first, there's no one to sign off for him.

So we do interpret the modalities very broadly. So if it's a new version or a new manufacturer for an existing modality like HDR gamma

knife teletherapy, we could still have someone that could sign off for that individual.

MS. FAIROBENT: But then I guess I question what the purpose of the vendor specific training is on that piece of equipment which may be different than an existing one.

DR. HOWE: I don't think the preceptor statement is necessary for somebody that knows that piece of equipment because you have to have a system that allows for growth.

DR. WILLIAMSON: That would be important to be more flexible like this.

DR. DIAMOND: This is Dr. Diamond.

Donna-Beth, I think that this flexibility satisfies me. For example, let's say that there is the next generation of a gamma knife unit that comes out. Let's say we're now in the Unite 4Cs. Let's say in the future a Model 5 comes out. The first users of the Model 5 will need to go to Sweden to be trained by ELEKTRA (the vendore).

As long as you tell me that a preceptor who is authorized for gamma knife in the United States can sign off that that treatment was being done and as long as you tell me that the vendor training can be satisfactorily completed in the country of Sweden,

there is no issue whatsoever.

DR. HOWE: I think we would accept that.

DR. DIAMOND: Okay.

DR. VETTER: Okay. To get back to the original question, if I can stick my neck out, I think the sense of the committee is that this isn't an issue for physicians because there are so many outside controls on licensing and so forth. Relative to physicists, it's a little grayer, but I think the sense of the committee is we would be okay with regions making decision if there were some guidelines put together to assure uniformity of decision making across the country. Is that -- is that close to the sense of the committee?

DR. WILLIAMSON: I think so.

DR. VETTER: Okay. Any other discussion on this topic or related questions? Yes, Mr. Leito.

MR. LEITO: You know, one of the things, just a comment is that I think in doing these reviews from the alternate in this case-by-case basis that we need to recognize that the issues that we're addressing are not so much the practice of medicine or physics to some degree, but the health and safety issues of that modality and what that person would be overseeing.

You know, I would think that there would necessarily -- that there shouldn't be, I should say, any exemptions to training and experience under an AMP or an AU, you know, for these case-by-case reviews. So I think it's really important that those individuals have a sense of the safety considerations of the regulations for the modality for which they're getting approved, which are not necessarily going to transfer from a foreign country to the United States.

DR. VETTER: Thank you, Ms. Flannery, for bringing the question to us and for giving us the opportunity to comment.

MS. FLANNERY: Thank you.

DR. VETTER: I'll turn the chair back over to Dr. Malmud.

CHAIRMAN MALMUD: Thank you, Dr. Vetter.

If we may, we'll move on to the next item on the agenda, which is Item No. 17, status of medical events, which is a standing item, open session. Dr. Howe.

Dr. Howe is going to seek our advice, recommendations and insights regarding the cause of medical events and possible methods to reduce them.

DR. HOWE: Sorry, folks.

CHAIRMAN MALMUD: If I may, I'll just use

a few minutes while Dr. Howe is getting the slides ready to let you know that I met with one of the Commissioners, which is why I was out for a few minutes, and one of the suggestions that he made was that in addition to requesting the information from the states as to how they're dealing with accelerator produced products, that we might wish to find out, if possible, how other nations are dealing with accelerator produced products, including those who have the largest volume of production: Canada, for example, United Kingdom, France, and Japan.

It doesn't mean that the models that they use are at all applicable here. On the other hand, it would be of interest to know how they are dealing with the issue in addition to our survey of the states.

The Commissioner asked me what I thought would be occupying our effort in the near future, and I said certainly the issue of accelerated produced products would consume an enormous amount of time, and that we had already begun to discuss the process here at the meeting and we were looking forward to trying to work out something that would be able to be applied nationally and to absorb as much as we could from each of the state regulations that we thought was a good role model, and then, of course, try to achieve some

degree of conformity.

I explained that there were different interested parties, industry looking for more uniformity with respect to marketing their products from one state to another, concerns, on the other hand, on the part of some research institutions that the regulations not be onerous, not add additional expense or layers of administration, and that clearly the concern of all parties, ourselves in particular, are that accelerator produced products continued to flow into the areas of medical research and medical care, and that we attempt to work out a system that achieved this at the least expense and the least delay in producing the end product for the betterment of patients.

We also described the working relationship between the NRC representatives here and the members of the ACMUI, and it was, in general, a very positive discussion.

DR. HOWE: I now have slides.

I'm bringing you essentially an update that we give once a year to the status of medical events for the preceding fiscal year, and the first slide is a summary slide that lets you know that we had essentially 40 medical events in FY 2005, and you

may have a question of, well, how does that compare to FY 2004. We only had 35 medical events in FY 2004.

Another major difference is that in 2004 for 35-600, all of our medical events were under HDR, and now we're beginning to see a few more events for gamma knife. Even though we only have three teletherapy units, we managed to have a teletherapy unit medical event last year, and we considered our first LDR.

The other major changes last year, we had a significant number of medical events that were in 35-1000 because of interavascular brachytherapy, specifically the Novos device. The Novos device is essentially gone, since Novoste has gone into a different business, and the Novos device is not available at this time.

So we have two medical events for the microspheres. It ends up that the microspheres are now coming up into a larger use. They're getting out into some of the smaller hospitals.

For about a year and a half, Medicare or Medicaid -- yeah, Medicare had identified microspheres as more or less a diagnostic nuclear medicine procedure and, therefore, wasn't reimbursing for even a small fraction of the total cost of the

microspheres, and that got rewritten about a year and a half ago. So microspheres are now a technology that's coming back into use.

Now, one of the other things I did this year, and last year, I think, if you'll remember, we had a significant number of 35-200 events that were due to diagnostic IO-131 treatments being prescribed, but therapeutic doses of I-131 being delivered.

We're not seeing that this year, but the thing that seemed to pop out was that this year we seem to have a significant number of events that were not identified rapidly. About 40 events, about 50 percent of them were identified on the same day that they occurred. We consider that the events that are identified within the same day or two to four days later could be patients coming back and realizing at that point that the events aren't correct or a rapid review of the administrations and realizing that in that review that there was an event that occurred.

We had two events that were out 15 to 60 days. One of those events was an internal audit. The 60-day event was a patient that came back with actual patient injury, and at that point there was a recognition that there was something wrong with the initial treatment.

One of our same day events was an HDR unit in which the medical physicist put the wrong parameters in back in October of 2004. Since that time we've done inspections, and the licensee has gone back to reevaluate its previous records, and so many of the events down -- two of them in the one to two years are from the same institution, and three of them in the two-year greater are at that institution, and they have to do with the medical physicist improperly inputting various parameters into the HDR procedures.

So a total of six patients were involved in that particular facility.

One of our facilities for the one to two years later, and we'll talk about this a little bit later, was essentially another patient injury. They recognized at 30 days they had a potential patient injury, and a year later they had radiation burns that hadn't healed, and they realized that at this point they would have to report to the NRC because they had what they thought might be a reportable event.

That particular event involved five different patients. We've done an information notice. It was a manual brachytherapy event that I'll describe a little bit later.

MR. BAILEY: That only adds up to 37.

DR. HOWE: Do I have all of my numbers in here? Maybe I have a number missing somewhere, but I do have 40 events.

MR. BAILEY: There were 40? Okay. And these were only NRC?

DR. HOWE: These are both NRC and agreement state.

DR. NAG: Do all of the agreement states report to you or only if they want to?

DR. HOWE: All of the agreement states are supposed to report to us. We do notice that for different years all of a sudden you'll see a rash of reports coming from one state or the other, and that's generally a year there was an impact done.

DR. WILLIAMSON: I think there are only 39 altogether. In the second slide there's --

DR. HOWE: Are there?

DR. WILLIAMSON: There's a miscount here. So it's 39 versus 35, I guess.

MR. BAILEY: But there are actually under 35-600, there are actually 18 identified in the breakout, but only 17 included in the --

DR. WILLIAMSON: I see. You're right.

DR. HOWE: Okay. Then that's where I --

DR. WILLIAMSON: That is 40.

DR. HOWE: That's where I have an errors.

Ralph, did you have a question?

MR. LEITO: I just wanted to clarify for my information and understanding. Fiscal year 2005, is that September to October?

DR. HOWE: October 1 to September 30.

DR. DIAMOND: Donna-Beth.

DR. HOWE: Yes.

DR. DIAMOND: I think it deserves some comment regarding why, for example, there were three medical events reported over two years later. It's my understanding that at least two of those three had to do with very reasonable licensee interpretations of what, indeed, constituted a medical event. I think perhaps you'd like to comment on that.

DR. HOWE: And I'll comment further when I get to them. Two of them in the one to two years later were identified at -- they were gamma knife procedures -- they were identified at the time as medical events, but they were thought not to be reportable medical events, and I'll go into a little more detail as we get to -- because I am going to go through very briefly what kind of events we were looking at.

In 35-200, we saw one of our diagnostic I-

131s were a therapeutic I-131, which gives -- no, in that case the iodine was ordered for the wrong procedure. We saw what we typically think of as a 200 medical event, and that is either the whole generator elution is given to a patient or a bulk technetium dose is given to a patient.

We did see two pediatric cases. We don't normally see pediatric medical events. So that's kind of a new one for us, and it's typical for us within one or two years to see one of these Technetium-99 bulk doses or entire generator given to a patient when you have technicians that are for the first time on call by themselves. They've been shown how to elute the generator. Everybody thinks they understand what's happening. They elute the generator, put that in the kit and give the whole thing to the patient.

In this case they had a syringe that came in from the pharmacy with a bulk dose. The corrective action is for the pharmacy to send the bulk doses in a vial so that the licensee can now split the dose.

Dr. Malmud, you look very puzzled.

CHAIRMAN MALMUD: Yes. What's the amount of activity in a bulk dose?

DR. HOWE: It can vary. In this particular bulk dose, it was 400 millicuries.

CHAIRMAN MALMUD: Thank you.

DR. HOWE: So you have to give a significant amount of technetium for an adult to trigger the medical event reporting requirements.

CHAIRMAN MALMUD: Four hundred millicuries is significant.

DR. HOWE: Yes.

DR. WILLIAMSON: Just out of curiosity, what is the criterion for a 200 medical event?

DR. HOWE: Two hundred has to exceed 50 rem to an organ and five rem whole body.

DR. WILLIAMSON: I see. Got it.

DR. HOWE: So you're up in that 350, 400 range before you even start to trigger it, but we do get cases where people elute the whole generator and give it to a patient. It doesn't happen often, but it does happen.

Three hundred, we have essentially your typical sodium iodide medical events. We did have one where they were supposed to be giving sodium iodide. They gave technitium instead, but it's still a medical event because the dose that they delivered was significantly less.

We're starting to see some of the new -- well, they're not new anymore, but some of the

slightly different drugs like samarium with calibration errors. We did put an information notice out a number of years ago about problems associated with calibrating samarium with those calibrators, and you have to be very careful with that.

The Yttrium-90 Zevalin, they gave the maximum dose possible to an individual because they had failed to write a written directive, and there was confusion between the ordering of the procedure and the activity that should have been given and the order that went to the pharmacy.

For brachytherapy --

DR. NAG: What do you mean by eight and 12?

DR. HOWE: There were eight events, but one event involved five patients, and so that's why you'll see that there were five patients in which the source moved to the wrong site. That was a Wang applicator situation where the medical physicist did not realize that there was a difference in size for sources, and the source was small enough that it slid right down the inside of the spring in the Wang applicator.

And so once the patient was elevated above 20 degrees, the source slide down to the end and

stayed there for the rest of the treatment, and this is one of the cases where they had radiation burns within 30 days of the initial treatment. They didn't recognize them as radiation burns, and they didn't call it in as a reportable event until well over a year later, and that particular facility was very confused as to how to interpret a medical event and patient intervention.

They combined the patient intervention with the medical event reporting requirements, and didn't think they needed to report. We put a paragraph in the NMSS newsletter to clarify how to interpret the medical event.

We had a leaking source in the prostate. It was I-125 using a MIC applicator, probably got stuck. The source actually was leaking in the patient. We had our typical prostate problems with ultrasound. Providing the interpretation of the ultrasound was not appropriate, and so the sources went into the wrong place.

We had cartridges being used, and the cartridges for the I-125 sources looked the same as the cartridges for the Palladium 103, and so when they picked up the cartridges to give all 1-I-125, they gave in some Palladium 103 seeds also.

We had a facility that sent the wrong activity of sources to an authorized user, and then down in the wrong size applicator, they were supposed to use a cylinder of a certain size. They used a different cylinder. They grossly overexposed the patient, and then they had a fouled up treatment in which the ribbon moved.

We had a lot more HDR units than we've had before, and I'm including the HDRs. The numbers look a little high because six of the HDRs were from the same licensee, and this is where the medical physicist entered in a various set of erroneous data. He did make the same mistake twice. He put in the wrong distance. He put in the wrong spacing. He varied it. So he had lots of errors.

We had a case that was discovered the same day that it happened, but the others were when they went back and looked at the files.

DR. NAG: Was that a new radiation physicist? Was that someone who just came into that department recently or is it someone who's used to it?

DR. HOWE: Well --

DR. NAG: What I'm trying to see is because he's not familiar with this new equipment or is it someone who is not trained overall?

DR. HOWE: I can't answer that. I can tell you that the events that were affected by wrong data input over a two-year period of time. It wasn't really identified as a problem until 2004. There were additional problems in 2005 with data entry, and then the licensee went back and did reviews and identified four more cases that were earlier. So this was a prolonged period of time with --

DR. WILLIAMSON: Is this an agreement state or non-agreement state?

DR. HOWE: No, this is an NRC licensee.

DR. WILLIAMSON: Yeah, I would be curious to know more details, especially about the background personnel issues there.

DR. HOWE: Yes. I have a call in to Region III, but I haven't got an answer back, but, yes, it is an interesting question. I'm assuming it's in inspection enforcement space.

And then we had other problems where they put the wrong distance in for the catheter, something called the wrong orientation. So the sources were in the wrong location. One catheter wasn't fully inserted. It was wrapped around the toe. They unwrapped it from the toe and they gave the procedure, and then they came back later and discovered it wasn't

in the location at all.

One was a software problem where they had a new software package, and they had entered a diameter, not a radius. So they gave a quite high overdose on that one.

And then the wrong source travel distance.

Gamma knife, we had five this year. We haven't had one for a while where they transposed the Y and the Z coordinates, but that problem is always out there. It came back again in 2005.

We very rarely have equipment problems, but there was a clip on a microphone that fell into the gamma knife, jammed the device, and so the facility was not able to give all of the positions that it was supposed to give.

In one case there was a records review later, and they discovered there was quite a large error in the gamma knife procedure, and they attributed that to it was in an agreement state, and they attributed it to poor communication between the neurosurgeon, the oncologist, and the team that was delivering the procedure.

We had two wrong sites. In both of those cases, the event was recognized right away, but the fact that it was a reportable medical event was not

recognized. There was an interpretation by two different licensees that patient movement, although NRC considered them a contributing factor, they attributed patient movement to patient intervention and did not report them.

DR. VETTER: Why wouldn't that be patient intervention?

DR. DIAMOND: I can speak to that. I was asked -- this is Dr. Diamond -- I was asked to look into these cases. As you know, there is very specific language in the rules that patient intervention is specifically excluded as a reportable medical event. In other words, let's say you're doing a low dose rate time to no void procedure on a gynecologic oncology patient. That patient is given very strict instructions regarding bed rest and so forth.

The language was inserted in case that the patient did not follow your instructions and she decided to move or pull the thing out that you as the licensee would not be penalized.

In these two particular cases, the circumstances are fairly similar. These were cases in which all of the standard operating procedures were followed as far as placement of the frame, checking of the coordinates, checking of the bolts to make sure

the frame was on tight. These were both very experienced center.

And what happened is that during these gamma knife procedures they can get quite long, and of course, the table is quite hard, and you can start having some back pain, and it's very common, for example, when you do these procedures that halfway through you stop or between fractions you take a break, and obviously you're monitoring the patient in real time and will give the patient some Verse]d or some Demerol to relieve their discomfort.

In these particular cases, the patient -- in one case the patient did not follow instructions and started twisting and squirming in real time. In fact, was a heavyset fellow who basically lifted up the entire small of his back so that all of the pressure of the force of his body rested on those frames, and what happened was in real time the frame slid, and so for the remainder of that particular fraction there was a movement.

So was that patient intervention, meaning did the patient not comply with your instructions? You're telling them in real time to stay still, stay still, or was that actually a licensee error because they should have had the foresight to recognize the

person was uncomfortable and perhaps they should have done some other steps to make the person less uncomfortable?

DR. HOWE: And in that particular case, the frame slid seven centimeters.

DR. DIAMOND: It slid completely until it hit the table. Now, as it turns out, it appears that that happened towards the very end of treatment. It turns out that it would have placed the isocenter in a portion of the skull where there was no physiologic consequence, and it turned out that the treatment was efficacious.

So it was really a matter of interpretation. Was it the patient not complying with your direct repeated requests and was patient intervention or not? And that's an example where in real time the licensees spoke about it internally. They talked about it within the review committee, and they felt that it, indeed, met the patient intervention criteria.

The second case was sort of similar. The patient was coughing, and in this particular case the licensees had to use a three pin technique. Usually when we do these gamma knife procedures there are four pins, two in the front and two in the back, for

maximum stability, but because of the geometries occasionally we have to take one of the four out so that there's no collision. And we do that all the time.

In this particular case, the person started coughing and was coughing apparently fairly vigorously, and at the end of one of the fractions, because of the vigorous movement of the head within the frame with the cough, the pins that are inserted into the calvarium slid a little bit, and of course you know the skull is not solid. It's not solid bone. It's an inner table, marrow, and outer table, and even with these screws, they can slide just like a screw can have some launch and movement if the threads are not secure.

So, again, was this a patient intervention or not, and again, they went internally to the committee and they thought it was not a reportable medical event, but then there was an NRC inspection, and during the course of just a routine review, this came up.

So these I do not think were any malevolent attempts to hide, cover up. They had been reported and discussed widely within our institutions. They had shared the information with the patients and

so forth, and I think these were both instances of individuals feeling that it really just met the letter of the law but not reportable medical event.

DR. WILLIAMSON: So is this -- it says 11th stage. Is that 11th isocenter or 11th --

DR. DIAMOND: Yes, in that particular case that you're looking at, Dr. Williamson, that was the 11th and final shot of a gamma knife procedure for an acoustic neuroma, and that actual transposition or movement of the screw happened at the very end of the 11th shot.

So, once again, the physiologic consequence was essentially nil.

DR. VETTER: Dr. Nag.

DR. NAG: Yes, a question. If these are patient interventions, and I agree with you that these are patient interventions and I would have classified similarly if it had happened in our place, why are they coming up in here as a medical event?

DR. HOWE: Because we did not consider them patient intervention. We considered them -- well, the one with the seven centimeters, we think that there was some equipment failure. We have not seen any other movements on the level of seven centimeters for a gamma knife. The device is designed

to hold people in place.

We think that on the -- we think that patient movement is a contributing factor, but we don't think patient movement is an intervention in these cases.

DR. DIAMOND: This is Dr. Diamond.

So, Dr. Howe, this is an example where the NRC staff holds one position and I, who was asked to review it as a clinician, hold a different opinion. To me the difference in the movement, whether it would have been a centimeter or seven centimeters, is irrelevant. The real question is what was the causation. What was the root cause, and making sure that experience is not replicated anywhere.

And number two, just from a regulatory point of view, did it fit or did it not fit a reportable medical event? And my feeling was it did not meet a reportable medical event for the reasons that I mentioned.

DR. NAG: I think that it is important to discuss in the ACMUI because, you know, from the physician's standpoint I agree that if the treatment was started correctly, if all the parameters were started correctly, and the whole basis of intervention, whether movement, accidental or not

accidental, that caused a failure or that caused a movement of the device, whether the HDL gamma knife, that really should not be a medical event.

And the intention --

DR. DIAMOND: Reportable, reportable medical event.

DR. NAG: Right, reportable medical event. And I don't think this should be.

DR. WILLIAMSON: Well, actually it should be medical event. It does say that it's included in the definition of medical event, specifically the exclusion of patient intervention.

DR. NAG: Right.

CHAIRMAN MALMUD: Again, Dr. Williamson, you were making a case that it is or is not a medical event that's reportable?

DR. WILLIAMSON: Well, a licensee shall report any event except for an event that results from patient intervention. I guess if you consider that to be the definition, then it goes on with a more detailed definition of medical event.

So I see that this definition does not actually contain the phrase "medical event," except up in the title, 35.305.

DR. DIAMOND: Right. I refer to it as a

reportable versus nonreportable because of that language.

DR. WILLIAMSON: I'm curious to know what the staff's definition or characterization is of patient intervention and under what conditions it needs to be reported and in which conditions the language can be accepted literally as it states here and it need not be reported.

DR. HOWE: We're intending to write an information notice on our cases, on the case history that we have to give some inclination as to indication from the NRC perspective what the medical events are and what is not patient intervention.

We have a history going back. Most of our patient interventions that we have considered patient intervention in the past have been actual patients that have ripped out manual brachytherapy sources or ripped out templates for other sources. Some of these patients have not known what they were doing because they have been older patients and confused. We've had patients rip things out, pass them to the nurse, thinking the nurse asked for it when the nurse didn't.

We have a wide variety of cases. We don't necessarily consider patient movement in and of itself to be patient intervention. We've had a number of

cases where patients have moved, and the sources have moved, and they have not been considered patient intervention.

DR. WILLIAMSON: And why is that? That doesn't seem reasonable.

DR. DIAMOND: That's not --

DR. NAG: Excuse me. I would strongly say that patient intervention would be, whether voluntary or involuntary movement, would be a patient intervention. I mean, if a patient is coughing, I as a physician cannot control the cough. If a patient is really cold and is shivering and because of that the application is moving, that is not the licensee's fault. It is not something the licensee can control, and basically that is a patient intervention, whether voluntary or involuntary on the patient's part.

DR. DIAMOND: This is Dr. Diamond again.

The way I look at these is, "Did the licensee in a correct and appropriate manner instruct the patients before the initiation of the procedureas to what was expected, what to do if they had a problem, explain the risk involved in the procedure?"

For example, we always tell our patients as was done in one of the cases I mentioned, "We are listening to you. We are watching you. If you have

any problems, we're listening. Tell us what's going on," and this way if there's a problem about to happen, you can stop the procedure.

If the person says, "I'm in pain. I'm hurting," they say it; you stop the procedure; you rectify the problem, you fix the problem; and that squirming does not happen.

I think it's wrong, Donna-Beth, to say that patient movement itself, provided the patient was adequately informed about the expectations and you took reasonable precautions to make the person comfortable, that to me is patient intervention.

If you tell a lady whose lying in a shielded room with a GYN applicator in place that this source is, for example, in the vagina. It's packed, but you need to stay still. This is why you need to stay still. If you're having pain or problems, call the nurse or call us and we'll come in and take care of it, and that person wilfully does not follow those guidelines, to me that patient movement would fall into the rubric of being a patient intervention without any question at all, without any question whatsoever.

DR. NAG: I agree wholeheartedly.

DR. WILLIAMSON: I agree, yeah.

DR. HOWE: The ones that we've had in the past, most of our ones in the past that have been like that have been patient intervention, but there have been a few where they knew the patient was not going to follow directions. I think in one case there was a sedative that was supposed to be given to the patient and the nurses didn't give the sedative. So there are a few of those that in those cases we have not considered.

DR. DIAMOND: Right. In that specific case, I agree with you. Again, if the patient was not informed or if the licensee did not take reasonable action, so, for example, if the patient was saying on the table, "My back is hurting. I need a break," and you did not interrupt the treatment and give some medicine; if you did not go and give reasonable sedation or pain medicines in advance to a woman who is about to start a 48-hour GYN application, I would agree with you.

What other example?

DR. WILLIAMSON: Or if you didn't take reasonable precautions to observe and follow up with the patient periodically to detect the event at a proper time.

DR. DIAMOND: And a reasonable sense that

the patient would not be able to follow your instructions to me is a contraindication for doing the procedure. If you have a woman, for example, who, let's say, has some mental disorder, let's just create a hypothetical of a woman with paranoid schizophrenia. That's probably not the best person to do a low dose brachytherapy implant upon.

DR. HOWE: I think one of the things that contributed to these events, especially the one with the seven centimeter movement was I don't believe the licensee had , that the coordinates were going to shift. Their expectation-they knew the patient moved,the patient asked to move-they knew the patient moved. They knew they moved a lot. They did not stop the procedure to check the patient again. They continued.

Their expectation was that the head frame would hold the patient in place. The same thing with the coughing patient. There was no expectation that there would be any change in the coordinates, and a recognition that the system was not as stable as it would have been in other cases.

DR. DIAMOND: This is Dr. Diamond again.

In that particular instance, the real question was this, and I commented upon this very

specifically in my report. Should the licensee have had the foresight to interrupt the treatment when they saw the patient was squirming or not?

And I can tell you as someone who has done a lot of these procedures, it is a simple judgment call. Any of us lying on this table for a period of time would start to have some discomfort and the question is at what point do you break it. If someone is 90 percent of the way through a treatment, oftentimes it's much better just to say, "Hang in there," encourage a patient and finish it up.

It is purely judgment, and this is an example of -- again, I'm not trying to be difficult, but unless you've done, you know, two or three or 500 of these, it's hard to kind of give you a little bit of clinical context, and that's just a professional opinion.

DR. NAG: Yeah, I think this is a situation where ACMUI members' input should be allowed to stand. Here we have an expert who has reviewed the case who is an ACMUI member, who hopefully has no ulterior motive, and is saying that this is something that happens in a medical treatment situation, and I think that should be allowed to stand. Otherwise, what are we doing here?

DR. HOWE: Orhan.

DR. SULEIMAN: Yeah, I think we've had this --

CHAIRMAN MALMUD: Dr. Suleiman.

DR. SULEIMAN: Yes, I think we've had this philosophical discussion before, but I'm going to say it again. With FDA we have severe, life threatening, adverse events report, adverse events. It's not a perfect system by anybody's stretch of the imagination, but the purpose of this is to report the medical events. Then you do an analysis. Is it a device specific problem? Is it a drug related problem? Is it a user problem?

And then if we get into the user situation, is it within that gray area of practice of medicine, this is tolerable, this is acceptable, or is it really something that's beyond the scope of normal practice and, in fact, represents a serious, you know, issue that needs to be addressed?

So did you categorize these in any way like that or just trying to evaluate them on a case-by-case basis?

DR. HOWE: We normally evaluate reports of potential medical events on a case-by-case basis. We do think that there were equipment maybe not failures,

but incorrectly -- either equipment wasn't set up correctly or there were equipment failures.

DR. SULEIMAN: Well, was it a design problem or was it a misuse; was it a use problem, you know? Or was it inadequate instruction, too, obviously?

MR. LEITO: What was the failure specifically?

PARTICIPANT: Of the equipment.

MR. LEITO: I mean, in your judgment -- this is Ralph Leito -- what specifically in NRC's judgment was the failure of the equipment that you're sort of overruling or setting aside Dr. Diamond's judgment?

DR. HOWE: We believe on the seven centimeter case that there probably was not correct tightening of the screws and the patient movement exasperated the problem.

We believe on the three pin, although three pin is a common thing, we believe that maybe the pins were not put in tight enough because they adjusted the pins and then they took the pin out. So they've got a totally different dynamic force than taking the pin out and then tightening the three remaining ones.

DR. DIAMOND: And, again, Donna-Beth, this is Dr. Diamond. I'm trying to do this as respectfully as I can.

But I'm telling you as someone who has put in a lot of pins in people's skulls --

DR. HOWE: It's an art.

DR. DIAMOND: Not only is it an art, but the anatomy is such that there can be some slight movement of these pins. That's it. You're not taking a screw and going in through a solid piece of oak. These are human skulls that have inner tables and outer tables and --

DR. HOWE: We recognize that.

DR. DIAMOND: -- and marrow, and it sometimes can happen.

In the other example that you referenced, I would put it to you that if the normal strength human being places torque on these pins and secures the frame and then you have someone who is 275 pounds, five foot, nine, and is pulling the small of their back up so that the entire weight and force of their body is resting on those things, it's just like if I were to go and stand on this head frame. I could certainly imagine that appropriately manufactured equipment that are tied in with the appropriate degree

of torque could certainly slide.

They're not designed for that type of stress, in my opinion.

DR. WILLIAMSON: Do you have evidence that the screws were improperly tightened?

DR. HOWE: The licensee has sent the Y-Z bars back to the manufacturer, but they just sent them back to the manufacturer for review in the last month.

But we were concerned that so far the manufacturer's information and other tests that have been done -- and the licensee themselves took a new Y-Z bar, and they had the RSO really pulled tight on it and tried to move it, and they demonstrated it could move, but it only moved millimeters.

But, again, the issue is not the distance that was moved. It's whether it was an equipment failure because once you have movement, all that happened is that those Z bars slid down until the frame hit the base of the gamma knife unit. So it doesn't matter if it was one centimeter or a seven centimeter translational movement. It was whether the equipment failed or not.

I mean, that's the basic issue, and I'm saying to you if I went and stood on this frame and the frame was manufactured correctly and tied in with

the appropriate degree of torque, I would think that it's perfectly understandable that that equipment at that point would start to slide, and again, in this particular instance with the specifics involved of a very heavy man rising his whole body up, I could see how that would happen in the case of appropriate procedures.

CHAIRMAN MALMUD: If I may, it sounds as if you have opinion from three members of the ACMUI that in this one case of the five that you've cited, that they perceive it to be a patient movement issue rather than a licensee responsibility, and we would hope that you would bring that into consideration in this one out of five cases.

DR. HOWE: Okay.

CHAIRMAN MALMUD: May we move on to your next item?

DR. HOWE: Our next one is the Yttrium microspheres. In this case both of our medical events were with the serospheres. We don't think the Theraspheres (phonetic) are being used very much right now. We think FDA is -- FDA approved the Theraspheres under an HDE, which is a humanitarian device exemption, and they're only supposed to be used for specific types of diseases that -- for one disease

under the humanitarian device exemption, and otherwise they go into research, and we think FDA has probably gone back to Theraspheres and making sure that they're only being used for this one particular use it has been approved for.

Serospheres, on the other hand, came through a PMA, and once it comes through a PMA, then under the practice of medicine, a physician can decide to use it for a different treatment than it was approved for. So we think there are probably more serospheres applications out there now, and there are very few Theraspheres.

In the first case there was a pressure build-up, and the description was it was from the liver catheter, and as a result one of the tubes on the V value -- V vial popped off, and the microspheres spilled out of the V valve, and they lost about 25 percent of the microspheres, and they continued the procedure. So it was a medical event. They weren't able to deliver the entire dosage.

The second one, the licensee had difficulty measuring to the precision that they believe they should have the Yttrium in the V vial before they went to the OR space to deliver it, and they came to a decision that they should use a visual

method of estimating how many spheres were left in the V vial to determine the dose that they were going to deliver.

They did not want to deliver the entire dose. They only wanted to deliver a fraction of the dose. So they carefully monitored the volume of the V vial. They stopped the procedure when they thought they had it at that point. They pulled the catheters out. They ended the treatment, and then in accordance with the manufacturer's instructions, they do a measurement of the tubes and the materials afterwards, and they found that the readings were much higher than they had expected, and that a significant number of the microspheres had caught up in the valve going into the patient and had not, in fact, reached the patient.

So that was our second medical event.

CHAIRMAN MALMUD: So if I understand you correctly, what happened is they did a visual estimate of the amount of the activity delivered and then discovered afterwards they had given a smaller amount than they had anticipated giving to the patient.

DR. HOWE: Significantly smaller because they had not realized -- and the manufacturer's rep. was with them at the time, and they had not realized that there would be as many of the microspheres caught

up in valve as there were.

CHAIRMAN MALMUD: Delivery device.

DR. HOWE: Yes.

DR. WILLIAMSON: Excuse me. What would have been the normal pattern of use that would have?

DR. HOWE: The normal pattern of use would have been using a radiation detection measurement to verify how many, or the relative percentage, of the microspheres that were delivered. So you put a meter in a certain place, and you'd still be measuring all of the spheres that are still within the delivery box system.

CHAIRMAN MALMUD: That's a calibrated approach to seeing what's left in the box versus what's the identified.

DR. HOWE: Yes. It's not necessarily calibrated because these are Yttrium microspheres. So that you're not going to really measure that much in the patient. You're not going to get that much of a measurement coming off of the patient.

CHAIRMAN MALMUD: Scatter.

DR. HOWE: But you can use it to do a more --

CHAIRMAN MALMUD: Thank you.

Dr. Nag, you had a comment?

DR. NAG: I do. I do the procedure routinely, and therefore, I'd like to comment. First of all, visually you cannot see what percentage. I mean, I have tried making some estimations. You can never make a visual guesstimate.

But the more important thing is that while you're injecting, you really cannot say how many microspheres put in. The only way you know it is after the fact when you measure the V vials later, within after a few minutes.

So, therefore, from my standpoint, what we do is we write a prescription or the interactive as to the total amount you wish to give, but at the end of the procedure, you accept whatever you did here.

So let's say I wanted to give most of the time it's about two Giga Becqerel to inject, and as you're injecting, you're looking into the flow, and if you see that the flow is not going well, you stop the procedure irrespective of whether you are anywhere near that two Giga Becqerel or not.

So you stop the procedure as soon as you see medically you should not give any more, and then you measure whatever is left, and you deduct that and say we gave X number of Giga Becqerel , and you sign, and if it is more than 20 percent below, then you say,

well, you know, you are allowed to rewrite the prescription because there was stasis or because you cannot give any further dose.

So on the first patient I have no problem because, you know, that was an absent thing, and there was spillage, but on the second patient, you know, you are allowed to, you know, rewrite your prescription because you stopped it when you felt that, you know, you had given enough, and you remeasure whatever is left. You really cannot judge what you have given.

DR. HOWE: Dr. Nag, the guidance that we have -- and your original statement was a little questionable, but as you described it, it is in accordance with our guidance. Our guidance is written because we recognize that the serospheres is monitored with fluoroscopy, and it is not important to give the total dose. It's important to give the dose until you see back scatter.

And that wasn't what happened in this case, and we do expect people to report medical events if they don't give what they expected because there is a problem in the delivery versus your medical endpoint, which is accepted by the NRC and it should be part of your written directive, and that's stasis. We recognize that as a part of medical practice.

But in this particular case, they weren't monitoring for stasis.

DR. DIAMOND: So this would be an example -- this is Dr. Diamond -- where I would agree with you, Donna-Beth, because the intent to deliver was not what was actually done. It's a matter of intent.

I would put it to you probably to say that this was an example of an inexperienced team not fully understanding it. So they were probably a little conservative, a little tepid. They didn't want to go and continue the administration of the isotope until stasis had been achieved. They went in and probably said, "let's just go and stop it once we estimate that so-and-so activity has been delivered."

And then, lo and behold, they realize that visual estimates of the V valve are very difficult to make. So --

DR. NAG: Impossible.

DR. DIAMOND: It's impossible to make. So this I would agree with Donna-Beth would be an example that would meet the criteria.

DR. HOWE: And I think we were especially concerned on this particular case because the manufacturer was with them, and we would have expected better guidance out of the manufacturer.

MR. LEITO: I was just mentioning that I agree with that wholeheartedly because if the vendor was here and they're not following a standard protocol, they should have kind of said, you know, is this really what you want to do, and caution them on that.

It's very bothersome that the vendor was there and didn't interact.

DR. HOWE: In this particular case, they wanted to give a certain activity, and they believed they had given that activity based on a less than routine method of determining what that activity was, and in fact, they had not because of equipment problems.

DR. NAG: So they didn't up the activity they wanted to. Normally --

DR. HOWE: No, they did not. They had a vial with a set amount of activity. They tried measuring it, and determining the activity they were going to use. They were having a lot of problems doing that to the level of expertise they wanted, and so in the end, they decided we'll take it to the OR, and we'll give 65 percent, and they didn't.

DR. NAG: But the question is if they didn't know how much they drew up, then how could --

they measured the amount of residual. What did they subtract from? Do you mean they took the whole vial instead of drawing up a second amount?

DR. HOWE: That's correct.

DR. NAG: Well, that's not -- that's not acceptable.

DR. HOWE: And that's part of their -- their corrective action is to take the time, draw up the right amount, and deliver it. They, too, have the ability to stop at stasis, and no one wants to have medical events reported when the physician is making the determination that stasis is reached, and that's why we put that in the guidance. We're hoping that the physicians are putting that in their written directive.

So you're not really revising the written directive, Subir. You are actually -- the written directive should say you're going to deliver this amount --

DR. NAG: Or stasis.

DR. HOWE: -- or stasis, and allows you to write how much you delivered if you went to stasis. So you're not really revising the written directive, but you are recording exactly what you intended to do.

CHAIRMAN MALMUD: Dr. Howe, let the record

show that the members of the committee are fully supportive of your recommendation in this case.

DR. HOWE: Okay.

CHAIRMAN MALMUD: May we move on to the next one?

DR. HOWE: I think that may be the end.

CHAIRMAN MALMUD: Thank you very much.

DR. HOWE: Okay.

CHAIRMAN MALMUD: It being 12:10, I will turn the opportunity over to Mr. Essig if he wants to say anything. If not, we'll adjourn for lunch.

MR. ESSIG: We can adjourn.

CHAIRMAN MALMUD: We are hereby adjourning for lunch. We'll return promptly at 1:15.

Thank you all. Thank you, Dr. Howe.

(Whereupon, at 12:10 p.m., the meeting was recessed for lunch, to reconvene at 1:15 p.m., the same day.)

CHAIRMAN MALMUD: Okay. Let's get moving.

DR. ZELAC: I'm sorry that Dr. Nag isn't here for these opening remarks. But I will proceed anyway.

CHAIRMAN MALMUD: He is here. We had lunch together.

PARTICIPANT: He was here just a moment

ago.

DR. ZELAC: Okay. There he is. Good timing. We held up the meeting just for you.

(Laughter.)

DR. ZELAC: Okay. I wanted to start by once again thanking the Advisory Committee for the recommendations which it provided and particularly for the efforts of the Medical Events Subcommittee. The document that was produced, and I know a lot about the effort that went in since I was the assigned staff member, really makes it easy for us to utilize this information and move ahead.

This morning or this afternoon, this is the next step in this ongoing process of looking at the medical event definitions and, when necessary, suggesting modifications that the Commission can consider.

Where we are at the moment, as you can appreciate, is staff having received the recommendations from the Subcommittee -- from the Advisory Committee, has now drafted a Commission paper which you on the Committee have had an opportunity to see.

And I'm going to review what the paper says essentially, this draft paper, with respect to

the various recommendations that were included in the document that we received from you.

Just in the way of background, you, the Advisory Committee, in looking at a specific event and in response to our desire for input from you, recommended in November of `03 that D90 be utilized as the criteria for prostate therapy under-dosing. The same criteria, however, was recognized immediately as not appropriate for the overdosing situation.

In March of `04, at the time of your opportunity to speak with the Commission, we, the staff, received direction from the Commission to consider the basis and adequacy of medical event definitions as they appeared in the regulations and as well to look at communicating associated risks to the public. And these efforts on our part were to be done in conjunction with input from you as the Advisory Committee.

From the period of October of `04, a year ago, to the end of this past July, the Advisory Committee, you, developed recommendations on these issues for staff's use. There are actually several categories that were considered in these overall recommendations.

The first was the basis for the plus or

minus 20 percent of prescribed dose reporting threshold for medical events that appears in the current regulation. The Commission wanted us to look at it again and determine whether or not this indeed was an appropriate threshold for medical event reporting for all modalities.

The second area in which you provided recommendations were on specifically the current definition itself. When it was appropriate and when it might not be appropriate.

And finally, you provided recommendations on the last question that the Committee posed to us which was improving public understanding of the risks associated with medical events.

Now I'm going to essentially tell you what our response is to these three different areas or categories on which you provided recommendations.

The first, the basis for the plus or minus 20 percent of prescribed dose as the reporting threshold for medical events. You recommended that we retain it -- plus or minus 20 percent of the delivered dose variation from prescription as an appropriate threshold for medical event reporting for all modalities except permanent implant brachytherapy. Staff endorses and supports this ACMUI recommendation.

CHAIRMAN MALMUD: Malmud, thank you.

DR. ZELAC: You included in your recommendations a caveat that medical events should not be treated by us as surrogates or harbingers of patient harm. Or even necessarily of increased probability of patient harm.

You indicated that medical events, in your judgment, should be considered as a quality assurance performance index indicative of technical or QA problems and accurately realizing the authorized users' intentions.

We, staff, endorse and support this ACMUI position which is, in fact, consistent with NRC's previously stated position.

CHAIRMAN MALMUD: Thank you Dr. Zelac. Next, permanent implant brachytherapy. Your recommendations for reformulating the medical event reporting rule with respect to this modality as well as associated definitions. You provided six recommendations, and I'll start by telling you that we endorse and support all of these recommendations in this item.

And I'm simply going to reiterate them in the way that I have, in some cases, reworded them perhaps, hopefully, adequately to reflect your intent

from your recommendation sheet that we received in July.

The first, for all permanent implants, medical events should be defined in terms of the total source strength implanted in the treatment site, not in terms of absorbed dose.

At any time, if you wish to interject, please feel free to do so.

Continuing, second, any implant in which the total source strength implanted in the treatment site deviates from the written directive, and that means the written directive prepared prior to the implantation, where there is deviation from the written directive by more than 20 percent in either direction, this treatment should be classified as a medical event.

However, as in the current medical event rule, the Advisory Committee intends that seed migration be specifically excluded as grounds for a treatment site accuracy medical event. Again, we completely accept this recommendation.

Third, implants in which more than 20 percent of the total source strength documented in the pre-implantation written directive is implanted in tissue or organs adjacent to the treatment site, which

means within three centimeters of the treatment site boundary, these implants should be classified as medical events.

In other words then if more than 20 percent of what the physician had indicated would be used in terms of the amount of activity in the pre-implantation written directive winds up in tissue or organ adjacent to the treatment site, that treatment should be classified as a medical event.

And again, seed that were correctly implanted but subsequently migrated are excluded as grounds for a medical event.

Ralph?

MEMBER LEITO: I think the words greater than should be in there. This makes it sound like if it is within three centimeters it is a medical event.

DR. ZELAC: That was the intent. That was the intent of the recommendation. Not in the target volume but in the tissues or organs that would be surrounding the target volume but within three centimeters, i.e., those that were nearby.

If 20 percent of the total --

MEMBER LEITO: You can't have more than 20 percent --

DR. ZELAC: -- activity --

MEMBER LEITO: -- that's correct.

PARTICIPANT: It was greater than.

DR. ZELAC: Yes, if 20 percent of the total activity that had been prescribed for putting into target volume wound up in this adjacent treatment site --

MEMBER WILLIAMSON: We had two criteria for wrong site. There was an adjacent tissue wrong site and a distant organ wrong site.

DR. ZELAC: This is the first of those two.

MEMBER WILLIAMSON: Yes.

DR. ZELAC: So it doesn't go into the target, it goes into the tissues or organs surrounding but near to the target. If you exceed 20 percent going into that perimeter, if you will, that becomes a medical event.

Next, and here we are to the other one, this one is longer because this is not only a placement but also then has some dose criteria associated with it. Implants should be classified as medical events if:

One, the sealed radioactive sources are implanted in distant tissues or organs, meaning beyond three centimeters from the treatment site;

Two, the excess dose to the distant tissue or organ exceeds .5 sievert, 50 rem; and

Three, the excess dose to the tissue or organ is at least 50 percent greater than the dose that would have been delivered had the seeds been implanted in the correct tissue volume.

The last two of those three conditions, of course, mirror what exist in the regulation today.

Seeds that were correctly implanted but subsequently migrated are excluded as grounds for a medical event.

Next, the authorized user is to complete any revisions to the written directive for permanent implants to account for any medically necessary plan adaptions or by the wording of our current regulation, the authorized user is to complete the written directive before the patient is released from licensee control following the implantation procedure and immediate postoperative period.

The switch from a dose based to an activity based permits the practitioner to account for what went where it should and what went somewhere else as soon as the implementation is done and to so make modifications if necessary to the written directive as opposed to weeks or months later based on a dose

criteria.

Next, an implant is a medical event if the dose calculations used to determine the total source strength that is documented in the written directive to achieve the authorized user's intention for absorbed dose to the target volume are an error by more than 20 percent in either direction.

Okay? Just in case you didn't know who I was.

(Laughter.)

DR. ZELAC: Again, in summary, for this section of your recommendations, we endorse and support all of these six items that you provided. And this will be reflected in the Commission paper which you have seen.

CHAIRMAN MALMUD: Malmud, thank you.

DR. ZELAC: Now that leaves one item and that has to do with improving public understanding of the risks associated with medical events.

You may recall from the meeting or meetings at which the recommendations from the Subcommittee were discussed that you as a group eventually provided some general guiding principles and, in addition, four specific recommendations for improving public understanding of these risks.

Before we get into the remainder of the slides, let me tell you that we, staff, at this point do support the general guiding principles that you provided. And those will be included as recommendations that we make to the Commission.

However, we do not support the four specific recommendations that you offered in this area. I will go over them one by one and provide you with some reasons why I said what I just did.

The first of these recommendations was that the patient reporting requirement which exists in 35.3045(e) should be amended to require informing the patient and/or friends and relatives only if the licensee determines that the medical event may have harmed the patient, could potentially harm the patient, or is materially relevant to the patient's future medical treatment decisions.

We did not support -- we do not support this Advisory Committee recommendation for the following reason. The Commission has repeatedly stated and endorsed its position that a patient or human research subject involved in a medical event should be notified of the occurrence.

Most recently, and this appeared in the Federal Register notice for the revision of Part 35 in

2002, and I quote:

"The NRC retained the proposed requirements for notifying individuals following a medical event in the final rule. As stated in the proposed rule," and the citation is given, "this position reaffirms statements made by the Commission during the mis-administration rulemaking earlier that patient notification recognizes the right of individuals to know information about themselves which is contained in records both inside and outside the federal sector."

There are other things that I could say but that, in essence, is the reason.

MEMBER WILLIAMSON: Well, I haven't had a chance to read your report carefully line by line and I see you've put the staff's rationale for, you know, rejecting our recommendation. I hope you will put our rationale for proposing this recommendation in there. Or have.

DR. ZELAC: The recommendations themselves, the document that was received by us from you is an attachment, in its entirety, to the Commission paper. So the Commissioners and their technical assistants in reviewing this entire issue will have the full information and the full rationale

provided by the Advisory Committee as well as the comments made by staff in terms of its proposed action on each of the recommendations. So that was the first of the four.

The second, NRC's medical reporting event and follow-up procedures should be designed to not increase licensee liability. Keeping medical event reports or at least the licensee's identity out of the public record is probably the single most useful improvement NRC could make in this regard.

Again, this is a recommendation, a specific recommendation that we did consider and our recommendation to the Commission is that we not move in this direction. We don't support this recommendation because it is counter to the Commission's policy of public openness in the conduct of its business consistent with national security.

A current statement of this policy of openness appears in the 2004-2009 Strategic Plan for the Commission. Specifically Goal 3, Our Openness, and I quote:

"The NRC views nuclear regulation as the public's business and as such it should be transacted openly and candidly in order to maintain the public's confidence. The goal to ensure openness explicitly

recognizes that the public must be informed about and have a reasonable opportunity to participate meaningfully in the NRC's regulatory processes."

And reading on, "The NRC believes in the importance of transparency in its communications as well as early and meaningful public involvement in the regulatory process. The agency is committed to keeping the public informed and believes that a responsible and effective regulatory process includes an involved public that is well informed."

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Well, all of those are rationales for involving the NRC in its decision-making process. I am not aware that the NRC involves the public in its disciplinary or technical decisions regarding individual events such as this.

And I will also note that, you know, you certainly do not follow this statement to the point of extremity that you are articulating, you know. It's not -- you do withhold certain information that has nothing to do with the national security. And a good example is you withhold individual patient names and identities.

DR. ZELAC: Well, that's clearly -- to do other than that would be counter to everybody's

position not just this agency's. So I don't think that's a particularly good example.

PARTICIPANT: Yes, right. That's a privacy issue.

PARTICIPANT: Under HIPAA, you are obligated to.

MEMBER WILLIAMSON: Well, I mean it points out that there are other considerations besides national security in not releasing information. And, you know, I think the arguments about transparency, you know, really have nothing to do with this position.

The decision-making processes could be as transparent as they can be but you do not have to release identities in all cases of corporate entities that you regulate.

DR. ZELAC: There's a lot that goes into this. For example, say there is a medical event at a hospital here in D.C., okay? And an announcement goes out, a press release or whatever that this event occurred.

Now the public is put in the position of knowing that something occurred at a hospital somewhere in their vicinity but not knowing which one. Do you think that is very satisfying from the public's

point of view? I don't. I think they would lose confidence frankly in us as the regulator by not making this information available to them.

MEMBER LEITO: I think there was nothing in this recommendation that precluded or said that the public would not be informed. I think the issues has to do with the fact of making it a public announcement before any investigation has occurred. And before its even actually been determined that it is an actual medical event that needs to be brought to the attention of the public.

And I think all those statements that you made here I don't think anybody has a problem with except the only thing is I think this national security issue is really not appropriate here. There's nothing that deals with --

DR. ZELAC: Of course not. But --

MEMBER LEITO: -- national security here in terms of reporting. But there was nothing I think in this recommendation that was intended that the public would not eventually be informed of the incident and maybe the licensee that was involved.

It's just that, like I said, how it's done basically makes this a public -- a national announcement, okay, on an unsecured web location that

precludes, you know, any determination that it's even valid to begin with.

DR. ZELAC: Let me make two comments in response. First, with respect to information being made available immediately, as we pointed out quite correctly yesterday, most of the licensees, and that include medical licensees, are in agreement states. That's not, you know, debatable. They are.

And the agreement states have the opportunity when submitted information about an event to request that it be held from posting for a period of time which I believe has a limit of two days, 48 hours. It might be a little more but I think it's -- in any case, just to that exactly what you're speaking about can be assessed by the regulatory group.

Is this, in fact, a reportable medical event? No, is there any reason why we at the agency couldn't do the same? I don't know but that's certainly something that could be and should be considered to handle the first of your comments.

The second is looking specifically at the words of the recommendation, NRC's medical event reporting and follow-up procedures should be designed to not increase licensee liability. Keeping ME reports out of the public record is probably the

single most useful improvement NRC could make in this regard. That's the substance of the recommendation.

MEMBER WILLIAMSON: It is the substance. That's correct.

DR. ZELAC: Don't put medical event reports in the public record. And I think that is extremely counter to the position that the agency has and continues to have and I expect will have in the future with respect to the release of information to the public.

We used to even put out more information and a lot of that has been pulled back for national security reasons. But that which can be made available by the Commission's policy, directive, and intent is made available. So it would have to be a hugely important and overriding rationale for not reporting medical events. I frankly don't see it.

MEMBER WILLIAMSON: What actually the recommendation says is to the extent possible, NRC's medical event and follow-up procedures should be designed to not increase licensee liability. Keeping medical events reports or at least the licensee's identity out of the public record is probably the single most -- so it's a little more complex than you presented.

DR. ZELAC: Yes.

MEMBER WILLIAMSON: It wasn't -- it did not say unequivocally keep the medical event out of the public record but it does suggest that in many cases where there isn't any question of public safety, you could do that. And that would substantially improve, I think, the value of medical event reporting as a quality assurance tool.

DR. ZELAC: Dr. Diamond?

MEMBER DIAMOND: Yes, Dr. Zelac, from my perspective what we were trying to do -- at least I was trying to do with my input was we are trying very hard to make the ME reporting a quality assurance indicator and in no way denote some patient error.

By -- I was hoping that until such time as the staff could review a medical event report and, in fact, conclude that it is reportable and then make some basic determination whether some harm existed or potentially could exist, that by going through that algorithm, some basic checks if you will, that could go and serve as a very reliable or robust was of allowing the licensees to actually feel confidence that this is a QA indicator and not necessarily punitive.

Let's take an example.

DR. ZELAC: I'm actually with you with one exception and that was when you put in the words relating to patient harm. If you exclude that, the rest of it we're right on track.

MEMBER DIAMOND: Well, for example, let's take an example of ASTRO: Brachytherapy procedure where the intent of the licensee is to go -- or the authorized user is to radiate the coronary vessel. And let's say you're doing the procedure and for a total of 15 seconds, the source gets stuck in the common iliac artery.

And then the flow is released. The procedure is carried out. It is a reportable medical event because wrong site however everyone is in agreement that there was no possibility of patient harm.

We are trying to encourage the licensees to report that type of incident so that the manufacturer can be made aware, the states can be aware, and corrective action be taken on the manufacturing side. We're trying to get these things captured for the public good.

But to go and release that information without any context I think serves to impede that goal rather than promote it. There's no way that an

individual or a member of the public has been harmed by that event. And what it actually will do is impede the licensees' sense that this actually is a QA indicator.

That's the flavor of what I was trying to get through.

DR. ZELAC: Do you think that the event that you just described is indicative of something relating either to the equipment or to the procedures used by the licensee as in need of improvement?

MEMBER DIAMOND: Certainly. And that's why I want to make sure that it is captured. I want all the licensees to understand that there are issues either with operator or with manufacturing. We need to capture those.

What we don't want to do is have a little situation where the authorized user or the AMP is not reporting that because they are so afraid that the sky is going to fall down upon them.

DR. ZELAC: Well, that really gets to some of the other recommendations that you've made specifically.

MEMBER WILLIAMSON: Where you unnecessarily --

MEMBER DIAMOND: I mean is that kind of

the sense --

DR. ZELAC: Yes, I understand exactly what you're saying.

MEMBER DIAMOND: So the question is how do you put that in statute? That's the tough part.

DR. ZELAC: Well, the other way, of course, is to take a look at the other element and that is the overall objective of improving public understanding of what a medical event means.

So you remove from public thought the possibility of it necessarily having any relationship to patient harm. But you instill the thought that it does relate to the procedures themselves and possible improvements required for the procedure by the users.

MEMBER DIAMOND: This is Diamond again.

MEMBER WILLIAMSON: Or the equipment.

MEMBER DIAMOND: I will say that I am less uncomfortable with the staff's decision because of the fact that you did endorse our position very clearly that we're trying to decouple this as a denotation of harm.

So yes, if it were up to me would I keep it the way that you are recommending it at this time? Absolutely not. But do I feel a lot better that I can go out to my colleagues and the professional societies

and say the NRC staff endorses this position of decoupling, that's going to make everyone feel better.

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: I too have a problem with the automatic posting. And as you are aware, many of the states have had problems with that. And most often brought up is that we don't know what is going on but we are required to report it.

I can tell you that we have seen two negative actions to things being posted immediately. The first one is the licensee instead of dealing on a technical level confronts the inspectors with lawyers. And the risk management people get involved. And it makes the investigation more difficult.

The flip side of that is where an employee is involved. We have a very good case now where as soon as it sort of hits the press there are a group of lawyers that want to make sure that someone pays. Them usually. Pays to them money. And so all of a sudden, the people who were there when the accident occurred don't want to talk to us either.

So it really -- it's not conducive to a good investigation. Now when you say things can be withheld, I would certainly hope that -- and this is sort of preaching for the agreement states and not so

much you -- is that there could be a mechanism generated where we say this is under investigation just as we do with our own public records.

We say this is under investigation. We will not tell you until the investigation is closed. And we need the same mechanism, and I think the medical facilities need the same mechanism where sometimes incorrect information is put out under the guise of openness and that information turns out to be totally erroneous.

And that's all I'm saying. We need some mechanism where everything just doesn't have to automatically go out.

MEMBER WILLIAMSON: I think our whole argument was it does harm to the process. It diminishes and undercuts the very effectiveness of the program you seek to promote. And so fine. If you want to be a QA kind of process for show that's not real, like window dressing, well then just keep it this way.

DR. ZELAC: Can I make a suggestion to the Committee?

CHAIRMAN MALMUD: Please do.

DR. ZELAC: The paper that you have opportunity to review is a draft. And that was the

whole purpose of bringing it to you to see what your reactions to it would be.

There is absolutely nothing that would prohibit -- and, in fact, I am encouraging you to focus some additional attention on this and to provide something else as a rationale to further support what you've said in your recommendations perhaps or to expand on them or just amplify them or bring them more to the forefront.

And that certainly could be included as an attachment to the Commission paper or embedded in it. You know obviously there are a lot of reasons why, you know, this recommendation was made to begin with.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: Yes, the way I interpret what's being done here, this is raw data. I mean --

PARTICIPANT: Correct. It's very raw.

MEMBER SULEIMAN: And you've got to be careful about -- even when you've analyzed and reached a decision sometimes the wrong people misinterpret it and it causes problems. And I think we've been the victims of some of that anyway.

But I think it is raw data. And so there wouldn't be anything improper to hold back on reporting it until it has been analyzed in a more --

in a better way.

DR. ZELAC: Just for my own clarity and understanding what you've just said, you're not addressing the issue of the licensee contacting the regulator.

MEMBER SULEIMAN: No.

DR. ZELAC: You're addressing the issue of the regulator releasing this information to the public.

MEMBER SULEIMAN: Correct.

CHAIRMAN MALMUD: Exactly.

DR. ZELAC: Okay.

CHAIRMAN MALMUD: Exactly.

Go ahead, Dr. Diamond?

MEMBER DIAMOND: This is Diamond. I'd like to make a motion. The motion would be that the ACMUI recommends to the NRC staff that the staff does not make available to the general public a medical event until such time as the staff has number one, confirmed that it is a reportable medical event, and two, that the staff concludes that there is at least a meaningful likelihood that there may be a patient harm.

MEMBER LEITO: Is there a second to Dr. Diamond's motion?

PARTICIPANT: For the sake of discussion, I'll second.

CHAIRMAN MALMUD: All right. Dr. Nag?

MEMBER VAN DECKER: No, I second it.

CHAIRMAN MALMUD: Oh, okay. May I address the motion?

MEMBER DIAMOND: Of course.

CHAIRMAN MALMUD: The first part that's reportable, I think we all agree. The problem with the meaningful likelihood of patient harm is that many of the exposures that we're talking about will really never result in patient harm but are clearly in violation of regulation.

So perhaps you can find some other words to express the same thing rather than meaningful likelihood of patient harm.

MEMBER DIAMOND: Well again, what are we trying to do? We're trying to capture the events, make sure that they are reported to the states or to the NRC so that they can be evaluated, analyzed, and at the same time, we're trying to prevent needless anxiety and concerns by the widespread dissemination of details regarding individual cases when we know that there is no meaningful likelihood that any potential harm could occur. That's what I'm trying to

express.

CHAIRMAN MALMUD: Mr. Leito?

MEMBER LEITO: My understanding of Dr. Diamond was that they are all getting reported, you know, all these events are getting reported. But then there is this analysis as to, you know, does this really -- is there some harm or likelihood of harm that needs to get out into the -- you know, needs to also be reported to the -- or that the public needs to be informed on.

Not necessarily that they are going to do anything. But that as opposed to a number of these events that just have nothing to do with anything that the public would need to get involved in or need to be informed about.

DR. ZELAC: Can I make a comment at this point?

CHAIRMAN MALMUD: Yes, Dr. Zelac.

DR. ZELAC: Part of the reason for the release of information about a medical event is to raise the awareness of others promptly to this occurrence so that they perhaps could consider the possibility of similar things occurring at their same facilities.

PARTICIPANT: You wouldn't need to release

a name to do that.

DR. ZELAC: No, you would not. I agree.

CHAIRMAN MALMUD: Whoever was next. Either Mr. Leito or Dr. Nag.

MEMBER NAG: Okay. You know, David, you made two motions within one motion, okay? I would separate them. The first part of your motion was that the NRC does not release the reported medical event until it has the time to investigate that. And really make sure that it is a reportable medical event. That's one motion. And I fully support that motion.

The second part, I think, should be made as a separate motion because there may be more debate in that as like, for example, Orhan said, that do we want to link this up and let people be aware that these sort of events can happen so that the other medical -- other authorized users are aware about these possibilities. And can prevent it from happening in their own place.

CHAIRMAN MALMUD: Dr. Diamond?

MEMBER DIAMOND: So if I may, I would like to amend my motion. The amendment would be firstly, that the NRC Advisory Committee recommends that the NRC staff release the details of a medical event to the general public only after such time as the staff

has confirmed that it is a reportable medical event. That's Motion No. 1.

Then the second motion would be again that the Advisory Committee recommend to the NRC staff that the details of a given medical event be released to the general public only if the staff determines that there is any reasonable risk of potential patient harm.

CHAIRMAN MALMUD: That's a motion.

MEMBER NAG: Two motions.

PARTICIPANT: I'll second the first motion.

MEMBER DIAMOND: I decoupled it for you.

CHAIRMAN MALMUD: All right. Was there a second to those two motions?

PARTICIPANT: Second.

CHAIRMAN MALMUD: Now may I ask a question? What would happen if a patient were harmed during a radiotherapy procedure and the NRC did not release the information but instead the patient's brother-in-law, a local lawyer, notified the press that this had happened.

And there was no indications that the responsible federal agency or state agency was actively pursuing it at the time that the press

release came out from an interested party other than the party who should be investigating it.

That would diminish the public's confidence in the regulatory process. So how do we separate what I know you are addressing, which are really issues that are relatively inconsequential, from significant issues. And sometimes there is a gray area as to what is significant or not so as to maintain public confidence in the oversight of the regulatory process, and and yet not create crises where there are none, which is what you are trying to avoid.

MEMBER DIAMOND: This is Diamond again. What we're trying to do is number one, make sure that the information that is disseminated is meaningful information. So, for example, if the release of medical events to the general public is limited only to events that we have confirmed to be reportable medical events, that has eliminated a lot of trash. Right?

If the staff deems that this does not meet the reporting requirements, then we've been able to produce data that is of true interest to the public. That's number one.

The second point, which has to do with

dissemination of information regarding a given event, what I am trying to do is I am trying to capture all of this data for the authorities but only release the details, the specific details, the details that could identify the licensees, the authorized users, for example, only release that type of identifiable information regarding an event if there is any likelihood of risk.

In other words, the example that I used before of an Iridium-192 ASTRO; Brachytherapy source being stuck in the common iliac artery for ten seconds, yes, it is a medical event. It is a medical event but we know that there is no potential risk really to that patient of a meaningful or reasonable degree. Why is it necessary that the Ohio State University, Subir Nag, authorized user, da-da-da-da-da -- be detailed.

Again, we want Subir to report his errors.

(Laughter.)

MEMBER NAG: I don't have any.

(Laughter.)

MEMBER DIAMOND: We're trying to encourage it so we can go and fine tune the system that he inadequately designed but we also don't want to go and impede that so that when I go and speak to Subir all

I speak to is the Ohio State University general counsel and the legal team.

So again, what I'm trying to do is the information can be released as a general informational summary or as a notice. But we don't need to necessarily release the identifying information that would cause anxiety in Dr. Nag unless there was any reasonable likelihood that there could have been a harm.

CHAIRMAN MALMUD: Dr. Diamond, I understand the goal. And I agree with the intent. I'm just concerned about how we achieve it. But I'm not sure that it is contained in the motion.

But Mr. Bailey wants --

MEMBER BAILEY: You asked what would the reporters say or whatever, I think this occurs on a -- well certainly not daily but fairly frequently. We'll get a call about something that has occurred, whether it be a traffic accident or whatever.

Normal response is yes, we are aware of it. It's under investigation. And when more information becomes available, we will give it to you. And I think that works better than sometimes the opposite happens when somebody puts out a press release and then has to say the next day, oh, never

mind, you know, it really wasn't that big a deal.

So I think it is the appearance of the agency. If the agency seems to always throwing stuff out there, it's like I want another press clipping or whatever as opposed to being right up front with the reporter and saying yes, we know there is this allegation or we know there has been this accident. And we are in the process of investigating.

CHAIRMAN MALMUD: So, Mr. Bailey, are you supportive of Dr. Diamond's double motion?

MEMBER BAILEY: I think I am.

MEMBER DIAMOND: Let's talk about Motion 1 and Motion 2.

CHAIRMAN MALMUD: All right Motion 1, do you want to take a vote on Motion 1? Or you have some more to discuss on Motion 1?

MEMBER BAILEY: That was actually Motion 2 but I'm not sure.

MEMBER NAG: I think Motion 1 is far easier.

CHAIRMAN MALMUD: Yes.

MEMBER NAG: Motion 2 has more discussion. So I would like to --

CHAIRMAN MALMUD: Do you want to call the vote on Motion 1? Okay. Just reread it.

MEMBER SCHWARZ: Dr. Malmud, would you reread the motion please?

CHAIRMAN MALMUD: Could Motion No. 1 be reread?

PARTICIPANT: Repeated perhaps as the case may be.

PARTICIPANT: I make it up as I go along.

(Laughter.)

PARTICIPANT: He recommends that the NRC staff release the details of a medical event to the general public only after such time as they have confirmed that it is a reportable medical event.

CHAIRMAN MALMUD: Thank you. That's Motion No. 1. All in favor of Motion No. 1? Any opposed? Any abstentions? So it is unanimously in favor of the motion.

All right, now Motion -- oh, Dr. Miller.

DR. MILLER: What I'm going to do here is I'm going to comment after you have voted on each of the motions.

CHAIRMAN MALMUD: Okay. Thank you.

DR. MILLER: That motion is related to the timing of the release of the information.

CHAIRMAN MALMUD: Yes.

DR. MILLER: That motion, I think that the

staff could entertain with regard to making a recommendation to the Commission without prejudging the conclusion that we come to.

CHAIRMAN MALMUD: Thank you.

Are we moving on to the second motion? Or do you want to -- do you have discussion regarding --

MEMBER WILLIAMSON: I want to ask a question about Motion 2.

CHAIRMAN MALMUD: Dr. Williamson has a question about Motion 2, Dr. Diamond.

MEMBER WILLIAMSON: Can you clarify, Dr. Diamond, if this was indeed your intent that when you say release details of the procedure, you mean identifying --

MEMBER DIAMOND: Right.

MEMBER WILLIAMSON: -- details that would identify the patient and licensee.

MEMBER DIAMOND: This is Diamond again. Based upon the input of my fellow members, perhaps I can amend once again my second motion to improve the language. Perhaps the motion should read the Advisory Committee recommends to the NRC staff that the identifying details of a specific medical event only be released to the general public in such cases where the NRC staff determines that there is a potential

risk of patient harm.

MEMBER NAG: I would like to amend the amendment. I think when you hear identifiable, I would like it to be clearly stated whereby identifying parameters of the patient, the authorized user, and the institution. I mean these are the identifiable things that should not be released.

CHAIRMAN MALMUD: We have to remember that we shall not identify the patient. We don't have the right to do that.

MEMBER NAG: Right. That's what I'm saying. That the identifiable parameters of the patient, the authorized user, and the institution not be released.

MEMBER DIAMOND: I don't think we need to worry about the patient because the patient's identity is never released. I think what you're saying is the identifiable details of the authorized user and licensee --

MEMBER NAG: Okay.

MEMBER DIAMOND: -- not be released to the general public until such time as the NRC staff determines that there is a reasonable potential for patient harm.

MEMBER NAG: Now the other question. Even

if there is a potential for patient harm, what is the need for releasing the licensee and the authorized user? Because you want to know what kind of problems went on. It's just like with a patient, you know, you want to know problems that have happened to a patient but not who that patient is. So we --

MEMBER DIAMOND: All right. Let's take an example. All right so there is an event at the Ohio State University. It is reported to the staff. The staff in one case determines it actually does not meet the criteria for a reportable medical event and, therefore, nothing else need be done.

However on the next patient that you see, it turns out that it is a reportable medical event. However it is a medical event involving this example of the ASTRO: Brachytherapy where there is absolutely no reasonable likelihood by anyone with common sense that a patient harm could be reported, we want to make sure that it is captured, that that information is disseminated to users in industry. But there's really no reason that the details of who did it and where it was done be released because it's just not necessarily -- it serves no public good.

However, the third patient that you've now seen in that one week, it is a medical -- a reportable

medical event. You really did perform an activity that really did pose a potential harm to that patient. And we would all be in agreement that if there is a potential for patient harm that the patient must know, the referring physicians must know, you need to be identified, the licensee needs to be identified so that appropriate corrective action can be taken.

MEMBER NAG: Yes, but that needs to go to the public. I'm not saying whether it needs to go to the NRC. Of course it needs to go to the NRC. But that information --

MEMBER VAN DECKER: It needs to go to the public. At that point, it really does need to be in the public space in my opinion.

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: I think if you went to the 33 agreement states you would only find one state, New York, that does not have an Open Records Act or similar thing that would allow anybody to come in at any time and look at anything in any licensee's file that is not a patient record or security-related material.

So I can almost tell you for sure that in all of the agreement states, and I believe the same thing would happen in NRC, if somebody came in with a

Public Records Act request or Open Records or Freedom of Information, they will get it.

And so the patient goes and -- or the patient's lawyer goes and gets it and I don't think the recommendation can be carried out under present law.

CHAIRMAN MALMUD: I have a question. Does any of you have concern? If you were practicing in a very short distance from another practitioner who was guilty of a number of errors and that practitioner were not identified as to the location of the incident, wouldn't you feel smeared by a brush that went across every provider in the area? That was a question for --

(Laughter.)

CHAIRMAN MALMUD: -- Dr. Diamond or Dr. Nag or anyone else.

MEMBER NAG: Well, I mean the question I had was somewhat different. If we have medical incidents happening, you know, all the time in a hospital. Let's say this same error did not involve radioactive material but involved a medicine where double the dose or triple the dose was given, it would come up in a QA meeting. It is a closed meeting. It is not discoverable. And, therefore, it is an openly

report and they openly discuss this in the closed setting.

However, if the same incident was in regard to a radioactive material, this now becomes a totally open reportable incident that is open to everybody.

So I'm wondering why should we make this difference when if you are using a drug that is ten times, you know, more powerful and that can cause the death, that is a protected discussion. And it's not discoverable by even lawyers.

CHAIRMAN MALMUD: Is that a question?

MEMBER NAG: That is an ethical question, yes. That is what I'm trying to bring up.

CHAIRMAN MALMUD: I understand. I'll play devil's advocate. We don't know the denominator of the number of incidents that occur -- of the number of services that are provided each year that resulted in 40 reportable cases this morning in this morning's session. We have no idea. But it is a very small percentage of the total.

We do know from the reports of the Institute on Medicine and others that medicine, medication errors are far in excess of the number reported. And are a much higher percentage of errors

than those with using radioactive material.

So although we're not patting ourselves on the back, we're doing a better job of it with this openness than we have succeeded in doing with our techniques of having quality assurance programs within the hospitals where we do not report to the public the number of errors that occur.

If the number of errors occurred in a manufacturing industry comparable to those that occur in a hospital, the industry would be out of business. And those data are available now nationally.

So I'm not sure that we should use that analogy because I'm not sure that analogy will carry water to use another analogy.

But the point is I think what we have to remember is that we are working within regulations that have been mandated by Congress and promulgated by this agency. So whatever we do has to be within the rules that we are asked to function under.

We all agree, 100 percent agree with Dr. Diamond's first motion. The problem is where do we separate an incident that's truly dangerous from one that isn't? And the answer is I don't think it can be determined all the time in very short order.

There may be a long investigatory period

and the public may lose confidence in our willingness or ability to investigate it. So I agree that we have a downside currently. But I'm not sure the downside is any smaller on the other side.

I say this as a member of the Committee not as the Chair of this Committee. I'm just offering my opinion.

MEMBER DIAMOND: I think this is an issue that we will not be able to resolve today. Perhaps this is something that we go back to our respective societies and entities to discuss.

Again, what I'm trying to put into writing is basically how -- by what methodology can a patient in a hospital who gets a Tylenol instead of an Advil with no adverse effect, how we can make the judgment that there's no need for the patient to be informed and the other physicians to be informed because we know there is no meaningful likelihood of a harm as opposed to the example of that patient who was supposed to get an Advil gets some morphine and has an event.

It's a matter of having -- of capturing information but also disseminating that information that serves the individual and the public good in the best way. And perhaps we should just table the second

motion and ruminate about it a little bit more.

CHAIRMAN MALMUD: So your motion is that we table the motion and ruminate?

MEMBER DIAMOND: Correct.

(Laughter.)

MEMBER NAG: The second motion.

PARTICIPANT: The second motion in our two-chambered stomachs.

PARTICIPANT: Just rumination?

PARTICIPANT: So can I ruminate with you?

CHAIRMAN MALMUD: Dr. Suleiman, did you want to make a comment?

MEMBER SULEIMAN: Yes, yes, why not.

(Laughter.)

MEMBER SULEIMAN: This is a rumination, okay.

PARTICIPANT: A little illumination on the rumination.

MEMBER SULEIMAN: I think the issue is a constant tension between trying to be open and being so open that you contribute to the public background which adds to the confusion. On the other hand, you don't want to be completely closed.

So I think we'd have to defer to the NRC's best judgment. I think it is too easy just to publish

everything. I think you have to assume some responsibility and say this is not going to contribute, you know.

But if you don't have an open attitude in collecting this information, how are you ever going to reduce medical errors? So I don't know what the answer is but I think we should appreciate the fact that if you go one extreme, it's too bad, and the other -- both extremes are not good.

But start someplace and you can adjust it later on. But I think you shouldn't report everything.

CHAIRMAN MALMUD: So, Dr. Zelac, we're throwing it back in your lap.

Dr. Miller?

DR. MILLER: From my perspective, okay, as a regulator and as an employee of the NRC, as a senior manager in the NRC, all public servant. So while I fully respect the views of the Committee on the matter of what we should report and what we should not report in the public forum, I think Dr. Zelac has clearly articulated the agency's view with regard to openness. I'm obligated to that.

I said I was sympathetic to the first motion because I think that that was a motion that

related to timeliness and it related to doing an investigation before you prejudge whether or not it was truly a medical event.

But I believe that if something is determined to be a medical event, since by our regulation it is required to be reported, that this agency has an obligation to be open about that.

You posed the question, Dr. Malmud, concerning what would happen if it wasn't reported. And then a local lawyer were to get it into the press. Well, Ed Bailey gave the view from the states' perspective. I'll give the view from the federal perspective.

What would happen would be the NRC would be contacted, probably through our Office of Public Affairs, and then we would be answering questions as to why we suppressed the information. And I don't think as a regulator that is a good place for us to be to continue to be credible.

This issue goes beyond the medical field. I think it goes beyond, you know, any events that the NRC gets reported and our obligation to openness. From that perspective, it just may be a point of departure between the views of the Committee and the obligations of the NRC staff.

And if a motion were passed and not ruminated on, if that's a word, I think, you know, the one thing that I try to bring and Dr. Zelac has clearly pointed out is I want to make sure that when the Committees pass recommendations and you have views, even if those views differ from the staff, that when we send things up to the Commission for their views and for their policy decisions that the Committees' views are clearly articulated in what we send up there so the Commission in its wisdom can decide if they agree with the staff views or if they agree with the Committees' views in setting policy.

From that perspective, I want to make sure that any actions that the Committee takes is fully articulated to the Commission in anything we send up.

CHAIRMAN MALMUD: Thank you.

Dr. Diamond?

MEMBER DIAMOND: Yes. As I continue to chew my cud, the reason that I primarily withdrew the motion, besides the fact that I didn't think we were going to have a conclusion today, is that I happen to disagree regarding the example you gave because your information officer could always retort well as you know, the dose that the patient received to that organ is less than that of a diagnostic x-ray.

The reason I actually withdrew it is that it would not be necessarily helpful or good regulatory language to go and thrust every single reportable medical event into your playing field and place the onus on your staff of determining whether there is a potential of a meaningful likelihood of harm.

That's the real hard part about it. Again, we all understand by way of analogy the Advil versus Tylenol example. We're in agreement versus the Advil/morphine.

But again, is it Ron who is going to decide whether 15 centigrade of common iliac versus 75 centigrade of the common iliac, utilizing this source versus that source? Is there a potential risk for the patient five years, ten years, twenty years from now? What happens if the patient is 70 years old? What happens if the patient is five years old?

That's really why I withdraw the motion because it's not really good language from which you would be asked to work.

DR. ZELAC: May I comment?

CHAIRMAN MALMUD: Please.

DR. ZELAC: A decision such as you've been discussing that would have to be made is really getting into the realm of practice of medicine. No

question from my perspective that that's where it is.

MEMBER DIAMOND: Of course.

DR. ZELAC: Secondly, we, as staff, do not represent ourselves as being in a position to make such decisions. What this would mean is that medical consultants would be obtained, their views would be obtained on all such cases. And we would be going with the opinions of such a medical consultant in making a decision on each and every one of these cases.

CHAIRMAN MALMUD: Thank you.

Dr. Schwarz?

MEMBER SCHWARZ: I think that the first motion that has been forwarded and approved is really a step forward. That essentially the timing issue has been addressed. And the remainder, as Dr. Diamond suggested, the practice of medicine, will essentially not be handled. It will be --

CHAIRMAN MALMUD: Thank you.

MEMBER SCHWARZ: -- it will be, you know, essentially put on the web and --

MEMBER NAG: Sally, I didn't hear you. Can you speak up through the mike?

MEMBER SCHWARZ: I think that the motion essentially has moved us forward. Just allowing the

timing issue to be considered. And that the practice of medicine stays with the physicians --

MEMBER NAG: Right.

MEMBER SCHWARZ: -- and that the staff is not asked to perform a function that really is not in their purview.

CHAIRMAN MALMUD: Dr. Van Decker?

MEMBER VAN DECKER: I just wanted to reiterate, so it doesn't get lost, Dr. Diamond's other point that in the first six list, the fact that there is a recognition that medical event does not necessarily mean medical harm to the patient is a key part of this. So that the description that is made to the public is a technical description of what went on for their own QA type modality type stuff. And that there is not -- and other assessments of that data for patient harm -- there are other forums and other technical expertise. And I think that is an important piece of this puzzle.

CHAIRMAN MALMUD: Thank you.

Dr. Nag?

MEMBER NAG: Can I make a suggestion? Whenever the NRC puts these out and say that this is a reportable medical event, at the end of that, the author puts a footnote that a reportable medical event

is not necessarily a harbinger of patient harm because that's something that we already stated.

But I mean if it is put along in that same context, people would remember that, you know, and make that connection. Because I know we have stated that in our policy. But then when you are sending out the report, the public may not associate that and may think that it might be a harbinger of patient harm.

So you can put that sort of a disclaimer basically on any of the reports that go out.

CHAIRMAN MALMUD: Thank you for that opinion, Dr. Nag. It's been heard.

DR. ZELAC: Does the Committee wish to entertain that as a motion?

CHAIRMAN MALMUD: Is there --

DR. ZELAC: I mean that's --

CHAIRMAN MALMUD: -- is that a motion, Dr. Nag?

DR. ZELAC: -- there is an action there. So there's really something very concrete --

MEMBER NAG: Okay, if that needs to be made as a motion, yes, I can make that a motion.

CHAIRMAN MALMUD: Is there a second to the motion first? Are you seconding it?

PARTICIPANT: No.

CHAIRMAN MALMUD: Is there a second to the motion?

MEMBER NAG: Well, I haven't made the motion yet. I was making a suggestion.

(Laughter.)

MEMBER NAG: First I made a suggestion.

CHAIRMAN MALMUD: I apologize. I thought that your suggestion was a motion. Sorry.

MEMBER NAG: I mean it didn't necessary make that as a motion, of course I think you know that. If it is necessary that I make that a motion then --

CHAIRMAN MALMUD: If you wish it to be followed through by staff, it is suggested that you make it a motion.

Did you still -- you giving up the floor, Dr. Nag?

MEMBER NAG: Well, he had his hand up first.

MEMBER LEITO: Well, I think -- if I could just -- I think there is a solution to this without making a motion.

CHAIRMAN MALMUD: Okay.

MEMBER LEITO: Because I don't -- I didn't mean to jump ahead but Dr. Zelac has, I think, already

addressed it to some extent in his second from last slide where he talks about improving understanding and publicizing these events and the wording.

I think if you just add to be included in any future releases of medical events what he already has in his recommendations, that would address -- so he's already -- Dr. Zelac has already alluded to that. We just need to expand where this is released at.

And the recommendation has already been made by Dr. Zelac. So if you want to just hold off until he gets to it, then, you know, we can just ask if it can be included there.

CHAIRMAN MALMUD: Acceptable to you Dr. Nag?

MEMBER NAG: Yes, I mean that's why I was making it as a suggestion and not as a separate motion because this was already included in many of the discussions. I just wanted to highlight it.

CHAIRMAN MALMUD: Let's move forward then. Dr. Zelac?

DR. ZELAC: Again, I think what we're really getting to is the fact that the overall objective is shared by all of us.

CHAIRMAN MALMUD: Yes.

DR. ZELAC: When we get down to some of

the specifics, there are details that we have to consider as regulators that might preclude our acting on some of the specific suggestions.

But the overall -- and in terms of, you know, that's a very good suggestion. And I appreciate getting it. And I think that we, you know, certainly can very, very seriously consider doing it.

I think that we went through two of the four specific suggestions and I think I will try to in the no time remaining finish up as promptly as I can with the other two plus the specific recommendations that Mr. Leito has referenced.

PARTICIPANT: You've got to three o'clock.

DR. ZELAC: I have until three? Oh, that's great.

(Laughter.)

DR. ZELAC: Since we do have just a little more time than I had thought, can I -- well, Dr. Diamond had made a motion which you have endorsed on release and the timing of a release with the implication that there are events reported by licensees which, in fact, turn out not to be reportable medical events.

And since Dr. Howe is in the audience, I was wondering if she or anyone else has any feel for

what the percentages are for events that we become aware of which turn out to not be medical events? Is it 10 percent? Is it 50 percent? Or something else?

DR. HOWE: This is Dr. Howe. I think our initial feeling is that most of the things that are reported do tend to be medical events. Because I think the licensees look carefully at what the requirements are because they don't like to report things if they don't have to.

Sometimes they will err on the caution side. So it's probably a fairly low percent that -- maybe 10 percent that don't end up being medical events that we're getting.

MEMBER BAILEY: May I?

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: We use the NMED system for lots of things. And, for instance, our medical events definition is definitely different from NRC's and involves a lot of diagnostic procedures. So when we look at it, and this is sort of a rough estimate based upon our IMPEP pecking, only about a fourth of the events we end up putting in NMED are actually reportable events under NRC's criteria for reporting.

DR. HOWE: And Mr. Bailey is absolutely right on that because when I went to print out the

medical events, I had to exclude tons of them that were in the diagnostic criteria because they were things that would have been mis-administrations prior to `92. But would not have been medical events after --

PARTICIPANT: 2002.

DR. HOWE: No.

PARTICIPANT: `92 or 2002?

DR. HOWE: No, `92.

PARTICIPANT: Okay, thanks.

DR. HOWE: In `92 when we revised the quality management rule and we deleted most of the diagnostic medical events. And so the agreement states are still putting in things that we no longer consider medical events from 1992.

MEMBER BAILEY: And some of those go in because we don't want to get pecked for not getting them in within 24 hours so we put them in. And if they don't turn out to be medical events or reportable medical events, it's not big deal.

DR. HOWE: So I was answering more from our NRC perspective of reports from our licensees.

DR. ZELAC: Okay. Thank you very much. I think that is helpful for everybody.

Moving on, I think this is number three of

the four that will be coming up now. The recommendation: NRC is encouraged to develop a more graded and risk-informed process for responding to medical event reports that ties the intensity and immediacy of its inspection response to the individual patient risk and public health implications of the event. For example, for a relatively minor ME where public health and safety is not in question, NRC could minimize reactive inspection of the licensee pending a satisfactory investigation and quality improvement response on the part of the licensee.

Staff does not support this recommendation because -- and I will expand clearly on these few words -- because NRC's approach to medical event assessment is already graded and risk informed. My expansion: NRC already has a variable time frame for initiation of medical event assessment that reflects the known or potential seriousness of the occurrence based on the initial assessment by NRC utilizing information in the medical event report supplied by the licensee.

Generally acceptable delay times for initiating assessment range from two working days for the most serious events to ten working days or longer. Also, the degree and type of follow up are based on

the type of medical event reported. Point one.

Second point. Once the medical event assessment is initiated, the site visit by the assessment group inspector is to confirm and/or to gather information to assure that all required information is available to enable the assessment group to complete its assessment.

I could go through and indicate what these pieces of information are but I think you get the general sense of it.

And finally, staff believes that the most effective and efficient approach for assuring the timely availability of information necessary for completion of these assessment process tasks is the assessment group inspector visiting the site of the medical event to confirm and/or to gather information.

Hence even for a medical event which the licensee considers to be relatively minor and not involving public health and safety, staff does not support this Advisory Committee recommendation.

That's the rationale for our position on that recommendation.

CHAIRMAN MALMUD: Do you wish to say something Dr. Van Decker?

MEMBER VAN DECKER: Yes, it's getting late

in the afternoon. I figure I'll wake people up.

How about you rephrase the last part of what you just said to say staff does support this recommendation other than the fact that we believe that a site visit is necessary at least to see -- or as least a point of order and maybe risk related at that time.

Because what you've essentially said in all that point fulfills the spirit of what was said above except you think somebody needs to visit to be sure it's not a tip of the iceberg-type issue.

DR. ZELAC: All right. It's taken under advisement.

CHAIRMAN MALMUD: Thank you. Thank you, Dr. Zelac, Dr. Van Decker. Can we move on to the next --

DR. ZELAC: Yes.

CHAIRMAN MALMUD: -- the fourth point.

DR. ZELAC: I'm obviously taking notes so that I can move ahead before the transcript is available.

CHAIRMAN MALMUD: Thank you.

DR. ZELAC: We do have actually time deadlines we try to meet whenever possible.

And lastly of the four specific

suggestions, NRC is encouraged to change the 24-hour operation center reporting procedure. Specifically medical events that have not harmed the patient, have little potential for harming the patient, and are not materially relevant to the patient's future medical treatment decisions as evaluated by the licensee, are to be reported to NRC by means of written notification within seven days of their discovery.

Staff does not support this Advisory Committee recommendation because the Commission has previously endorsed staff's position opposing different reporting periods depending on the initial assessment of the event by the licensee.

And if I can, I'd like to expand a bit on those few words. Another quote from the 2002 Federal Register finalizing the revision of Part 35. All medical events may not be associated with serious consequences. However, we believe that a requirement that allows for different reporting periods depending on the initial assessment of the event by the licensee would lead to differing interpretations and confusion as to whether the magnitude of the event requires notification of the NRC no later than the next calendar day.

Continuing, the NRC continues to believe

that licensees should promptly notify the NRC of medical events that trigger these thresholds because the circumstances of the medical events need to be evaluated as soon as possible to determine if any immediate follow-up action or corrective actions are necessary.

The telephone notification allows the NRC to promptly take any necessary action based on the circumstances. For example, to dispatch an inspector or medical consultant or notify other licensees of potential generic problems.

And since this is a rather contentious one let me continue and give a bit more in the way of explanation for our position. Further, the 24-hour reporting requirement for medical events for NRC to "conduct a timely, thorough, systematic, and formal assessment", and I've referenced where that's coming from in our documents, is consistent with NRC 24-hour reporting requirements for other events involving licensed material which permit NRC to promptly assess the potential health and safety consequences for individuals or actual impact on licensed operations.

For example, 30.50 for byproduct material, 40.60 for source material, 70.50 for special nuclear material all require 24-hour reporting. And there are

a list of conditions under which that is required.

And if I could just finish, I'll then certainly entertain as I know you'd like, further comment. Finally, the 24-hour reporting requirements for all these material use events, meaning those specially called out in 30.50, 40.60, 70.50 which enable the NRC to promptly assess the potential health and safety consequences for individuals or actual impact on license operations serve a parallel purpose to NRC's 24-hour reporting requirement for medical use events, to promptly evaluate the circumstances of the medical events to determine if any immediate follow up or corrective actions are necessary.

CHAIRMAN MALMUD: Does that complete your comments?

DR. ZELAC: That completes --

CHAIRMAN MALMUD: Dr. Williamson has been chomping at the bit.

MEMBER WILLIAMSON: Yes. Well, I mean all of the -- this recommendation as well as the three previous ones that you've rejected all flow from a common base of observations by us in the Medical Event Subcommittee and within the ACMUI that we hope you will take the trouble to try to record accurately in your white paper to the Commission so they understand

what our perspective is.

And the perspective is that even though the majority of reported medical events that are, you know, agreed are really medical events, don't result in license infractions or actions that you view as punitive.

I think we're trying to get the message across to you that we, in the regulated community, view the process as punitive. That this is not useful as a QA indicator from our perspective. This becomes a sort of a legal struggle where we as institutions try to minimize the negative and harmful consequences to our patients and to our practices.

This is the point we're trying to make, that the process of reactive inspections, the process of casting negative publicity on an entire institution because of a few events which aren't representative of the overall quality, all of this does harm.

When there is harm associated with following good QA practices, this discourages people from adhering to them. The industry standard principles are don't punish people for trying to make the process better.

And so we made these suggestions in the spirit of trying to make the medical event reporting

process more effective as a quality assurance tool which you have argued, I think, kind of undercuts various other values that you have as a regulatory agency.

But we would like, I think, our message to get through to the Commission so I think that they at least understand what the dilemma is from our perspective because I think the changes, while you have advanced all sorts of legal reasons which have little to do with the practice of medicine, why none of these -- why you can support none of these and why they can't happen, I think a good case can be made that the fact that you can't do this does indeed undercut the effectiveness of these tools and promoting good quality care.

And if you could figure out some way to mitigate what you may not think are punitive consequences but what we definitely perceive as punitive consequences. If you could minimize or reduce those, I think that the effectiveness of this process would increase.

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: Let me get back to the comments that I made earlier on which Mr. Leito has referenced as well, that overall the objective we

agree on. The tactics for getting there are what we're really discussing.

The overall suggestions that came from the Committee with respect to what we should be attempting to do, we endorse. And that's going to be in the next slide. And we've received even another specific suggestion from Dr. Nag as to how this could, in part, be accomplished.

With respect to why there are these reactive inspections at all, I skipped over the listing but I think it is probably appropriate at this point to go through it quickly as to why go to the licensee's facility when a medical event is reported.

What it is that the medical assessment group, medical event assessment group is trying to achieve, what its objectives are, what its goals are, what it must complete in order to satisfy its charge.

First, identify the sequence of events leading to the medical event.

Second, identify the root cause or causes and contributing factors to the medical event.

Three, assess any probably deterministic effects on the patient and/or other exposed individuals. And recognize this is where the medical consultants come into play.

Four, identify and determine the adequacy of corrective actions taken.

Five, determine whether licensee management was aware of the violation of NRC regulations, if any, that contributed to the cause of the medical event if any violations were identified during the assessment.

And six, identify the licensee's immediate and long-term corrective actions.

Finally, seven, determine licensee's compliance with the reporting and notification requirements for medical events.

These are the reasons why there is an assessment group. And these are the things that it needs to accomplish from the point of view of oversight, from the point of view of encouraging good quality.

Lastly, my comment is that I've been on the other side of the fence. And unfortunately at the institution where I spent most of my time, there were several occasions when things didn't go quite the way they should have for whatever reasons and we were visited by NRC inspectors in such reactive inspections.

It's simply something that they had to

deal with as part of the business of providing patient care. It wasn't viewed by us at the time as being onerous. It wasn't viewed -- although it did take up a lot of time generally, it wasn't viewed by us as being -- having an intent to find something wrong that we could be cited for although that may have happened. I don't recall specifically.

But the point I'm trying to make is that we're trying to look at this -- or at least personally I am from both sides. From the point of view of us as a regulatory agency as well as from the point of -- and I'm very sympathetic to it -- the point of view of the user that has to deal with these when they occur.

Now we get to the good stuff.

CHAIRMAN MALMUD: I think there's a question from Mr. Leito.

MEMBER LEITO: Back on the last slide there, Dr. Zelac, on the --

DR. ZELAC: I'm trying to go back but it doesn't seem to be doing it.

MEMBER LEITO: -- I think the -- in terms of the -- well, let me ask NRC staff a question. When a person calls in, a licensee calls in to the 24-hour operations center. Basically this person is just a data-taker. I mean he's not making any assessment,

judgment, or whatever. He's just taking the information that's coming in.

It's my understanding that as soon as that information is taken in, it then goes out into a release on the NRC website. Is that true or not true? Okay. I think this gets to what we were alluding to earlier in that you have this person who is very competent in what they do who is taking all this information, the licensee, who, what, where. And it goes out onto a public forum within a matter of hours of reporting.

And they're sort of basically taking all that raw data that Dr. Suleiman referred to earlier and just throws it into the public domain. And I think what we were trying to get to in the recommendation is that there needs to be some way that there is an assessment on this before you're going to do that.

This raw data should just be thrown up there, you know, because it is not going to encourage people, as Dr. Diamond said earlier, of reporting these things because as you know, as soon as you hang up that phone, okay, everybody in the country or for that matter anyone who has internet access is going to have access to that information.

And that's why our recommendation as stated was meant to be a potential alternative that yes, it can be reported maybe within 24 hours but is there another mechanism similar to the way it used to be before it wasn't required to go to the 24-hour operation center, you reported it to the Regional Office right away, okay?

And then you were required within -- I thought it was seven days and it might have been even longer -- you had to provide a written report that was then sent to the Regional Office and then things went from there.

And if there is another way that we can skin this cat so to speak without the information of the licensee, because as we said earlier, it may not even be a reportable medical event. Until some type of an assessment and the information can be obtained before it goes out into that public forum.

So this is sort of I guess a corollary to those earlier -- or a subset of that earlier information or recommendation that we had that we find, you know, very, very bothersome.

DR. ZELAC: I think your -- if I could comment just for a second -- I think your comments now do, in fact, reflect the motion that came to us at

this meeting which is different than the recommendation which came to us previously upon which, you know, I have provided comment.

The previous one said, you know, wait seven days, okay? This one says wait until you've assessed that it, in fact, is a medical event, okay, that's fine. The Committee has essentially, if you will, added something which we can further consider through this meeting today and this discussion.

MR. ESSIG: And I would just, if I could, that we have a process for reviewing events. We do it every day. Every event, not only medical but industrial, academic, commercial, other commercial sources, we review them every day. And our management is briefed on each event.

But where we have the -- we still have the event notification form that does go on the public website as you have noted. And this other process goes on in parallel with it.

So what we could -- I see your recommendation is to maybe do a little bit more review of that prior to -- and we have considered that particularly for events that maybe have some security aspects to them. And that is looking at them carefully and then deciding whether or not all of the

details in there or some of the details could be withheld for security reasons.

And we could take under advisement your recommendation to look at them for the purposes you have stated.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Yes. More of a clarification. Now is it 24-hours or is it one working day? For example, if something were to happen at our hospital at say 5:30 p.m. or 5:00 p.m. on Friday. I would not have many of my staff people in there. I would not be able to have any details about the incident until most likely the next Monday.

So is it 24 hours or is it one working day? And if it is 24 hours, how am I expected to get those details when the people involved are not there?

DR. ZELAC: To read from the regulation, this is in 35.3045(c), the licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of the medical event. That's what we're living with.

To answer the rest of your question, I'm not going to attempt to do that.

(Laughter.)

MEMBER WILLIAMSON: I think that you --

the language says discovery of the medical event. So I think that traditionally you may have a suspicion of a medical event that falls short of it being a discovery. So I think within the context of being reasonable --

(Laughter.)

MEMBER WILLIAMSON: At five-thirty on Friday, one has to have all of the facts assembled in order to make a determination as a licensee whether it is a medical event or not.

DR. ZELAC: Well, as Dr. Donna-Beth Howe pointed out just a few minutes ago, licensees are certainly reluctant to report things in general unless there is some reasonable uncertainty that it, in fact, it has to be reported.

On the other hand, there are a few that will be very conservative and report anything knowing that they can always back off later on. So there are some in both camps.

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: I think my assessment is a little backwards from yours. I think people report things before they have all the facts and can really say it is a medical event because the only violation is not if you have a medical event it is if you don't

report it within time. So you go ahead and report it and say okay, I've reported it. It turns out it wasn't. Sorry for wasting your time.

MEMBER NAG: Yes, but then by then, it's already up on the web in the whole public's eye.

DR. ZELAC: I think we've kind of got a complete understanding at this point on this particular issue. So since we are now very close to 3:00 p.m., I'd like to move ahead.

CHAIRMAN MALMUD: If I may, Dr. Zelac, it is close to 3:00 p.m. I'd like to thank you for the thoroughness -- oh, you have one more point?

DR. ZELAC: I have two good points.

CHAIRMAN MALMUD: Oh, I thought you had four more. If you have two more beyond this, please go ahead.

(Laughter.)

CHAIRMAN MALMUD: We always have more time for more good points.

DR. ZELAC: At the very start and as I've repeated a couple of times during the presentation, I think we are certainly in agreement with you as to the spirit and the intent with respect to informing the public about the risks associated with medical events.

And while we couldn't, as we have just

painfully discussed, accept while we are not inclined to accept the specific recommendations that you made, you did include in your recommendations to us broad overlying principles to achieve this objective.

And those we do agree with. And those we do wish to endorse and incorporate into policy. Is this it? Yes.

First, publicize that NRC's medical event definitions provide thresholds for identifying events that are indicative of technical or QA problems and accurately realizing the clinical intentions of authorized users and their prescriptions.

Secondly, publicize that thresholds in the NRC's medical event definitions if exceeded, are not necessary surrogates or harbingers of patient harm or even increased probability of patient harm.

So these -- you provided these. We endorse. And with respect to how we might accomplish this besides the very appropriate specific suggestion that we received from dr. Nag a few minutes ago, vehicles for accomplishing this suggested conveyance of information could include first, an article in the NMSS Quarterly Newsletter which goes out to all licensees.

Second, issuance of a regulatory

information summary on this whole question.

Third, letters to and/or discussions with professional organizations that represent medical use authorized individuals such as clearly WAAPM, SNM, et cetera, et cetera. So there are things that we can do to further is objective. And these are just some of the examples of things that we would he considering assuming the Commission agrees with this recommendation to it.

So in summary, we are intending to reflect in our paper to the Commission the various positions that I have enumerated in this discussion this afternoon. Endorsing the preponderance of recommendations which came from the Advisory Committee on this total issue and not recommending some of the very specific things relating to the last of the three points, which was informing the public about risks associated with medical events.

Are there any additional questions?

CHAIRMAN MALMUD: Now I would like to make a closing comment and that is to first of all thank you for the thoroughness and the usual precise order of your response. And particularly for explaining the reasoning that didn't permit you to agree with several of the recommendations as well as the reasoning which

allowed you to achieve or allowed the NRC to achieve agreement with us at this level.

And then to remind anyone who reads this document that it has been very clear that during this discussion, although there was not agreement on several issues, that the concern of each party was for the welfare of the patient, the anxiety that might be generated in the minds of the public, and for the overall well being of those for whom we provide services.

I didn't detect in any of the comments a concern for one's own area of interest or for protection of one from unnecessary observation. So it was very, very enlightening, very thorough, and a very comforting discussion. And a stimulating one. And we thank you.

DR. ZELAC: Thank you very much for your comments. I'd like to make one final comment just simply as a reminder to those members of the Committee.

You did receive a copy of the draft Commission paper. This is definitely, definitely pre-decisional information which is not to be given to others or copied or disseminated in any way whatsoever. Clearly we've talked about the content of

it based on the publicly available recommendations which you have supplied previously. But keep the paper close to your vest.

CHAIRMAN MALMUD: Thank you.

Mr. Essig, you had a comment?

MR. ESSIG: Just is there any question about the timeline on the paper? When is it due to the Commission? And what sort of obligation are we asking -- the turnaround time on the part of the Committee, is that clear?

DR. ZELAC: We have received -- we, staff, have received from you today one additional recommendation in the way of a motion which was approved unanimously. That will clearly be factored in and included in the paper which goes up to the Commission.

I am not looking to the Committee at this point for anything further. And we will be able to proceed from this point on unless there is something that you think you need to convey before we move ahead.

CHAIRMAN MALMUD: Thank you.

We are adjourned until 3:30 -- no, 3:20, 3:20.

(Whereupon, the foregoing matter went off

the record at 3:08 p.m. and went back on the record at 3:29 p.m.)

CHAIRMAN MALMUD: This will be a discussion of the guidance on I-125 seeds as markers for breast cancer localization. And the presenter is Robert L. Gallaghar from the state of Massachusetts. Is it the state or commonwealth?

MR. GALLAGHAR: It's the Commonwealth. Please don't ask me to define a commonwealth and a state. Because I'm an HP, I'm not a politician.

CHAIRMAN MALMUD: I'm from the Commonwealth of Pennsylvania, and I have the same problem.

MR. ESSIG: Dr. Malmud, if I may?

CHAIRMAN MALMUD: Yes?

MR. ESSIG: Just a couple of words of introduction to the topic.

What you will be hearing about today is, we have a national materials program, and it has a series of projects in it, pilot projects. There are five of them altogether.

This was a means of sharing resources between ourselves and the agreement states and CRCBD. Some of the projects which may have been involved in producing guidance documents. It's been a shared

effort. Some, the NRC has the lead. One the CRCPD has the lead.

And on this particular one, the organizational agreement states has the lead. So they are taking the lead on a guidance document that will benefit both the NRC and the agreement states.

And it will be their document. It's clear to us the committee has seen an earlier version of the document. We were almost going to invite Mr. Gallaghar back I think it was the last meeting. But then we elected not to, because we wanted to make sure the document was a little more ripe so to speak. And it is in that position now.

So I believe you were sent, probably electronically a couple of weeks ago, as part of the agenda, you were sent a copy of that.

And I think as you will hear from Mr. Gallaghar, and I will emphasize it right now, the comments, if we have any on the pilot #4 are due to him by November 15th.

CHAIRMAN MALMUD: November 15th? All right, thank you.

MR. GALLAGHAR: Thank you, Tom.

As Tom mentioned this project, pilot project four, is one of five projects on the National

Tools Program.

The goal of this particular pilot project was to have an agreement state or group of agreement states assume responsibility for the development of our licensing and inspection guidance.

This group as Tom mentioned was led by the organization agreement states, and it was composed of four state members, and one NRC regional member. We have representation in the state of Florida, Debbie Gilly. Georgia, Eric Jameson. Gil Vincent from Illinois. And Cassandra Frasier from NRC's region three office.

Our first priority when the working group was formed was to select a new medical use of material, or a new modality, to focus our efforts.

To accomplish we reviewed regulatory needs identified by the NFP pilot five working group. We surveyed the agreement states, NRC headquarters and regional offices. And we contacted major medical institutions in the United States.

After reviewing a number of the new uses of material, we decided to develop the guidance for Radioactive Seed Localization, or RSL.

We chose RSL because iodine-125 and palladium-103, which can also be used for this

procedure, are Atomic Energy Act materials, regulated by both the NRC and the agreement states.

In addition the use of this application does not fit under the current guidance under 10 CFR .200 or 35.400 or the equivalent agreement state regulations.

Therefore its use would fit into the newly created 10 CFR 35.1000, other medical uses.

And no review by the NRC and agreement states have been performed to date.

Radioactive Seed Localization calls for the use of currently available seeds, previously approved for permanent implantation for the treatment of cancerous tumors.

Typically the activities run between 200 and 300 microcuries per seed, implanted into the breast lesion using a standard 18 gauge needle.

The seed or seeds in the case of regularly shaped lesions are then localized by the surgeon using a technique with which they are familiar, because of the similarity to sentinel lymphnode biopsy and radial guide parathyroidectomy. I had to look at my notes to be able to say that. And then surgically removed.

The seed may be removed from the specimen at surgery, or the specimen with the seed or seeds may

be sent to pathology for removal of the seed and analysis of the tissue.

The seeds are then disposed per 10 CFR .92, or the equivalent agreement state regulations.

What are the elements, key elements, of the licensing guidance? As with any guidance for licensing, the locations of use are very important for the licensee to address. They should include facility diagrams where the seeds will be stored when not used; implanted into the patient; explanted from the patient; removed from the tissue sample; and stored for decay.

The authorized users, we need to know all the authorized users and document his or her training.

The authorized user will be considered qualified if they meet either the criteria in 10 CFR 35.490, or 10 CFR 35.290 in preceptorship training by 35.490 authorized user to include work experience at ordering, receiving, unpacking materials safely, performing surveys using proper instrumentation, implanting and removing brachytherapy sources, the emergency procedures, using administrative patrols to prevent the medical event involving this device, and maintaining running inventories of materials at hand.

For general surgeons who locate and remove

the tissue containing the seed or seeds, they should complete the training that includes performing related surveys, using appropriate instrumentation; preparing, implanting and safely removing brachytherapy sources; and emergency procedures including how to respond to a leaking source.

This training must be performed under the guidance of an authorized user qualified under 35.490 or 35.290, plus preceptorship training.

The licensee should also provide procedures addressing safety procedures and instructions, including survey procedures; identifying individuals who must be present; source accountability and leak testing; and verification of source activity, either by assay prior to implantation or by the manufacturer's certification.

They should also supply procedures for responding to an abnormal situation such as patient follow-up, should they not return.

Description of length of time the seeds remain in the patient, and notification of a medical emergency of a patient prior to removal.

In addition the licensee should describe if the conditions of the use exceed those stated in the SSND certificate, the limited scope licensing will

have to amend its license to allow for use under the new conditions.

Some states, however, will not allow variations unless the original SSND certificate is amended, or custom valuation is performed.

We have received comments from the NRC and OAS which were reviewed by the working group and incorporated into the final document.

The draft licensing and inspection documents were submitted to the NRC in September of 2004 as part of the final report of the National Tools Program Pilot Projects.

The final draft of the RSL licensing guidance was submitted to the OAS board for their review and approval in September of 2005.

The OAS board approved this document, and it has currently been sent out to the agreement state directors, and the NRC for comment.

The comment period is currently open, and as Tom mentioned, it will end November 15th of 2005. I encourage those of you on the committee – and I understand the FDA now has the document as well – to provide those comments directly to me. I can give you my email address, or it might be in the documents that were provided to you in your handout.

But it is Robert.Gallaghar@state.ma.us. And I encourage those of you who wish to make a comment to provide those to me.

Are there any questions? Robert.Gallaghar, and as you can see, the last name is spelled with an a-r on the end, @state.ma.us. Unfortunately I only brought one card with me, and I've already handed that out.

MEMBER NAG: Since the activity is so low, what would the licensee do if the patient did not do a follow up? Because the damage – potential damage to the patient if the patient never even returned, is really minimal. I mean when we do prostate implant we have 10 percent of patients who have one or more seeds that goes to the lung and nothing happens, and these are much, much lower activities than those seeds.

MR. GALLAGHAR: Our guidance is not prescriptive in telling the licensee what they need to do. All it is stating is that they have to tell us what they would do in terms of follow up.

MEMBER NAG: I know. But if the likelihood of damage is so small, and if when we are doing a prostate implant we don't do anything if they go to the lung, what should they be required to do? Really there is nothing that they need to do.

MR. GALLAGHAR: I would tend to agree, and I don't really have an answer for that question. We would have to review that.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: I assume this document is the one that we received, and Ralph and others have commented on. And I would think that since this is lower activity, it would be considered lower risk than regular manual brachytherapy, and that therefore you would not be warranted in imposing more restrictive or prescriptive requirements on this activity than are present in the 35.400 precautions for regular manual brachytherapy.

So just some little things I've noticed. Why facility diagrams for all these rooms which you don't have to provide for --

MR. GALLAGHAR: Well, these are standard elements of a submittal for an amendment that exists currently.

MEMBER LEITO: I just submitted a license renewal. I didn't submit all my OR floor diagrams for my operating rooms for my license renewal. And that's where these things are done at.

And I don't think it's ever been asked for in the past, and I think it's been pretty well

understood that you could be doing a brachytherapy implant for prostate in almost any operating room of the facility.

I guess I would ask some of the broad scope people --

MEMBER WILLIAMSON: I've never had to identify specifically the rooms I do manual brachytherapy in in a license application or an amendment or ever had to have drawn diagrams of them. Only for HDR and fixed-source devices, but not for something like this.

MR. GALLAGHAR: I tend to agree, and as a license reviewer myself I would be much more interested in where they were going to be stored than where they would be implanted and removed.

Seriously, the procedure that we're going to look at is what you would do with these temporary users, if you want to call them that, if you can't account for all the seeds, or if there is something that goes awry.

MEMBER LEITO: I would ask that the working group kind of look at these as how sentinel node studies are done. The activities are comparable – granted your using tech instead of I-125. But the time periods involved are similar and the activities

are quite similar.

In fact with sentinel nodes they are unsealed. With these they are sealed, and it's a little bit easier to address.

So I would ask that the precautions that are being set up be comparable to, as you said, the inventorying, the surveying before and after, those types of things I think are more critical than because the burden of doing all this is not trivial.

One of the questions I had is more of a generic nature. You said that the reason these were put under 1000 is because of the sealed source device registry definition if you will.

MR. GALLAGHAR: Certification; right.

MEMBER LEITO: Is it - not having this for the iodine seeds, is it because it says they are,(does it say), for therapeutic use only?

MR. GALLAGHAR: All the slides you'll see for example on the best certificates, it states, for 10 CFR 35.400 use. Period.

MEMBER LEITO: Now maybe the better thing would be to address that the sealed source registry be revised or stated to say interstitial use which would then obviate all this 1000 and a lot of this, the need for this --

MR. GALLAGHAR: That is a question that we spoke to very earlier in this procedure. And one of the advantages of having Gil Vincent from Illinois (Best Industries is in Illinois)which manufactures a large number of these I-125 seeds.

And they were contacted, and they were not willing to amend their SSP certificate to allow that, for their own reasons; I don't know what those reasons are.

MEMBER LEITO: Again I don't have an appreciation for this, so maybe NRC staff can help. How difficult is it to amend the sealed source device registry? Is it kind of a detailed laborious time-consuming expensive effort?

MR. ESSIG: We have Dr. John Jankovich in the audience who is a team leader for the sealed source device review, if you would care to speak to that, over to the microphone right on the other side.

DR. JANKOVICH: The NRC and the agreement states issue their registration certificate in response to a licensee's request and application, and they specify what use they want to put those sources to.

I point this out that the action comes from the manufacturer. It is not the licensing agency

who is initiating the action.

We don't tell the licensee that you should permit this, the use of these sources for something else.

So Robert was referring to that procedure. And that is what past industry was following. Therefore I cannot give you a direct answer that we dictate what these sources should be used for.

MR. ESSIG: But John, would it be fair to say if Best Industries decided that it was in their best interests so to speak to request an amendment to their SSD certificate, that would be a fairly straightforward process, would it not?

DR. JANKOVICH: That I can answer. If we get an application to change the registration certificate, we can do that fairly easily. We have routine procedures to do that; not too time consuming, provided that the application gives us the information that these sources can be used under these circumstances.

We usually ask for prototype testing or comprehensive studies which tells us that the source can be used in such an application.

Obviously, we are concerned, we would be concerned about the structural integrity of these

seeds under the - if they retain their integrity.

Maybe you are familiar with a similar situation. A manufacturer make strands out of these sources so the seeds are at predefined distances from each other.

And during the manufacture of those strands they got caught in there, and several seeds were damaged. Actually we had to implement preventive measures, extra quality assurance measures during fabrication – this is an NRC licensee in Connecticut – to prevent those leaking strands to go out to hospitals.

So of course the tissue here is different than the material they are slicing these strands, embedded sources, in plastic on hard surfaces, that is different. That is the reason why we would ask for prototype testing or cooperative studies.

MR. GALLAGHAR: Just before we move on, one further element that would need to be considered if Best for example comes in to renew or to amend their certificate, as I understand it, many of these sources were never tested for puncture early on. So now if they are going to be approved, most likely they would be required to be tested for puncture; is that not correct?

DR. JANKOVICH: Correct. For iodine seeds, we don't have a well established prototype test protocol. Each manufacturer comes up with their own test sequences, and either the NRC or the agreement states reviews that and makes a professional judgment if it is sufficient for its intended use.

So far, of course, the intended use is implanting to prostate.

CHAIRMAN MALMUD: Dr. Vetter.

MEMBER VETTER: Yes, in that regard, relative to your draft guidance, you indicate that relative to puncture and that sort of thing, a broad scope licensee should perform its own engineering and radiation safety evaluation addressing these differences, but you don't indicate what is they should do. And I don't think there is an ANSI guide that says how you test for puncture in seeds.

So it is a matter of professional judgment, I guess, right? And I'm sorry you weren't here at our last meeting. We actually did this sort of thing at Mayo, we did some cutting and puncture tests.

But there is no guidance to follow. There is no ANSI standard to follow. So we simply tried to envision under what circumstances would a seed be put

under a knife and so forth, and we didn't get any leakage.

So does that satisfy this requirement? We did it that way, Mr. Leito might do it a different way, and Dr. Williamson a different way.

I'm not sure what this means when you say we have to do – unless FDA has some specific guidance in that regard.

MR. GALLAGHAR: That's an excellent point. It's a point I'd like to see resolved. It's something we talked about in our committee. And like others have done testing on their own, in Mass General Hospital, after my discussions with them, they went out and did similar testing involving chicken breasts and later with some sauce and things.

In that case also they were unable to rupture a source. In all cases, no matter how physically hard they tried, they were unable to successfully breach a source.

And I will also say that in my review of NMED, of all the incidents involving I-125 seed rupture, there were none that were involving a surgical procedure. There were some as Dr. Jankovich mentioned involving scissors, but I do not believe historically there has been an actual seed rupture

caused by a surgical removal.

And I also understand, and perhaps you gentlemen can confirm this, there are times when a prostate seed would need to be surgically removed from the patient.

MEMBER LEITO: That is one of my comments. Obviously I guess it didn't get forwarded to you yet. Because I'm wondering what is the difference between what you are requiring for implanting these sources for a couple of days than a prostate patient that comes back for some type of urinary obstruction where they've got to kind of open things back up, and they are digging around there in the prostate and so forth. And that doesn't require Part 1000 application to be able to do that.

And so it, I think a lot of the guidance here is good, but it seems like it's just overly prescriptive and burdensome for the risks that are involved.

A question I also had was there assessment done by the working group in what the dose to the breast is per seed if you will for one of these that are left in for what is it like one to five days, say for five days, what would be the breast dose?

MR. GALLAGHAR: I don't remember the

numbers, because that was more than a year ago that we did this. What we did do an assessment --

MEMBER LEITO: Was it more than a mammogram? Less than a mammogram?

MR. GALLAGHAR: I'm not a medical physicist. I don't know how much dose is delivered in a mammogram, but we did review that.

CHAIRMAN MALMUD: Mr. Bailey.

MEMBER BAILEY: If I'm remembering correctly, there were some testing procedures that ANSI had for radium needles and plaques and all that sort of stuff that involved crushing and cutting and so forth.

Perhaps those might be applicable. When I was listening to Dr. Vetter, I was thinking, he's already got a consulting project done for Best Industry.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Two questions. One is, in your element for cleaning up the general surgeons, you have mentioned that you need to do all that, but do you have any guidance, like is there any hourly requirements or anything like that?

Because that is the place where I as a radiation oncologist with the .490 experience would

have to generally supervise the surgeons. What am I going to tell them? What do I need to tell them? And it is very difficult for us to tell the surgeons, oh no no, we know the agreement, we'll just go ahead. Unless I have a requirement that if I need X number of hours or so on, I can only tell them, these are the precautions you take. So that is one.

The second thing, for palladium-103, if the palladium is made from a cyclotron would that still come under the NRC because it's not the reactor byproducts?

MR. GALLAGHAR: Well, under the current regulatory environment, no. I think that is under consideration for a change, but currently the NRC is only responsible to regulate the Atomic Energy Act material.

MEMBER NAG: So that palladium would not be included?

MR. GALLAGHAR: Correct. But to address your first point, if you recall last year when I came back here in October, there was a time allotment of eight hours for general surgeons, and there was considerable discussion amongst the committee that that was overbearing. So we listened to your comments and took that under advisement, and removed that

hourly criteria.

You still have to provide what the training will include, and what I provided in my talk was some of the general components of that training.

CHAIRMAN MALMUD: Dr. Vetter.

MEMBER VETTER: Yes, thank you for taking that hour requirement out for a couple of reasons. One is, we did consider it onerous. Second is, depending on where they train, the procedures that they would be involved in might be quite different.

For instance in a large academic medical center there is not a physician that orders radioactive material. There is a much more or less automatic process. The physician puts in an order for it, internally, but they don't end up calling the vendor. They don't check in the package. They don't unpack it.

That is all being done to facilitate the process to make sure that the physician in this case would get the seed at the mammo suite. It would be delivered ready to use.

So of course we would go through those things so they would be aware, but they wouldn't be going to the lab to unpack it, and so forth.

So we appreciate the flexibility that you

have built in.

CHAIRMAN MALMUD: Comments from the audience? Yes, microphone right here. Please introduce yourself.

MR. SHAY: This is Kevin Shay from NRC Office of State and Tribal Programs. I just want to have one clarification. It is my understanding that OAS sent a guidance document to all the agreement states, and then to NRC, for reviewing comments.

And my understanding is that when we received the comment – actually the state program received a comment, we distribute to NMSS and it is our understanding that NRC – NMS and the state program, we will consolidate all the comments from the region's office, from SCMUI and from OGC and provide only the final set of NRC comments to the OAS.

So I just wanted to make it clear that all the comment maybe should go to NMSS and then NMS and STP and OTC, and then we will have only one consolidated set of consolidated comments back to the OAS.

That is my understanding. And maybe Tom can --

MR. ESSIG: We will serve as the collection point for any comments from the committee.

MR. GALLAGHAR: So to clarify for the committee, they would then send their comments to Angela McIntosh or who?

MS. FLANNERY: You can send them to me, Cindy Flannery.

MR. GALLAGHAR: And then STP will be responsible for funneling them over to me in one document?

MR. SHAW: One NRC document, consolidated document.

CHAIRMAN MALMUD: John Jankovich wanted to be recognized.

DR. JANKOVICH: This is John Jankovich again. I'd like to give you an update on the testing regarding the standards.

We in NRC, I am personally the NRC delegate to International Standard for Sources, that is ISO standard 2990. The working group responsible for this standard met in February.

One of the initiatives there was that we would include test procedure for iodine seeds.

One of the working group members took this responsibility and said that in six months he would contact all the manufacturers, get their input, see

what they would recommend, what they would think reasonable.

So this is not the American ESME standard, the ANSI standard; this is the international standard.

That was in February. We closed out all the other issues for updating the standard, but I haven't heard anything regarding the seeds. So it looks like it is still open. And there may be some progress once we conclude and finally update the ISO standard.

Of course it is also possible that the individual couldn't get any response from the manufacturers. When we have some updates, I will let Thomas know about it, and he can convey that information to you.

CHAIRMAN MALMUD: Any other comments? Mr. Leito.

MEMBER LEITO: I had a question, and I didn't know if it was clear now, but in the document that was forwarded to us a week or two ago, it states that this performance evaluation has to be done because it's under Part 1000, because as you alluded to, the cutting and whatever.

It wasn't clear to me, does every licensee, would every licensee have to do that? Or

would one licensee do it and sort of everybody piggybacks on it? Or would the vendor have to do it?

From the way the document is worded, it made it sound like you made your application to use these sources, you had to submit your evaluation for that, which makes it sound like every licensee has got to do it.

MR. GALLAGHAR: For the use of the seeds in this procedure?

MEMBER LEITO: Right. This engineering and radiation safety evaluation addressing the differences in the sealed source registry.

MR. GALLAGHAR: This is an area where, the whole process has not been developed yet, meaning the working group put together this licensing document, and as I understand it early on, the intent then was to post this document on the NRC's licensing website. They have I believe four Part 1000 uses, the guidance for them listed on that website now.

As I understood it then, this guidance would then be posted on there as acceptable guidance for the reviewers to use to approve an amendment request to use as material.

CHAIRMAN MALMUD: Comment?

MEMBER BAILEY: I don't think he answered

your question. The ideal situation I believe would be if the manufacturer came in and amended the SSND. Then each individual user would not have to do it. But you are thrown into the weird situation that you have got, quote, a custom use. So at least in theory each custom use is individually evaluated.

I think what in practice happens is that the second guy who comes in in a state takes what the first guy sent in, or the reviewer realizes it's already been done and go with it.

MEMBER LEITO: Another question I had was, the way the document is written, it's almost like a new licensee coming in for this application.

Isn't it in actuality the only ones who would be doing this are the ones that have to already be licensed for 400?

MR. GALLAGHAR: I think that is a true statement.

MEMBER LEITO: Some of the things that are being asked for are things that should be part of the license approval process already, and it's almost like a new license application almost to be submitted.

MR. GALLAGHAR: I would agree, a lot of the elements in that guidance would have already been submitted to whatever regulatory agency is overseeing

that licensee; I would agree with that.

CHAIRMAN MALMUD: Other comments and questions?

DR. ZELAC: Dr. Malmud.

CHAIRMAN MALMUD: I beg your pardon?

DR. ZELAC: Over here.

CHAIRMAN MALMUD: Oh, Dr. Zelac.

DR. ZELAC: Following up on what Mr. Leito said, is it the expectation that seeds that would be used for this purpose would in fact be seeds that had been received by the institution, not used for therapy implants, and were simply available as opposed to holding them strictly for decay, no use, or returning them to the manufacturer, they would be used for this alternative purpose.

MR. GALLAGHAR: As I understand, after discussing with the physician in Florida who came up with this, that is exactly the case. He identified these sources that were not being used for prostate implantation, and saw that they might serve another purpose for this localization of nonpalpable breast lesions, and essentially created a procedure to address both issues.

The fact that they are reusing what would have been a waste stream into a beneficial use for a

medical use for a woman.

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: Just to clarify an answer to Ralph's question, if you have a 35.1000 use, you do not have specific regulations that address that use.

So if you are using say a brachytherapy source that has been approved for 400, and you are already approved for 400, you are approved for use under 400 for therapy.

Now it comes in to 1000 as a diagnostic use, you may have to commit that you are doing the things you did under 400 for the seed as it is being used in its diagnostic purposes, because it is no longer being used for a therapy seed.

And that is one reason you will see some repetition of things that you may already have requested under a 400 use, or whatever use the 1000 use comes under.

CHAIRMAN MALMUD: Mr. Leito.

MEMBER LEITO: Well, my reason for asking that was, some of the things they were asking the surgeons to do, okay, for example, performing surveys, package receipt procedure, they are not going to do that or be involved with that, or ever see those types of - well, I shouldn't say see them but be involved

with those activities.

Those are going to be done via other licensee personnel, and areas, and so forth. So it didn't seem like – it didn't seem appropriate that this would be addressed to surgeons, because other members – or other parties of the licensee – the licensee's control would be doing those duties.

DR. HOWE: There is also an – when you are writing guidance for 1000 there is also an expectation that there is a wide spectrum of users. So they may not be in a large hospital that you might be used to.

And so that is one reason the guidance is there to make sure everybody ends up with the right training. They may get it for another reason somewhere else, but it's also possible you have a licensee that isn't authorized, and doesn't do the things that you are thinking of in a bigger hospital.

CHAIRMAN MALMUD: Thank you.

Any other comments for Mr. Gallaghar? If not, thank you again.

I believe that the next item is Angela, correct?

MS. McINTOSH: We're a little ahead of schedule, but it's fine with me if it's fine with you.

DR. MILLER: Dr. Malmud, as Angela is

coming up, there was an issue that came up today that I'm going to ask if, for those that can remain, I recognize, since we're a little bit ahead of schedule, there was an issue that came up today that would have us go into a very short closed executive session following the conclusion of the open agenda, for a brief period of time.

MEMBER NAG: The other one was about the homeland security issue, and HIPPA, the requirement that you need to give permanent implant, that should be in an open session. That didn't need to be in a closed session.

DR. MILLER: Dr. Nag raised an issue to me yesterday, and perhaps before Angela starts, if it's okay with you --

CHAIRMAN MALMUD: Certainly.

DR. MILLER: We could have Dr. Nag frame the issue for some discussion by the committee.

MEMBER NAG: I had sent an email to the ACMUI about a week or two ago. I don't know whether that was involved in the email or not.

But the issue is as follows. When you have a patient with permanent implant, you are supposed to give them instructions that tells them what implant they had, the isotope, and how long

they've had it and so on, and the number that can be contacted on for 24 hours seven days a week.

We did not involve them. We can identify people in the hospital, and they can answer the question. But the problem is, then, the – we call them homeland security issues. The state was – or the state had asked that there be personnel available in the hospital who will be able to respond to any inquiry whether from the police or airport authority, et cetera.

The problem now is we all know HIPPA regulations are based in privacy laws. If the police or the hospital or the airport authority calls back the hospital, the hospital cannot give out any information without the patient's written consent.

So the requirement of the HIPPA regulation, and the homeland security requirement are at odds with each other unless the police would then fax a release of information to the hospital, and then the hospital can release that information.

So it does become somewhat of a problem, because of this at least in Ohio, the Department of Health in Ohio, which put this into effect, has temporarily withdrawn or temporarily delayed the institution of this rule, and I had to tell them that

since this is a matter and we were having an NRC meeting, we would discuss at the NRC meeting to see whether other states are having a problem to see how either NRC states or any other state has solved the problem.

CHAIRMAN MALMUD: Dr. Vetter would like to comment.

MEMBER VETTER: I discussed that issue with our compliance officer, and he indicated that if in the set of instructions that you give the patient, that you indicate that they would be giving their consent for the release of pertinent information to the authorities in the event of something like this, that they understand they would be giving – that that would be given up.

They sign the instructions, then they sign that sheet saying I understand the instructions and I give consent to give that information out if it's necessary, then you have it.

DR. MILLER: So what that would mean, Dr. Vetter, then if the hospital got a call from security officials, let's say a person is standing in airport security and is challenged, then the hospital would already have that patient's authorization to supply that information to security officials?

MEMBER VETTER: That is correct. And we are fairly confident it would be about that patient, because only that patient knows that and has that information.

MEMBER NAG: That was one of the things that was under discussion in our hospital. But we still hadn't finalized anything.

CHAIRMAN MALMUD: Does that answer your question? Okay.

MS. FAIROBENT: Dr. Malamud? Lynne Fairobent from AAPM.

This question is surfacing in the professional communities, because I also got an email from Ask The Experts from HPS, from Genevieve, asking what is being done on giving identification to patients, again.

So it is surfacing from perhaps a couple of other areas that maybe someone has been caught in this dilemma situation, I don't know, and has raised the question.

So I just want to throw it out that it is surfacing in the general community again.

And one of the other questions that had come up was the verification of you releasing that information verifying that that truly is a request

from a legitimate authority asking you. And I don't know how you resolve that issue.

CHAIRMAN MALMUD: Dr. Vetter.

MEMBER VETTER: I was going to respond directly to your concern. According to my compliance officer, we can be reasonably assured that it is about that patient, because only that patient knows that question. So it has to be – whatever authority is calling about that patient, the patient has to have been involved in the conversation.

MEMBER NAG: I think the question was different. It was the policy. If I called up and say, I am the policeman from so-and-so and I want to know about this person.

MEMBER VETTER: Well, how did you know about the patient? You can't just pick a name out of the air and call and expect to get some information.

CHAIRMAN MALMUD: Mr. Bailey.

MEMBER BAILEY: Two items: You can't have a number on that. That is unique to that patient, that would also do it.

I believe the Southern California chapter of the Society of Nuclear Medicine has a suggested card or form or something on its website. The bad news of that is, anybody can get it. But again then

trying to correlate some code number or letters in the individual name, and knowing which hospital, with three things you've got to get right, is pretty small.

CHAIRMAN MALMUD: Thank you.

We are currently giving our patients a business-sized card which indicates the patient's name, the isotope and the dose, and the date that they received it. And if they are stopped, they can show that.

Thus far, none of our patients have been stopped.

MEMBER NAG: In addition they need a number, a name of an official and the number that they can call.

CHAIRMAN MALMUD: Oh, our RSO office number is on the card for the official to call in the event that they wish to confirm that this patient has in fact received the radiation.

MEMBER NAG: How would the RSO have that information? The hospital or the department would have the information, but not the RSO.

CHAIRMAN MALMUD: The RSO would know because the dose was administered.

MEMBER NAG: Not for the permanent implants.

CHAIRMAN MALMUD: Oh, I don't handle permanent implants. I have them for the I-131 dose.

MEMBER NAG: Right. I think what I was going to suggest, since Dr. Vetter had already solved this problem at his institution, is that if from many other institutions and many other states, if the NRC and/or the agreement states would make this information available so people will not be asking – will not be trying to solve a problem that has been solved already. Is there anything for that?

DR. MILLER: I think what the NRC would have to do is take this matter up with the Department of Homeland Security with regard to – we can certainly make people aware, but that aspect of it wouldn't necessarily be within our jurisdiction, I think.

We can make people aware, and what would concern me would be, you know, someone tried to get through airport security, they are probably in a hurry to catch a flight. And if there is a long delay in trying to check out if it's really them, they could end up missing the flight. And that would be a concern for one example that I would see.

So the other question would be, when they have to call the hospital or whatever, is there someone on duty who can answer that question 24/7?

MEMBER VETTER: In some cases, yes, in some cases, maybe not. But in our case there is always a physician on call, in radiation oncology if it's seeds, who would be able to answer the question.

MEMBER NAG: Actually, we discussed that in our hospital. The physician on call would not be able to answer in a minute or two, number one, because it may take a long time when you get the physician on call.

Secondly, that person on call would not know whether person X got an implant unless they go back to the department and, what we decided was that in our hospital at least that there is always a nursing supervisor on call that is available for any emergency question about any patient in the hospital who is either in the hospital, or has been treated in the hospital, who is located within the premise of the hospital who has access to all the patient data on computer, and that person is the one who is put in charge, because we realize that if we get the physician on call, let's say I'm here, or I'm at home, it will take me half an hour to go to my department, look up the data, and that is not really practical.

CHAIRMAN MALMUD: Excuse me, Dr. Nag, do you have a nurse who is available 24/7 to determine if

an outpatient was treated with therapy?

MEMBER NAG: There is a nursing supervisor for the entire hospital who has access to all patient data for any emergency.

CHAIRMAN MALMUD: Including outpatient treatments?

MEMBER NAG: Including, yes, anything that is in the hospital computer system. So any treatment is automatically in the hospital computer system, they will have access.

There must be someone of similar capacity in every hospital. In our hospital the nursing supervisor.

But there is always someone on location who has access to the hospital computer system.

CHAIRMAN MALMUD: Something to consider for the next meeting.

MEMBER BAILEY: And Dr. Malmud, are there any instances where a patient could have received the radioactive treatment in other than a hospital, a clinic, where it would be only open 9:00 to 5:00 or something like that?

CHAIRMAN MALMUD: Yes.

MEMBER BAILEY: So that is a potential problem also. I think it is an issue that we probably

need to look into harder. But it is an issue.

CHAIRMAN MALMUD: We have different clinical situations. I'm treating patients with radio iodine either for hyperthyroidism or for thyroid cancer, and I tell them, "don't enter into any federal office buildings." "Don't cross the bridges or the tunnels into New York City." And, "if the president is visiting town, stay in your house."

That is pretty effective in getting them to adhere. Also, I don't want them riding on public transportation, because it means they will be sitting right next to somebody else, and that goes against the six-foot rule which we discuss with these patients post-therapy.

And thus far I have had no feedback in terms of them having to explain why they are triggering off a radioactive monitor.

But I do understand that patients who are just getting thalium scans are triggering monitors in some situations. We haven't run across that yet.

So it's – I don't think it's a problem we'll solve here at this meeting, but it is something worth looking into for a future meeting.

MEMBER NAG: And the problem is different for I-125 implanted where the half-life is six – I

mean two months, so they are active for six months, and the energy is fairly low, and therefore they can go out in the public and sit next to a person.

CHAIRMAN MALMUD: Mr. Bailey.

MEMBER BAILEY: I think there is an ongoing effort to educate all the people that people have radioactive material.

And I know most of the states are trying to get with all the different agencies. If you don't have the magic black boxes that tell you what the isotope is, and they are developing lists now of, these are the isotopes you are looking for, if they are not those, they may accept them.

But I think all of the states are now saying, if you've got one, call us, we will send somebody out to help you determine whether this person has enough material there, number one, to cause a problem, and number two, to identify what it is.

And we encourage NRC regional offices to do the same.

CHAIRMAN MALMUD: May we go on the next item on the agenda? Angela, I think you are on.

MS. McINTOSH: Good afternoon. My name is Angela McIntosh, and I will briefly provide the committee with an administrative conclusion that will

include the recommendations, action items and the tentative scheduling for the spring 2006 meeting.

Feel free to jump in and add any recommendations that you remember, because I'm working from a very rough draft, and I have not necessarily captured every recommendation. So feel free to jump in if you remember one.

The first recommendation was actually brought to the floor during a closed-session meeting, and that recommendation, ACMUI requested that the NRC provide a more detailed explanation of our board certification approval process.

The next recommendation that I have recorded is actually a recommendation supporting the actions of Penn State University with regard to the unauthorized injection of radioactive material. The committee just formally made a motion to show its support for how Penn State handled that situation. That is actually the only other recommendation that I have been able to capture.

Are there any others that anyone else remembers that were brought forward and seconded?

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Yes, I think Dr. Diamond made the recommendation, you had ours. You can read ours

again.

MS. McINTOSH: Okay. I have a record of Dr. Diamond making a recommendation, but was it seconded?

MEMBER NAG: It was. It was seconded, and it was unanimously accepted.

MS. McINTOSH: Can you –

(Voice speaking off-mike)

MEMBER NAG: The second one he would do.

MS. McINTOSH: Dr. Vetter.

MEMBER VETTER: Yes, relative to the issue of physicians and physicists trained in foreign institutions, the committee concluded that it was not really an issue for physicians because there are so many other controls. But for physicists, the issue that came before us was, would we support the NRC allowing regions to make a decision on whether or not a physicist trained in a foreign institution should be granted authorized medical physics status.

And the decision of the committee was to support that concept as long as guidance was prepared for a region so we had some uniformity of decision making.

CHAIRMAN MALMUD: Thank you.

No other recommendations that are aware

of, Angela.

MS. McINTOSH: Okay, I do have one action item that was captured that has already been fulfilled. During the discussion on the energy policy act, we requested that the ACMUI provide a member to participate in that roundtable discussion. And it has been decided that Mr. Leito and Ms. Schwarz will attend the November 9th roundtable discussion.

So that is an item that is now closed.

CHAIRMAN MALMUD: That's correct. And Mr. Leito will be at the table. And Dr. Schwarz will back him up.

And Mr. Essig has agreed to bear the expense, not personally, for their transportation.

MS. McINTOSH: Are there any other action items that anyone remembers being brought forward?

DR. ZELAC: Angela, with respect to the first one that you mentioned about NRC's review of applications from boards recognition, there was a motion made during the group presentation on the question of status of board applications, but it wasn't quite what you read.

As I have it written, it was that the advisory committee wished to be advised of reasons why particular groups of diplomats of a recognized board

cannot follow the board certification pathway.

Does that seem to ring a bell with anyone?

CHAIRMAN MALMUD: Thank you.

MS. McINTOSH: Okay. Now we would like to discuss setting some tentative meeting dates for the spring 2006 meeting. The last meeting was April 20th and 21. We would like to – would someone like to provide input as to whether or not that week, two days in that week, would work again for the spring meeting?

MEMBER NAG: If you are doing it on a Tuesday, it will be 18 and 19, Tuesday and Wednesday; Wednesday and Thursday is 19 and 20. So I guess somewhere within that 18, 19, 20 timeframe should be okay.

DR. MILLER: I do know that that week is problematic for me if you want me in attendance.

CHAIRMAN MALMUD: That range of dates is okay with me.

MR. ESSIG: Angela, do we know if this room is available on that date?

MS. McINTOSH: Not at this moment.

MR. ESSIG: So I'm wondering if we should propose dates in two back-to-back weeks.

MEMBER NAG: If that is not workable, the previous week is between 11 to 13 of April, so you

would have two weeks.

MS. McINTOSH: For the week – for April 18th – for that week of April 18th, are we proposing the 18th or the 19th, or the 19th and the 20th?

MEMBER NAG: Whichever you have available, when you can get the room available?

CHAIRMAN MALMUD: Do we have the dates of Easter and Passover in April?

MEMBER NAG: Passover is the 13th of April. Good Friday, 14th of April.

DR. MILLER: And Easter is April 16th, so it would be after that.

CHAIRMAN MALMUD: Good Friday, therefore, is the 14th as well. So it probably would be best not to have it that week. Which is also the week of Good Friday.

MEMBER NAG: That 13 and 14.

CHAIRMAN MALMUD: And Passover is April 13th – first two nights we want to avoid Passover, so the night of the 12th and the day and night of the 13th are the ones I want to avoid.

DR. MILLER: And we were looking at 17, 18, 19, 20 somewhere in there.

CHAIRMAN MALMUD: That is fine from my perspective.

DR. MILLER: 18th and 19th would be Tuesday and Wednesday.

MS. McINTOSH: So do we want to propose the 18th and 19th for the first set of dates?

CHAIRMAN MALMUD: It looks good so far.

MEMBER NAG: The following week would be bad for me.

MR. ESSIG: Rather than the week before, how about two weeks before?

MEMBER VETTER: No, the NCRP is here.

MS. McINTOSH: Well, would that work to tie NCRP in with the ACMUI meeting, the week of the meeting?

DR. HOLAHAN: Well, would that work, to tied NCRP in with the ACMUI meeting that week?

MEMBER VETTER: The NCRP is the April 3rd and 4th. The board meets on the 5th. So that would put you out to Thursday and Friday of that week.

MS. McINTOSH: What about March?

MR. ESSIG: Well, wait, we're all happy with 18th and 19th.

MEMBER NAG: Yes, but we don't know if this room is available. 19th, 20, 20 or 21, you have three or four possible sequences for that week.

MS. McINTOSH: So what are we proposing

for the second set of dates?

MEMBER NAG: So I like 18 and 19. If that doesn't work, 19 and 20. If that doesn't work, 20 and 21. So you will have any two days.

MR. ESSIG: The problem with this room, when it's taken, it's typically taken for the entire week.

MEMBER NAG: It's taken for the whole week?

MEMBER VETTER: What about the following week, April 24th through 28th? Is that a problem for people?

MEMBER NAG: The later part of the week is a problem for me.

MEMBER VETTER: So April 24th through 26th?

MS. McINTOSH: 24th through 25th?

MEMBER VETTER: 26th. Within that window.

MEMBER LEITO: Mr. Chair, would it be advisable to maybe have Angela send something out after today, and have all the members respond say by Monday - not even that long. Say next Tuesday, because that would give them a couple of days to read their email and just say, what's unacceptable. So that maybe by next Tuesday you could have an answer,

and go from there. Would that be okay?

MS. McINTOSH: Yes, we would have to do that. Since we have several days. We're going to have to lock in one of them.

DR. HOLAHAN: That would give members an opportunity to look at their schedules and the meetings they have to go to.

MEMBER VETTER: But you could do that this week yet?

MS. McINTOSH: I could do it early next week.

MEMBER VETTER: Okay, if you do it early next week then I need 2-1/2 weeks to respond.

MS. McINTOSH: We'll get it done.

CHAIRMAN MALMUD: Okay. So tentatively, at least until we can confirm the availability of the room, it will be the week of April 19-20.

MEMBER SULEIMAN: On of the last two weeks in April, is that what it is, either/or?

MS. McINTOSH: What I have as proposed dates are April 18 and 19, or April 24 and 25, 25 or 26.

MEMBER NAG: April 18, 19, or 19,20, or 20, 21. I mean you have those three for that week, plus if that whole week doesn't work then you have

the following week.

MS. McINTOSH: Okay, so the week of April 18th.

MEMBER NAG: The week you have that big window.

MR. ESSIG: So we'll try to get this room. If we cannot assure this room, then we will work on the auditorium.

MEMBER NAG: The other thing, if the Marriott is available, is that a problem?

MR. ESSIG: I'd rather not do that again, because it was pretty costly to do that. And we can't video to the regions from there, either.

DR. HOLAHAN: And we have to justify that nothing is available in this building.

MS. McINTOSH: Okay, I believe that is it.

CHAIRMAN MALMUD: Now, may I ask a question, Angela, administrative? When we put our expenses in for this meeting, do we put them in today?

MS. McINTOSH: That would be preferred.

CHAIRMAN MALMUD: Give them to you today?

MS. McINTOSH: That is the best way to go.

MEMBER NAG: Otherwise you have until Friday.

CHAIRMAN MALMUD: Right. No, I was just

asking because I gave it to you and then you gave it back to me.

MEMBER VETTER: You were talking I think about motel expense.

CHAIRMAN MALMUD: I'm not going to do anything for this committee tomorrow or the next day. So I'm done.

MR. ESSIG: No, I was just asking, was your question related to your hotel expense or your time. Time is the thing that is due by Friday. Your hotel can be submitted somewhat after that if you need.

CHAIRMAN MALMUD: Okay, great.

Is there a motion for adjournment?

MEMBER NAG: So move.

MEMBER VETTER: I second it.

CHAIRMAN MALMUD: It's been moved and seconded and everyone agrees.

Everyone have a safe trip home.

Now if you still want to have a closed session, Dr. Diamond is not here, Dr. Williamson is not here.

DR. MILLER: It's an informational session. Once we close it, I will explain what we want to discuss, and those members that want to remain

for the information can do so. We need to terminate the video and telephone lines.

(Whereupon at 4:35 p.m. the open portion of the above-entitled proceeding was adjourned.)