UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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MEETING WITH THE ADVISORY COMMITTEE ON THE

MEDICAL USES OF ISOTOPES (ACMUI)

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ROCKVILLE, MARYLAND

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WEDNESDAY, MAY 28, 2003

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The Commission met in open session at 9:30 a.m., at the Nuclear Regulatory Commission, One White Flint North, Rockville, Maryland, the Honorable Nils Diaz, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

NILS DIAZ, Chairman of the Commission

EDWARD MCGAFFIGAN, JR., Member of the Commission

JEFFREY S. MERRIFIELD, Member of the Commission

(This transcript was produced from electronic caption media and audio and video media provided by the Nuclear Regulatory Commission.)

STAFF AND PRESENTERS:

DR. MANUEL D. CERQUEIRA, Chairman, ACMUI

MR. RALPH LIETO, Medical Physicist

MS. RUTH MCBURNEY, State Government Representative

DR. RICHARD VETTER, Radiation Safety Officer

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

CHAIRMAN NILS DIAZ: Good morning. It's always a pleasure to meet with ACMUI. I think we don't see you often enough. But I want you to know that we do appreciate all you do. Dr. Cerqueira, it's good to see you again. And my staff has been having a problem with your name. I keep saying Cerqueira. Is that correct?

DR. MANUEL CERQUEIRA: That's correct. But Cerqueira --

CHAIRMAN NILS DIAZ: Cerqueira is Portuguese. I stand corrected. Thank you so very much. Well, it is a pleasure to have you here today to brief us on the status of your activities. And unless my fellow Commissioners have something to add, Dr. Cerqueira, please go ahead.

DR. MANUEL CERQUEIRA: Thank you very much, Chairman Diaz. On behalf of the ACMUI, it's an honor and a privilege to present to you some issues that we would like to update the Commission on. We will have a total of four presentations. And we'll have one other member of the committee make a presentation as well. I'm going to be doing an overview. And all of you, I believe, have the slides. The committee currently has three vacancies, a vacancy for nuclear cardiologist, an agreement state representative, and a patient advocate. We've been working closely with staff to try to get these positions filled in a timely fashion. And we're making good progress. And we anticipate that these three vacancies will be filled by the time current positions expire on the committee.

The issues over the last year or so have made both the committee as well as the staff really consider the creation of a Vice Chair for the committee. And I think that Dr. Charles Miller, when we assumed his position, you know, agreed with this, that all the other committees do have a Vice Chair.

The Vice Chair will establish a very important role of establishing an orderly transition from the new Chair to the incoming Chair. And there will be a continuation of business. It also

allows the Chair to take a more active role on those issues that are relevant to his own sub-specialty. Because many times as the Chair, you cannot be as strong an advocate for your constituents. And by having a Vice Chair, you can actually step down and become a regular member and be very supportive of the issues that are important to you. In this recommendation of creating the Vice Chair, we're supported by both the committee members as well as the staff.

The next item really relates to sort of the ACMUI staff interactions. And I think those of us who have been on the committee for a number of years have been a little bit concerned recently. Over the last two years, certainly since 9-11, the issues related to national security, shifting of staff within the NRC itself, has really resulted in quite a bit of turnover among staff supporting the committee. And this creates problems in certain ways because there's a lack of continuity among the committee and the staff related to issues that have not been, you know, a one month or a two month issue, but have rather been on-going for several years.

And, you know, in discussions with Dr. Miller and other members of the staff, it appears that this is going to be an on-going situation, that people within the NRC will be shifted to different roles as national priorities dictated. And I think it's the feeling of the ACMUI that this may cause some difficulty with the continued work of the committee, primarily because of the inability to have a continuity of care. So this issue of reassignment, some issues of retirement where people are leaving, I think certainly that, in combination with the on-going national situation, has raised some concerns about the ability of the committee to go on.

In order to remedy some of these issues, we have implemented a series of follow up conference calls where, after the committee has met, we will generate minutes. We will have the staff review some of these issues and then try to deal specifically with follow up and action items related to the minutes of the meeting by having a conference call at some point.

There was also some concern expressed by the committee at the meeting last week of just having, the committee being able to have access to the Commissioners. There are issues that the committee and additional members feel very strongly that certain actions should be taken. As an advisory committee, we don't actually -- we basically advise. And some of the committee members expressed the desire to have more direct access to the Commissioners in case it was felt that the staff didn't necessarily see the importance or the priority of some of the issues that came up. And we certainly, at the end of my presentation, we welcome the input of the Commissioners on that.

The last two items of my follow-up are really related to the work of the committee for the last several years, which is the revision of Part 35 and the progress of the implementation of the revised 35. Shortly after the revisions were completed, we realized that we had unintentionally created some problems for medical physicists and for radiation safety officers in terms of requiring board certification, that some of the boards would probably not be able to meet the requirements. And as a result of that, a temporary two-year commitment was made to continue, both under the old Part 35 as well as the revised Part 35, to try to deal with some of these issues. We also have created a subcommittee that's giving us some new recommendations for rulemaking. And Dr. Vetter will make some presentations of that.

So currently we're operating both under the old as well as the new requirements. But we feel that it is important to keep this on track so that when the new rulemaking becomes the sole governing body in October 2004, that the expiration of people being able to come in under the guidelines of the old rule, that we will be able to have that fixed in such a way that we will not disenfranchise people like radiation safety officers and medical physicists. And Dr. Vetter will be giving us an update on that.

The last item I have really relates to the Agreement State compliance, especially for the Training & Experience requirements, because we felt that because of the geographic mobility of authorized users, medical physicists, radiation safety officers, and radio chemists, it's really important to get a complete agreement between the NRC and the Agreement States. So far we've gotten feedback that seven states have agreed to adapt their requirements and revised 10 CFR Part 35 completely.

The majority of the other states are expected to meet the August 24, 2005 deadline for compliance. But we feel that it is important that the Commissioners keep on top of this as best as possible so that we don't find ourselves in October of 2005 having a lot of the regulated community encountering problems when they go from an NRC regulated state to an Agreement State or from one Agreement State to another where the same rules, specifically for Training & Experience, may have some untoward problems for the authorized users. Those are my only comments at this point. We'll be happy to entertain questions now. We could go through the whole presentation.

CHAIRMAN NILS DIAZ: Let's just go through the whole presentation. I would appreciate it.

DR. MANUEL CERQUEIRA: Okay. the next presentation on the feedback an the national materials program will be made by Ralph Lieto. And at the end of his presentation, Sally Schwarz, who is a member of the committee, would also like to make some additional comments to supplement Ralph's presentation. Ralph?

MR. RALPH LIETO: Thank you. On behalf of the ACMUI, I wish to thank the Commission for this opportunity to comment on the National Materials Program Working Group Report. We recognize that the report and the process is early in addressing and making changes to the national materials program, but because it's early on in its process the ACMUI

wishes to express a few issues that relate to the medical use for the NRC's consideration as this program develops and goes forward. Hopefully, we'll provide these comments in a proactive context.

I do wish to express thanks to the NRC staff, especially Paul Lohaus and Mike Markley for assistance in clarifying some issues in the working group report. As background, the working group report originated from a 1999 directive from the Commissioners to report on options for NRC consideration because of three issues: one, the impact of the increasing number of Agreement States coming on-line; the decreasing number of licensees under the NRC purview; and the trend of technologies and expertise to either emerge or be centered in Agreement States.

The working group submitted its report in mid 2001 to the Commission, recommending that of various options that a national materials program be an alliance between the NRC and Agreement States and that this would be essentially a partnership, if you will, that would provide a cooperative consensus building process between the states and the NRC to regulate radioactive materials.

It also recommended the development of an implementation plan for this national materials program in that regardless of what option was chosen there were enhancements or components to enhance the national materials program. The ACMUI became aware of this, of the working group report, in early 2002 and provided comments to staff at its October 2002 meeting. Since then, the ACMUI has become aware that the Commission has approved a blend between the alliance option and the current regulatory program, and that several projects are now underway to assess the implementation of such a blended program.

The ACMUI supports the recommendation of an alliance option for a national materials program to regulate radioactive materials. Such a program would provide a single group or

agency to establish standards and regulations. This is also consistent with other industrialized nations in their regulation of ionizing radiation.

The ACMUI also supports three of the four components that were in the working group report to enhance the implementation of the national materials program. The first component is the use of and support for centers of expertise that are established in Agreement States or may arise from Agreement States; to maintain an informational infrastructure; to facilitate and encourage the exchange of ideas, informational resources, events, et cetera. Of course, this infrastructure of information exchange needs to balance its goal with the security of high activity sources used by medical licensees or licensees supporting the practice of medicine. And a third component was the creation of a standing compatibility committee between Agreement States and the NRC. The ACMUI supports an implementation plan to initiate these enhancements or components to the national materials program as early as feasible.

There are two areas of concern of the ACMUI that deal with the implementation or the recommendations in the working group report. These are the costs to medical licensees of implementing the changes in the working group report and the assumption of regulatory authority by the NRC for naturally occurring and accelerator produced radioactive materials, more commonly called NARM.

An assumption is implied that all states can provide financially to implement the changes in the national materials program. It is unclear how an expansion in the program will result in cost savings for regulatory programs, especially in light of the increasing regulatory authority that would have to be assumed, and also providing for the enhancements recommended in the working group report.

A serious concern is that there would be a shift in the cost of a regulatory program from the federal level to the state level and how this would be funded by the states or supported

financially by the states. This is an area that obviously needs further consideration and evaluation.

Another thing is that the number of NRC licensees will continue to decrease in the near future. And the funding of a national program in NRC regulated states cannot reasonably be expected to continue while NRC license fees support the federal portion of the program. Accordingly, a change in the funding mechanism must be considered as a part of any change in the regulatory authority by Congress for a national materials program.

Lastly, an area of concern is the assumption of the blended national materials program is that the NRC will obtain Congressional authority to regulate NARM. The ACMUI recognizes that the NRC is concerned for high level -- or excuse me, long lived NARM materials for security reasons, but is very concerned that the production and use of PET radio-pharmaceuticals will be adversely caught up by burdensome regulations. PET stands for Position Emissions Tomography. It is a diagnostic modality in nuclear medicine that employs short-lived positron emitters tagged to common biological compounds. The most common form of this that's used currently is fluorine 18 tagged to an analog of glucose.

For non-Agreement States, the NRC would become the sole regulatory authority for NARM. There is concern that an increase in regulatory burden for accelerator produced radio-pharmaceuticals may be imposed, when it should be realized that there have been no incidents involving PET radio-pharmaceuticals in patients that have occurred, and the need for increased safety in the medical use of PET radio-pharmaceuticals has not been demonstrated.

The NRC must be practical and not adversely affect the use and availability of this modality to patients. PET imaging has great potential in diagnostic nuclear medicine and continues to demonstrate its usefulness in the diagnosis, the staging, and treatment planning of

various cancers. Besides the management of various cancers, it's showing increased usefulness in the diagnosis and management of other diseases.

Again, on behalf of the ACMUI, we appreciate the opportunity to provide our views, hopefully in a proactive and constructive manner as the national materials program effort and implementation goes forward.

COMMISSIONER NILS DIAZ: Thank you, Mr. Lieto.

MR. MANUEL CERQUEIRA: Thank you, Ralph. Sally Schwarz who is a committee member would like to make some follow up comments related to NARM. Sally?

MS. SALLY SCHWARZ: Thank you. My name is Sally Schwarz. I represent Nuclear Pharmacy on the ACMUI committee. My concern that I would like to bring to the Commission today is that since there is currently legislation pending to amend the Homeland Security Act to include NARM under the AEC, there will be a problem with that regulation, if it would pass, in regulating PET drugs. And this essentially could shut down PET in the United States.

The actual problem is that under Part 35 regulation the NRC regulates FDA approved drugs which also includes drugs holding investigational new drug applications, IND's, new drug applications, or RDRC approved drugs.

PET drugs are not FDA approved drugs. There's only one approved NDA application in the United States approved by the FDA. Otherwise, there is no FDA approval for PET drugs currently that exists. They fall currently under a special group, a separate group of drugs regulated by a FEDAMA amendment. Essentially this allows us to follow the United States pharmacopeia monographs for their preparation and use. This needs to be considered before amending the Homeland Security Act, or potentially PET drugs will not have an FDA approved route since we are not currently FDA approved. And if we would then fall under Part 35

regulation, there would be a problem in terms of regulating PET drugs, which could potentially shut down PET until these issues are resolved. Thank you.

MR. MANUEL CERQUEIRA: Thank you. The next presentation is the report from the ACMUI Training & Experience Subcommittee that was formed. And Dr. Richard Vetter will be making the presentation.

DR. RICHARD VETTER: Good morning. Thank you very much for this opportunity to be here. As you recall, the new Part 35 authorizes individuals to practice in various specific specialties, such as radiation safety officer, authorized medical physicist, and so forth. The new Part 35 provides for individuals to become authorized to do these for these particular physicians by either meeting certain specific prescriptive Training & Education requirements or by becoming board certified by a specialty board that incorporates these requirements. So the ACMUI, as they discussed this, felt it was necessary to appoint a subcommittee to address the issue and bring forth recommendations. And you are familiar with that history.

Under the new Part 35, only one specialty board met those prescriptive requirements, and therefore all other authorized individuals would have to go through the alternate route. And there was some concern about affecting the supply of authorized individuals and also the increased burden that would be put on NRC staff because they would have to look at all of these applications rather than being able to accept the fact that the individuals were board certified.

This was most problematic for sections that dealt with the radiation safety officer and authorized medical physicists. However, the recommendations of the Training & Experience Subcommittee apply across the board. So this came to the Commission, the Commission, for the most part, approved the recommendations of the ACMUI. And I want to express our

appreciation for the fact that you took our recommendations seriously and addressed these issues and agreed, for the most part, with our recommendations.

In particular, we appreciate the fact that the certification by a specialty board is now a default pathway. And so once an individual demonstrates that they're board certified, they can become -- I will use radiation safety officer as the example throughout my presentation, although this does apply to others. So once they are board certified by a board that meets these specific requirements, then they can become authorized to serve as a radiation safety officers.

The one area where the Commission disagreed with the committee was on preceptor attestation. I'll address that in a moment. The committee is very appreciative and strongly believes that the default pathway will serve these new regulations well. We strongly believe that boards that meet this pathway actually surpass the minimum requirements for safety that is intent in the rule.

Relative to boards being listed on the NRC website, the committee originally suggested that these be written into the regulations. But we certainly do support the listing of the boards on the NRC website. So those boards that meet the special requirements, special criteria in the regulations, would be listed on the website. And that's clearly available to everyone who needs to know.

The area where the Commission disagreed with the committee's recommendations was in the area of preceptor attestation. And one thing that I would like to try to make clear is that in the SRM, you had indicated that the staff should clarify the language relative to candidates -- relative to boards, that boards should require candidates to demonstrate that they have the knowledge to fulfill the duties of the position -- underscore position -- for which certifications are sought. Individuals do not seek certification to become an RSO or an AMP. They seek

certification to demonstrate their expertise in their specialty, then they apply for various positions.

For example, at Mayo Clinic where I work, I am the radiation safety officer. I have three health physicists who are board certified who work for me. They are not radiation safety officers. They did not take the boards to become radiation safety officers. They took the boards to demonstrate to Mayo Clinic and the profession that they have a certain body of expertise. So they did not take the boards to become radiation safety officers, but they have, in fact, demonstrated by taking the boards that they have the expertise to serve as radiation safety officers. And consequently, relative to the preceptor attestation, it's more or less a mute point for the board. The board doesn't care whether they want to become a radiation safety officer or not. The board simply cares that they demonstrate that they have the expertise for that particular specialty, whether it's radiation safety, medical physics, et cetera.

Well, I want to assure the Commission that the ACMUI stands ready to assist the NRC staff in addressing this issue. We certainly don't want to get caught up in the problem we had before where none of the boards meet the specific requirements of Part 35 because they don't require a preceptor statement. They certainly do require someone to attest that they have the knowledge and the expertise. So I want to assure the Commission that we will work with the staff to address this issue to try to adequately accommodate that requirement in the regulations and also to address other issues that may arise. I have some back up slides that I won't go through that are there simply for purposes of discussion.

DR. MANUEL CERQUEIRA: Thank you Dick. The next and the last presentation will be emerging technologies and some issues related to that by Ruth McBurney.

MS. RUTH MCBURNEY: Thank you. Good morning. The uses of radioactive material in medical and industrial technology is constantly changing, as you all well know, I'm sure. This

is especially true in new modalities being used in the medical field. And as such, ACMUI has been asked to assist and provide input to the staff on licensing issues dealing with some of those new technologies. And we're doing that through a subcommittee mechanism of the ACMUI. The committee is made up of representation from radiation oncology, nuclear medicine, hospital administration, nuclear pharmacy, medical physics, health physics, and patient advocacy, as well as myself from state government.

Our charge that was made to the subcommittee was to provide the Nuclear Regulatory Commission staff with recommendations on licensing guidance for the new modalities that do not fit into subparts D through H of 10 CFR, Part 35. These are modalities that use radioactive materials that do not quite fit into, for example, manual brachytherapy or thigh dose rate brachytherapy or nuclear medicine but must be licensed specifically and under specific license conditions specifically for limited scope licensees.

Our initial task was to provide input on licensing guidance for Intravascular Brachytherapy, the GliaSite System and Yttrium-90 microspheres. Intravascular Brachytherapy uses sealed source stints or seeds or wires inserted by a catheter. Some of this may fall into manual brachytherapy, some of it may be high dose rate brachytherapy. But a team approach was recommended for that. The GliaSite System uses liquid in a balloon catheter, so it's considered a sealed source but it's actually liquid inside of a balloon and it's sort of like brachytherapy once it's in use. The Yttrium-90 Microspheres use very small sealed sources. There are administration and contamination issues that are more like the radio-pharmaceutical therapy because it is so small and its administered more like a radio-pharmaceutical therapy.

So some of the issues that were brought up on these particular modalities as well as what we'll be looking at in any additional emerging technologies are the, of course, Training &

Experience for the authorized user, do you require them to be trained for manual brachytherapy, for nuclear medicine, and so forth. Is a team approach needed?

For example, in the Intravascular Brachytherapy the cardiologist is usually involved and the medical physicist is also involved in that modality. And who needs to be present during the administration of these types of medical procedures? Does the medical physicist need to be there the whole time? Does the physician, the authorized user, and so forth? What should be required in the written directive from the authorized user for these different types of modalities and any unique radiation safety procedure? As I mentioned in the microspheres, there is a potential for contamination if some of these little tiny microspheres get loose.

So in addressing our charge, I first gathered information from various stakeholders as to other government entities, how the Nuclear Regulatory Commission is licensing these, how other Agreement States are licensing them. And then I invited several of the medical stakeholder groups to a meeting that we had last week in conjunction with our ACMUI meeting. We had a separate subcommittee meeting to discuss the licensing guidance that NRC is using.

The one area that got a lot of discussion was the Yttrium-90 Microspheres because it does kind of overlap a couple of modalities. We had input from the Society of Nuclear Medicine, the American Society of Therapeutic Radiation Oncology, and American College of Radiology. We came up with the consensus that both those physicians that are trained in brachytherapy and those that are trained in radio-pharmaceutical therapy could, under certain conditions, be authorized users for that modality.

We are going to get further input from those groups, and they're going to be providing input to the subcommittee by July. And we'll have further discussions on this issue to provide our final recommendations on the licensing guidance for these particular modalities. And then

we also plan to have continuing communication with the staff as other emerging technologies come up.

DR. MANUEL CERQUEIRA: Thank you very much, Ruth. Chairman Diaz?

CHAIRMAN NILS DIAZ: Thank you very much, Dr. Cerqueira. We appreciate your being with us and bringing these issues to our attention. Let me assure you that although you are small you have our full attention, because the issues that you deal with are very important. And that is, you know, something that you might not realize. But we do care, and we do worry about you a lot. And with that, I pass to Commissioner McGaffigan who is first today.

COMMISSIONER EDWARD MCGAFFIGAN: Thank you Mr. Chairman. You've given me a lot of things to ask questions about. I'll try to be disciplined and get through this. You asked Dr. Cerqueira about access to Commissioners. And I can tell you, we all have an open door. I mean, you know, some folks take more advantage of it than others, but we're happy to hear from you, particularly when the staff isn't agreeing with you. I'm amazed that you feel that you don't have that opportunity, but you clearly do. And we're happy to listen to you directly. And so I think that's there, and there probably is no use hitting --

DR. MANUEL CERQUEIRA: We appreciate your reaffirming that. We will take advantage of that.

CHAIRMAN NILS DIAZ: If I might stop you, I think this is a reaffirmation of our commitment to be open and be available. And you all have that opportunity.

COMMISSIONER JEFFREY MERRIFIELD: I was going to withhold, but given the invitation, Chairman, I agree with that same sentiment. But I do want to counterbalance that in one respect. And that is that I don't want to leave the impression that the Commission isn't aware of or kept informed by the staff. I mean, our staff goes to great pains to keep us informed about what is going on in their interactions with the organization. And as much as it is

painful sometimes, sometimes I think that although the Commissioners may not necessarily take your guidance it doesn't mean we haven't been informed by staff. We may have been informed precisely as to your views on the issue. We may just come to a different decision.

COMMISSIONER EDWARD MCGAFFIGAN: But I'm perfectly happy to have your views directly. That is something that I think would be useful.

With regard to an ACMUI Vice Chair, if there is as much consensus as there is, as far as I'm concerned the SRM for this meeting can say we support there being a Vice Chair.

COMMISSIONER JEFFREY MERRIFIELD: I'll second that one as well.

COMMISSIONER EDWARD MCGAFFIGAN: That makes the SRM easy. Let me look at some of the other issues. There are some important ones that I want to get to, but I didn't want to skip past things.

The issue of the national program. You know, I think the issue that was raised about the provision that we have adopted with -- or are urging the Congress to adopt with regard to regulating NARM, I believe the transition issues can be handled, including the FDA issue. That is not a statutory issue. That's an issue that our Part 35 would need to be modified during the transition period. And I think that's our full intent. Our full intent on NARM is that we're going to take advantage of what the Agreement States are already doing. I think more or less the Agreement States are supporting us generally on seeking this authority. And I think our commitment to the Agreement States is that we're going to try to put into place a regulatory program that is compatible with what the states are doing.

Now, if the states are wildly different, you know, Texas versus California, we'll have to sort that out. But if the states already have a decent program with regard to PET scans in particular -- and we're not going to be, we're regulating the material. Our goal is to regulate the material, not the accelerators that produce the material, not the -- I'll guess we'll end up,

because the material is being regulated, we'll regulate PET scans to the extent the material is in there.

I've had four PET scans in the last couple of years. I've had melanomas, so I keep getting staged for it and I'm very familiar with the technology. I'm sure Chairman Diaz and other Commissioners are, but Chairman Diaz in particular is familiar. So we're not going to disrupt the medical use of PET scans. I think we make that commitment to you. On the other hand, we do think that having a rational national program makes a lot of sense. And the only non-accelerator produced material we're likely to regulate is radium 226, discreet radium 226 for security reasons. But the other NARM materials, I don't think, are going to ever qualify under this statute as its currently drafted. So it's radium 226, accelerated produced radioactive materials which are generally short lived like fluorine 18.

You know, I'm a Nuclear Regulatory Commissioner, so when I go to the Washington Hospital Center to get my PET scan, even though I'm not regulating this guy, he's quite aware the I'm a Nuclear Regulatory Commissioner. So he's following all the procedures just as if he were in the nuclear medicine department.

CHAIRMAN NILS DIAZ: You make sure of that, right?

COMMISSIONER EDWARD MCGAFFIGAN: He's a really nice guy. In fact, he used to be a pharmacist and he didn't like the doses he was getting as a pharmacist which is why he's now a technician on the PET scan machine because he gets a lot lower annual dose.

COMMISSIONER JEFFREY MERRIFIELD: Commissioner McGaffigan, not to interrupt you, but knowing you as I do, having worked with you now for five years and actually knowing you a lot longer than that, I have to remind myself to send a sympathy card to your poor doctor. I'm sure you've grilled him quite thoroughly in that regard.

COMMISSIONER EDWARD MCGAFFIGAN: You should see, sometimes when I really was in the nuclear medicine department, how anxious they were. So I think the PET scan issue can be worked, I really do. And I think, you know, if the FDA issue is simply a matter of a small change to Part 35 that we would have to do in the transition period in order to bring our program into compatibility, the states must have already dealt with this issue on their own programs. So I'm quite confident that we can get that done.

The one thing I was going to ask you, you said you supported three of the four, and I forget what the fourth is.

MR. RALPH LIETO: The fourth is the assumption of NARM.

COMMISSIONER EDWARD MCGAFFIGAN: Are you formally opposed to our assuming authority for NARM, or are you opposed unless you hear sweet music coming from the Commission?

MR. RALPH LIETO: Well, I think, because of this whole working group report and the national materials program is very early on, we wanted to express our concern with the assumption of NARM regulation by the NRC. Past history has not been, shall we say very kind to the regulation of radioactive materials in medical use. So we thought that by bringing this to the attention of the Commissioners early on in this process, because as it was pointed out, there are pilot projects, projects going on right now that are addressing the implementation of this. We wanted to make our comments early on so that things didn't get way into the process of formulating a program and then we're starting to raise red flags then.

COMMISSIONER EDWARD MCGAFFIGAN: I appreciate the early heads up, but I do think that this makes a lot of sense. I think we're waiting for Congress to act. The provision that we're advocating has a transition period in it, and so I think that during that period, if Congress should enact the legislation and the Senate Environment Public Works Committee

has thus far supported it -- I believe it's only recently been given to the Congress, so the House hasn't had a chance to react.

But if it's enacted, which will probably be on the Energy Bill or some bill that has almost nothing to do with your area, but if it's enacted we will have a period of time in which to work out these details. And I think our full intent would be to do so. Now, will there be fees associated with this program?

Yeah. I mean, it's not cost neutral, obviously. But hopefully, will be compatible with what our other medical fees are. And if somebody is already a licensee, as many people will already be a licensee, the fee increase may be very small.

COMMISSIONER JEFFREY MERRIFIELD: Mr. Chairman, I hate to keep doing this. I would just like to associate myself with some of the comments made by Commissioner McGaffigan. And I want to underscore that just a tiny bit with your permission. For my part, I mean, we talked a lot about the whole issue of NARM. I mean, this is an issue that the Commission considered at great length and was a topic of very active discussion about what we wanted to do. This was no flip of the hand in terms of our decision to do this. I mean, I think the Commission as a whole went into this with great consideration, great deliberation. And I agree with Commissioner McGaffigan to the extent that there are issues that have arisen and some complications. I share Commissioner McGaffigan's commitment to the belief that we can resolve that. Certainly, none of us here would want to take modalities out of place that are important for protecting public health. And obviously, we need to coordinate in that regard.

DR. MANUEL CERQUEIRA: I just hope there's enough time between -- you know, that transition period would give us enough time to make regulatory changes so that the stakeholders would not be compromised in any interval between, you know, legislative enactment and implementation.

COMMISSIONER EDWARD MCGAFFIGAN: I guarantee you that the issue that was raised will be resolved before that goes into effect. And we can do that. We can do it by exemption as we did. There are lots of ways that we can tackle that. We're not going to put the PET industry out of business over a technicality in Part 35.

COMMISSIONER JEFFREY MERRIFIELD: And to give a compliment to our Chairman, I think this is a Commission in its current form that has demonstrated its willingness to act quickly. I credit him in that regard.

DR. MANUEL CERQUEIRA: I very much appreciate it.

CHAIRMAN NILS DIAZ: And since we're being so informal, Commissioner McGaffigan says that he believes we can do this. I can tell you that we will do it. We will make it happen in a manner that in no way are we an impediment. We want to actually be helpful in the implementation of these processes in the manner that we always do things. But with the learning process that's already taken place with Part 35, which has been long and good and solid. And so we will implement it in a very, very effective manner. I can assure you.

COMMISSIONER EDWARD MCGAFFIGAN: In fact, I would encourage this. I don't want to anticipate legislation. If we start expending resources, it's going to be fee payers who are going to be paying for the resources. And if the legislation doesn't pass, then we will have wasted resources. But anything that you all want to continue to bring to our attention --

And I personally think this should be a national materials program pilot, you know, if it's going to happen. Because we definitely want to learn from the states in this instance. We want to look at some model regulation. I don't think CRCPD has a model regulation for NARM, for regulating NARM in medical practice. But we can take Texas or California or any state's current regulation and then try to work off of it and make it work.

The issue of -- the last issue I'll mention, you do endorse the Standing Compatibility Committee. And I always, especially with this group here -- Ruth may or may not appreciate this, but the Standing Compatibility Committee will make recommendations. The Commission will make decisions. And I can tell you the Agreement States have met with us at least three times to tell us that they don't agree with our decision which you guys do agree with, with regard to compatibility for Training & Experience requirements. Because you all recommended and we agreed that, because somebody might practice medicine in Virginia, Maryland, and D.C. that they shouldn't be under three different regimes. Depending on where they happen to be, I guess D.C. and Virginia would be our regime, maybe two different regimes.

We saw the mobility, and therefore we made it a hard compatibility issue. And to this day, I think the majority of Agreement States, or certainly a vociferous minority of the Agreement State people, strongly disagree, which gets me to T&E.

I voted for doing what you all recommended. And I'll get to the preceptor issue. But I'll tell you it was with some reluctance. This doesn't come across in our votes. We had worked on Part 35 for a long time. The cardiologists had managed to meet the requirements, but we told people this was coming, the staff met with the medical boards and then, you know, it was last year at our meeting that suddenly folks said: oops, this is going to be a big problem, people don't want to do what you all are requiring in the way of the educational program that the board has to include as part of board certification.

And it sort of took me aback to some degree. As I said, we're going to work to solve this. I voted for the change, but since you're the radiation safety officer, I'm looking at 35.50 as it was enacted. What part of B-1 was the big problem in terms of things that the board didn't want to do in radiation safety officer space?

DR. RICHARD VETTER: Well, there are two things. One is the prescribed number of hours. I'm not a member of the board at the moment, but I have served on both the American Board of Medical Physics and the American Board of Health Physics. And they firmly believe that you demonstrate expertise through an examination process, not by sitting through 200 hours of courses. And they do not require that you sit through those particular prescribed number of courses,

rather they require that you have a degree in physics or whatever.

They have a number of possibilities for meeting the requirements, but you have degree and experience, and that you go through a process. One part of that process is to take an examination. And I can assure you, these examinations are not easy. And they demonstrate that you have the knowledge in those 200 hours of courses. They far surpass that minimum requirement.

COMMISSIONER EDWARD MCGAFFIGAN: But why didn't that come up in the four year Part 35 process?

DR. RICHARD VETTER: I think that's a very good question. I think it caught all boards asleep. I'm assuming that they all assumed that because they were required to have degrees that covered this subject area, they assumed -- and that's all -- if you read the requirements to qualify for a board, it doesn't refer to hours, most of them don't. They refer to having a degree, a medical degree, a physics degree, whatever. And they assume that that certainly meets the requirements. And then when the process came through that they had to demonstrate that, they couldn't demonstrate they had the 200 hours.

COMMISSIONER EDWARD MCGAFFIGAN: Why could the nuclear cardiologist?

DR. RICHARD VETTER: Because that board was -- I'll let Dr. Cerqueira answer that.

DR. MANUEL CERQUEIRA: Well, I think cardiologists usually come into the area through a different pathway. And you know, not all cardiologists are required to take it. Here I think it's been sort of an added requirement. And I think it's sort of a quality control issue within the field that people have a certain number of hours required of training.

COMMISSIONER EDWARD MCGAFFIGAN: The preceptor issue you raised -- I'm looking at the radiation safety officer provision 35.50. The SRM may have mentioned the word "position." What has to be done, and I don't think it's changed is -- has obtained written certification signed by a preceptor radiation safety officer that the individual has satisfactorily completed the requirements in paragraph B-1 or equivalent, presumably the board, of this section, and has achieved a level of radiation safety knowledge sufficient to function -- not for a position -- but sufficient to function independently as a radiation safety officer for a medical use licensee.

So those words are okay, aren't they? The board is willing to say that somebody who has passed their board certification has a level of radiation safety knowledge sufficient to function as a radiation safety officer, even if he isn't planning to be a radiation safety officer.

DR. RICHARD VETTER: The current requirements for the board's are to have someone write a letter, more or less along these lines, that says you have the knowledge and expertise to pass that examine, that they believe you have the knowledge and expertise it takes to qualify to pass that exam. Not to function as an RSO, because they're not all going to be RSO's. They're taking the exam to be a certified health physicist.

COMMISSIONER EDWARD MCGAFFIGAN: But is there a gap between the exam then and what they need to know to be a radiation safety operator?

DR. RICHARD VETTER: No. In fact the exam surpasses the knowledge you need for radiation safety officer. But the preceptor statement, because they're not taking this to

specifically be a radiation safety officer but rather to be a practicing, board certified health physicist, the preceptor statement doesn't mention the word, radiation safety officer. It simply asks someone, typically their supervisor, to write a letter saying, we believe this person has the knowledge to qualify and pass that exam.

Now, the exam is difficult, and still only about two-thirds of them pass the first time around.

MS. RUTH MCBURNEY: As an example of that, I'm a certified health physicist. The person who sent my letter of recommendation was not a radiation safety officer. I'm not a radiation safety officer. However, if I applied to be a medical radiation safety officer, my board certification would not meet that requirement in that the preceptor was not a radiation safety officer.

COMMISSIONER EDWARD MCGAFFIGAN: I see.

RUTH MCBURNEY: But otherwise, I could qualify as a medical radiation safety officer.

COMMISSIONER EDWARD MCGAFFIGAN: You're saying that by rejecting your recommendation about preceptor statements we have set up a catch 22 where the boards will be unwilling to -- because they're not capable of -- they're capable of saying they have a lot of information with regard to radiation safety, but they are not willing to say we think this amount of information is enough to be a radiation safety officer or certified health physicist or whatever?

DR. RICHARD VETTER: No. I'm saying that the boards currently don't have a requirement that the preceptor say the individual would qualify as a radiation safety officer. They would qualify as a health physicist. Once you've qualified as a health physicist, you do qualify as a radiation safety officer. But not everyone who's taking those boards is doing it for the purpose of someday becoming a radiation safety officer. They may become the head of a state program, they may become a consultant, a lot of different things.

COMMISSIONER EDWARD MCGAFFIGAN: Again, my frustration is that the boards sat through -- I mean, there were special meetings with the boards to go over this text. And, you know, during the four year process of doing Part 35, you would think somebody would stick up their hand. I mean, this partly goes to what the definition of the preceptor is. We have a definition of what a preceptor is. A preceptor means an individual who provides or directs the Training & Experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a radiation safety officer.

So in some sense here, the way all of this hangs together, you're saying, doesn't necessarily meet the practice of boards. And yet the boards had access to this. It's just a frustration. It's a frustration that we spent so much time on this. And we generally followed almost all of your recommendations, including the compatibility recommendation over the Agreement State opposition. And then in the end we had -- we're going through this drill which, I agree, we have to get complete by next year, to try and fix these T & E requirements so that the states in turn can fix them in good faith by the following year. So we've put ourselves on a tight deadline on something that I wish we could have communicated better on during that long process.

I mean, part of the frustration is that these massive documents, we would have them sit out for two or three months just in case somebody had a comment on them, you know, hoping that people were pouring over them, looking for this sort of things.

The last issue -- and I'll look to Karen to make sure I'm okay to ask the question. I'm not going to get to the details of a particular enforcement case that's pending, but all of us received a diatribe from Carol Marcus, one of your former colleagues on this committee a few weeks ago who had seen a press release from NRC and went to battle stations over whether we could have possibly been calculating properly the dose received by the loved ones of this particular

patient who passed away. And her seat of the pants calculation was indicating that we were talking about hundreds of millirems rather than large numbers of rems for this loved one who would not leave her mother's side. Do you all get involved in such calculations? And, you know, do you advise the staff -- I mean, this is a fairly significant case. Are you all familiar with the case?

DR. MANUEL CERQUEIRA: It was reviewed at the last committee meeting, I believe.

DR. RICHARD VETTER: We didn't review it in detail, but we're aware of the case.

COMMISSIONER EDWARD MCGAFFIGAN: But none of you actually did independent calculations? The licensee had very large numbers too as to what they thought the dose was to the family member. It wasn't just our staff that came to this conclusion. I think the licensee came to a similar conclusion.

DR. RICHARD VETTER: The committee has not been asked to address that issue at all. Now, we do, as individuals, get involved in situations like that at our own institutions. And we advise nuclear medicine or the radiation oncology staff accordingly. We have not been asked to --

COMMISSIONER EDWARD MCGAFFIGAN: The thing that raised her e-mail which I hope you all have seen. I mean, the whole rest of the world has seen it.

DR. MANUEL CERQUEIRA: I believe we have not seen it.

COMMISSIONER EDWARD MCGAFFIGAN: Okay, well, we'll give you a copy. But her e-mail basically, I mean she indicates as to how she does calculations with regard to, you know, loved ones having access to people in California. And I think she supports our 500 millirem limit, which is what we have now for loved ones, up from the 100 millirems we had before.

For patient release we have 500 millirems. Some states don't agree with that. But if there really is a wide disparity in how one makes these calculations -- I mean, if I had a child or

a loved one, you would just have to tell me what I would have to do for ALARA, and if I was going to get 5 REM, I would get 5 REM. And you would have to yank me out of the room probably to prevent it. But I think there are ways to get it done. But if there's a big difference in how one calculates what the dose is for loved ones, we should know that. I mean, if there's a big variation among the states, we should know that so that people can make, you know, realistic estimates as to what people are getting as they try to care for their loved ones in perhaps their final hours and all of that. But it might be a tasking for you all to look at is there a wide variation.

In any case, I will give you a copy of the Carol Marcus diatribe for what it's worth. And I do want to publicly commend Commissioner Merrifield for the response that he gave to that diatribe. Because he basically said, we'll look into it but you don't do a lot of good by adhominem attacks on individual staff members, which is where Dr. Marcus seems to always start.

DR. MANUEL CERQUEIRA: We were unaware of the e-mail. We did address the issue. We sort of reaffirmed your feelings, that if family members were knowledgeable and aware of the risks and were willing to assume it, then we felt it would be appropriate for them.

And I don't do these sort of calculations, so I don't know how to do it. But I think that's something the committee could review, so that if people are willing to take that risk they should have as much information as possible.

COMMISSIONER EDWARD MCGAFFIGAN: I think you can keep it to 500 millirems generally, without a lot of effort. I mean you can put an extra shielding on the person, tell them how many hours a day they can be there realistically and to stay under 500 millirems. And if in the end they absolutely refuse, as I might, I don't think it's the hospital's fault at that point. Because as Marcus said in her e-mail, that person could walk out of the hospital at that point.

You know, that is something they can do. We wouldn't encourage it, but it's something they could do.

CHAIRMAN NILS DIAZ: Thank you so much, Commissioner McGaffigan. Commissioner Merrifield?

COMMISSIONER JEFFREY MERRIFIELD: Thank you, Mr. Chairman. Commissioner McGaffigan has already discussed many of the areas I was going to address so I'll try to keep mine brief. One of the issues that you did talk about that we haven't addressed so far is the issue of turnover of staff that we have. And I understand that, I'm very sympathetic with that issue. We face a similar issue on the reactor side. Many of our reactor licensees are concerned about the turnover of our project managers, people who they directly associate with at the agency. Part of that, I think, is a function of the aging that we've been confronting here at the agency, I think actually confronting quite well, and making sure that we have a qualified staff force down the line.

It's also a function, obviously, of the security issues. We've been taking qualified people from a whole variety of areas and putting them into different positions, in part to take advantage of their capabilities, and also in part to make sure that we have a well trained cadre of folks with a diversity of different qualifications. So it's a tough battle, one where I hear you and certainly we will try to monitor. But it's a difficult one for us.

In that regard, I know recently Dr. Charles Miller, you mentioned him in your presentation, Charles has taken over a much higher profile on these issues, directly associated with all of you. And I have to say in my own personal regard, Charlie is a terrific guy and I think you will be well served by that relationship. He served a vital role in our incident response office, and I think he will bring good things to the relationship.

DR. MANUEL CERQUEIRA: We totally agree with that. And anybody who was willing to sit through two days of meetings for the entire session should really be commended. And his efforts were very much appreciated.

COMMISSIONER JEFFREY MERRIFIELD: Well, I think having Charlie there will bring a level of continuity that you were hoping for, even if there is a turnover of some of the other staff under his charge.

I want to underscore a comment made by Commissioner McGaffigan regarding Agreement State compatibility. And I am in the same position, perhaps even more so. Maybe it's may Republican leanings when I recognize that in one half of my brain there's a strong belief in state's rights and federalism. On the other hand, there's a strong part of my brain that believes in the need for national uniformity and its ability to enhance commerce. Those are two very conflicting thoughts and one that we have to counterpose quite often here at the Commission.

As Commissioner McGaffigan reflected on, there were certain of the Agreement States that were very articulate and strong willed in their opposition to our taking the recommendation of your group regarding compatibility. And there's no one solution. It's one we're going to have to grapple with for a long time. But I do believe we did not make the right decision in that regard.

On the issue of precursor attestations, I was sort of listening to that dialogue. And perhaps because of my background as an attorney, this seems to be one that is imminently solvable in terms of a further dialogue. You know, whether it's modifying the attestation to qualify a wider vary of disciplines or capturing in some different way, I think there's a way of getting to a win/win on this, to meet what we're trying to get but at the same time providing some flexibility. So perhaps further dialogue with Charlie and his staff would be helpful.

DR. MANUEL CERQUEIRA: We agree with that. And during the last committee meeting last week, there was language that I would, I think, be acceptable to both the boards as well as the Commission. So I think that will be worked on.

COMMISSIONER JEFFREY MERRIFIELD: It sounded imminently solvable. I thought the discussion that Ms. McBurney had on new technologies was quite interesting. And that's one, I think as we dialogue down the line, keeping us up to speed on those emerging technologies, I think, is a very important role for ACMUI. It does cause me to wonder, however, and that is obviously part of what drives the new technologies is manufacturing, those researchers and technologies who are moving those to the disciplines. And I'm wondering whether there's a way of sort of capturing some of that technology as it develops earlier so that we can better anticipate what we may have to deal with from a regulatory format, whether it's having appropriate manufacturers come in and talk about some of their research and the directions that they may be going or some other way in which either ACMUI or our staff may be better able to have a better understanding and be better prepared to have a flexible regulatory scheme, given those new modalities coming down the line. And I didn't know if you had any thoughts in that regard.

MS. RUTH MCBURNEY: That was one of the things that we discussed last week, that it would be beneficial to know what else is coming down the pike. And of course, the labeled antibodies fit right in with nuclear medicine therapy and some of the other things that people were thinking of from our stakeholder groups. But that is a good point, that we need to know soon enough so that if staff needs input on any licensing issues that they may be facing in the next year or so. That would be good to know.

COMMISSIONER JEFFREY MERRIFIELD: I think as a general matter, I think the Commission has been committed, in the time that I've been here and I think it's in the time that

any of the members currently sitting at the table have been here, to making sure that our regulatory scheme is responsive and flexible enough to emerging technologies so that we are meeting our regulatory mission of protecting public health and safety, but at the same time not doing it in a way that unnecessarily burdens new technologies that can benefit the American people.

So the earlier we can have access to that information and our staff can, the better we can respond to that so that the transition to new modalities will be as seemless as possible.

DR. MANUEL CERQUEIRA: That would be very important. And some of the issues that always come up with these emerging technologies, it's a turf issue, whose going to be doing it. And I think our patient advocate sort of keeps the right perspective, you know, how can we provide this to the most people with the fewest involved people in a safe manner. And that's kind of the priority that the subcommittee has tried to keep.

If you look at the composition of the subcommittee, it's practically everybody who's on a committee trying to, you know, make sure that everybody's interests are represented. And we're hoping that that will move forward with some strong recommendations in terms of radiation safety, but also making the technology available and not to encumber it with additional people or requirements.

COMMISSIONER JEFFREY MERRIFIELD: Let me ask one final question that was raised by a comment that Commissioner McGaffigan made. And that is the issue of events. We track, either through the Agreement States or directly through nonAgreement States, various activities that have been undertaken as a result of misadministrations or other things that have gone awry. And I'm wondering, it's not clear to me the extent to which ACMUI does a sort of a historic yearly review of those. Is that considered part of your charter?

DR. MANUEL CERQUEIRA: I don't know if it's part of the charter. We actually did it at this last meeting to go through. But we have not done it systematically over the years. But it's certainly looking at the NRC states as well as as much information as we can get from the Agreement States. As spotty as it is, I think, it would be a value.

One of the things that came up is we can look at the events, but we don't know the denominator, you know, how many potential events could there have been. So if we have two events, what percentage is that of all procedures that were done? And that would be an important way to get the impact of those events in terms of the numbers.

COMMISSIONER JEFFREY MERRIFIELD: The reason I asked that question is that it seems to me ACMUI and the members have spent an extraordinary amount of time, which we appreciate, in terms of focusing on the development of where we are on Part 35. That has been a longstanding and very time consuming effort. And it would seem to me that as we go forward that there's a usefulness in sort of taking a look -- I mean, one of the things we do with other of our boards is take a look at, you know, what happened and are there lessons to be derived from those activities and improvements we can make in our regulatory or enforcement scheme.

So it would strike me in that respect, that having ACMUI take a more systematic approach at looking at events during the course of the year and then making recommendations as to whether there are procedures we need to explore, activities we need to be considering, or further enforcement that would be appropriate, or engagement with states in that regard. I mean, that to me would be a very useful function in terms of informing the staff and the Commission about how we can do our job better. That's something I would to certainly have you all consider.

DR. MANUEL CERQUEIRA: On behalf of the committee, we would be happy to do that. And we'll discuss with staff how to get that implemented. We actually did that at the meeting last week, but we could make that a regular function of the committee.

COMMISSIONER JEFFREY MERRIFIELD: Thank you, Mr. Chairman.

CHAIRMAN NILS DIAZ: Thank you, Commissioner Merrifield. I think you're seeing the results -- I don't know whether good or bad -- of a very seasoned Commissioner. I'm not calling you old, just seasoned.

Which, you know, it's an important time to get fixes to issues because, you know, the Commission fully understands most of the issues. We have actually grown old and have what I call scars over most of these things. So we welcome the interaction, and we want to make sure that as issues come that not only will we give our intention, but we are intent on resolving them.

COMMISSIONER EDWARD MCGAFFIGAN: I don't remember any gray hair on Jeff Merrifield when he arrived here.

COMMISSIONER JEFFREY MERRIFIELD: A couple of my children were either born or very young at that point. So those are coexistent in that regard as well as well.

CHAIRMAN NILS DIAZ: See I'm having to dye my hair with white hair so I can keep up. You know, one thing that, when we look at some of these issues, it was going through my mind the fact that, practically in every area but especially in this area, I think I should make the statement that the Commission is not only not going to be an impediment but we try to do things that we believe are beneficial. Because we seriously believe that this is a very important area. And if sometimes we, you know, overstep into an issue, it's always with the fact that we want to have this as a risk informed regulation of the very best that we can do with the variability that exists and without intruding or maybe minimal intrusion into the area of medicine, you know, how you do your things. And that has been an objective of all of us from the very

beginning. So that should be represented in our products. And if it's not, I think we count on you to bring them out to make sure that if there's a correction needed that we'll do that promptly. So that's a fundamental base of how we look at this issue.

I think that the issue of continuity of care, as you nicely put it, we are aware of it and I'm sure that, you know, we're going to find that things will be better. But if they ever slip, please let us know, because we do care.

Commissioner Merrifield brought out these last things, an issue, and I've just put notes in here, not in any particular order, but this issue of trends in the events or abnormal occurrences is an important issue because sometimes we tend to be extremely focused on those that are very high level, abnormal occurrence, whether we report or not.

And there might be actual trends that should be noticeable if we look at what was the root cause in what happened, rather than just what was the value of the dose or whatever happened. And do you have any suggestions on that issue? Because we're now looking at precisely those points. It certainly will be helpful, because we believe that there might be underlying trends regarding how people actually follow procedures. This always seems to be at issue, always an issue. And what can we do about it? And how do we determine some trends that are not in the noise level, but they're not, you know, at that high level of occurrence. And then that certainly is an issue.

MS. RUTH MCBURNEY: We have done that in our state program. In fact, a professor at one of the state universities at the health science center in Houston has taken all of our compliance data and put it into a statistical format and plotted out some trends and things and looked for root causes. And he has also gotten some information from a couple of the other states, I believe, as well. So I mentioned that to one of the staff members here, that he would probably be interested in taking some of the NRC data and doing that.

CHAIRMAN NILS DIAZ: We would be interested in doing that and following through really.

DR. MANUEL CERQUEIRA: We'll be very happy to work with Dr. Miller and his staff to try to use the committee's expertise to review some of these trends and to give you feedback on that.

CHAIRMAN NILS DIAZ: Alright, that sounds excellent. The national materials programs -- you know, there's an issue that is taking place in this country which I think we all realize that we need to put it in a balanced perspective, that is what is security or counter-defense and security, and what is safety, and what is the actual application of all of those things. And it's a very tough, you know, very dynamic situation right now.

We have been very concerned with the issue of cost to the states and, you know, funded or unfunded mandates. And funded sometimes doesn't actually make it. And how are we going to deal with those issues?

I think the Commission is fully aware that this is an issue. And we will be really carefully watching it because we want to make sure that we do it the right way. We don't know how all of these things are going to come out, but we do realize sometimes that the burden from our fees on some small licensees is disproportional. And that is something Commissioner McGaffigan alluded to. And this is an area that again, even if it's not precisely the technical issue of the day that we're concerned with, your input is valuable. I think that a lot of the things have already been covered by my fellow Commissioners. But again, I want to repeat that I do have a particular interest with PET. I was a very young Ph.D when we started work on these issues. And actuallly I worked with doing the computer program that actually looked at the images and made them usable. And I don't want to tell you long ago that was, because it will show why I

have gray hairs. But it is definitely a very useful process. And in no way are we going to let this go and be haywire. We're going to take care of that.

DR. MANUEL CERQUEIRA: That's reassuring.

CHAIRMAN NILS DIAZ: Dr. Vetter, I think Commissioner McGaffigan addressed the issue of the receptor. And I think we certainly will be looking to take care of that issue. We're all very well intended, and sometimes these things happen. But I hope the discussions this year will take care of that.

And Ruth, I appreciate you bringing out the emerging technologies. I think that's an issue that we need to be very aware of because we don't always want to be reacting to these things at the very last minute. We want to actually be actively involved, because like I said, we think these are very important. These are, you know, related to health and care. And in no way do we want to be delaying or causing the problems. We want to be actively involved in making them as usable and as beneficial as we think as in our mandate of public health and safety.

COMMISSIONER EDWARD MCGAFFIGAN: On the security point, I know the Commission's position on security funding was that it should come out of the general fund with very small exceptions, things like our OSRE, or force on force exercises, our inspection program for reactors should continue to be on the fee based. But the vast preponderance of the additional security work that we've been doing since 9-11, we felt, should be off the fee base. The first year it was. Unfortunately, last year the Congress did not approve that, and we are now in a situation where 90% of -- because we're getting 10% of our funds off the fee base in fiscal year 2005.

CHAIRMAN NILS DIAZ: Eight next year.

COMMISSIONER EDWARD MCGAFFIGAN: Well, we've been trying to deal with this issue. I think that we're going to try to find second best alternatives now to try to get some of

these security costs off the fee base. And the other security issue, I just mention to you because Chairman reminded me when he raised it, I would encourage you to get briefed on what we're planning to do with regard to security requirements for those entities who have, including hospitals, who have above action levels of radionuclides of concern.

That's going to happen, but it's not written in concrete at the moment, that we are going to have some additional security requirements if you have greater than action levels of radionuclides of concern. And our action levels may bounce around a little bit this year because the IAEA is working on a tech doc 1344 that has slightly different action levels. A factor or two, two and a half, for the most part, different from ours. And we'll obviously adopt the international action levels because we can't have like our export/import regime for these radionuclides of concern. We can't have one export/import regime in the United States and a different one in England, and a different one in France.

But I think you should get briefed. The hospitals do have things like cesium blood irradiators. And you need to look at whether what we're proposing makes sense in that setting. But I will also tell you that the White House kept asking us where in the Washington area are these radionuclides of concern in quantities significantly above the action levels. So what we gave them was a list of hospitals. That was basically it.

So we think we're focusing on the right things. We think the international community, through this code of conduct on high risk radioactive sources and this tech doc 1344 is focusing on the right things. But then the question is, how much of this stuff is self protecting? You know, it's primarily cesium but you also have some cobalt in quantities above the action levels. You may have other isotopes above action levels. But it's a relatively small and bite sized problem. But I think your group needs to be on top of it. You need to see it as it's coming, and if we're doing something wrong, you need to tell us.

Most of this stuff is safeguards information. But I think you all should have safeguards information clearances as a result of being on the committee.

CHAIRMAN NILS DIAZ: If not, I think you should.

COMMISSIONER EDWARD MCGAFFIGAN: Otherwise, we should just get them for you. I think you have a need to know what we're trying to do with regard to these radionuclides of concern above the action levels, whether we need a gradiated approach or a one size fits all approach. You all need to be involved in that as it affects the medical community. It is never going to affect an individual.

I mean, a year ago, we were putting out information to those who had knowledge. Ruth probably saw some of this stuff. And it looked like we were going to be going after everybody, an endocrinologist in his office who had a little bit of iodine 131. And that was because we hadn't thought the stuff through. Now we've thought it through. We have a limited number of radionuclides that we're concerned about. We have significant action levels in the tens of curies, so if you're below that level you're probably not going to face a lot of additional requirements. But if you're above the tens of curies level for these radionuclides of concern, you're going to have to -- we're trying to put together a regime that makes sense.

And large panoramic cobalt irradiators are about to get orders from us. And we're then going to look at the rest of the folks in this thing. And everybody in this category has gotten the March 17th advisory from us. So they know that we're thinking about them.

DR. MANUEL CERQUEIRA: I think that would be important, certainly for the committee and the regulators.

COMMISSIONER EDWARD MCGAFFIGAN: Have you been involved at all thus far? Have you been briefed on the compensatory measures or any of that?

DR. MANUEL CERQUEIRA: Well, we had one briefing today, going over some of these things, but not in any great detail.

CHAIRMAN NILS DIAZ: But it is an important issue. You know, on this area, again, I want you to know that the Commission is unanimous in trying to address the issue of cost and how we don't sock it to people. And they even send me on these missions, and sometimes I call them kamikaze missions, but I refuse the terminology, to the Congress.

COMMISSIONER EDWARD MCGAFFIGAN: He keeps coming back.

CHAIRMAN NILS DIAZ: That's right. Anyhow, do my fellow Commissioners have any further comment? If not, we certainly appreciate your being here. We do care. We're going to make sure that you know that we care. And we appreciate all of your input and look forward to seeing you here or, as Commissioner McGaffigan said, in our open door as needed.

Thank you so very much. We're adjourned.

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(Whereupon, at 11:00 a.m., the briefing concluded.)