UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING:

MEETING WITH THE ADVISORY COMMITTEE

ON THE MEDICAL USES OF ISOTOPES (ACMUI)

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Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland
Tuesday,
February 19, 2002

The Commission met in open session, pursuant to notice, at 2:00 p.m., the Honorable RICHARD A. MESERVE, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

RICHARD A. MERSERVE, Chairman of the Commission

GRETA J. DICUS, Member of the Commission

JEFFREY S. MERRIFIELD, Member of the Commission

EDWARD McGAFFIGAN, JR., Member of the Commission

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

STAFF AND PRESENTERS:

DR. MANUEL D. CERQUEIRA, MD., Chairman, ACMUI

KAREN CYR, ESQ., General Counsel

SALLY W. SCHWARZ, Nuclear Pharmacist

RUTH E. McBURNEY, State Government Representative

SUBIR NAG

DR. RICHARD J. VETTER, Radiation Safety Officer

ANNETTE VIETTI-COOK, Secretary of the NRC

DR. JEFFREY F. WILLIAMSON, Therapy Physicist

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

2:00 p.m.

CHAIRMAN MESERVE: Good afternoon. The Commission meets today to hear from the Advisory Committee on the medical uses of isotopes. The Commission meets regularly with the Committee to discuss regulatory issues that impact the medical community.

One of the subjects we will be discussing is the Revised Part 35, which are the regulations for the medical use of byproduct material. At the Congress' request, the Commission recently issued a report on Part 35, concluding that the revised Part 35 generally achieved a significant reduction in the regulatory burden associated with diagnostic nuclear medicine. Our intent is to submit the revised Part 35 to the Office of the Federal Register for publication in approximately 30 days.

We acknowledged at the time we submitted our report, however, that our stakeholders have identified substantial concerns related to the perceived burden of the guidance and inspections programs that will implement the revised rule. Base on this feedback, the NRC will improve the licensing and inspections guidance and train license reviewers and inspectors during the six-month date period preceding the effective of the revised rule. As both NRC and our licensees gain experience with the revised Part 35, we remain open to the possibility of future rule changes.

I understand that the staff consulted with the Committee extensively during the development of the revised Part 35, and the Committee provided expert advice on rulemaking and other initiatives at various critical stages of regulatory development. Over the next several years, the expert advice of the Committee will be especially important to assist with the implementation issues that I've just mentioned with regard to Part 35.

So for that reason, we very much appreciate your willingness to join with us today, and we very much appreciate today's briefing.

As you have no doubt noted, there are only four of us here at the table today. Commissioner Diaz regrets that he is not able to be with us at this meeting. He wanted me to assure you that he is very interested in the topic and that he will review the transcript of today's meeting.

Dr. Cerqueira, why don't we underway, and why don't you introduce your colleagues.

DR. CERQUEIRA: Thank you very much, Commissioner. My name is Manuel Cerqueira. I'm at Georgetown University representing nuclear cardiologists, and on behalf of the Committee, we'd like to thank you and the other commissioners for taking the time to meet with us and updating you on some of the important issues.

We'll start and maybe people can introduce themselves down the row, and then we'll --

DR. VETTER: Sure. I'm Richard Vetter. I'm the Radiation Safety Officer at Mayo Clinic.

DR. WILLIAMSON: I'm Jeff Williamson, Radiation Oncology Physicist at Washington University in St. Louis.

MS. SCHWARZ: Sally Schwarz, Washington University in St. Louis. I'm representing nuclear pharmacy.

MS. McBURNEY: Hello. I'm Ruth McBurney. I'm with the Texas Department of Health, Bureau of Radiation of Control, and I'm the state government representative on the Committee.

CHAIRMAN MESERVE: Thank you all for joining us.

DR. CERQUEIRA: It's our pleasure and what we've prepared for your today is a presentation dealing in part with the Part 35 revision process but also to try to identify for the Commission issues that we feel will be important in the next three to five years that will influence the medical use of isotopes. And so we'll go over our material, and we'll be happy to take any questions at any time from the commissioners.

I'll be doing the first presentation, if we could have the slides up, and it's really looking at the 10 CFR Part 35 revision and feeling that it's a balanced and a fair process. It is not complete, and there are still some outstanding issues, but overall we felt that the process did try to involve all the stakeholders and to address the issues appropriately.

If we go to Slide 2, the basic approach that was taken by the Committee and the NRC staff was to make this a risk-informed, performance-based approach to the revisions. We had significant stakeholder input at all time during the process, and the ACMUI was extensively involved in advising the Commission and providing information.

Page 3, the process was an open process. There were seven public workshops that were held seeking input from members of the stakeholder community as well as the general public. There were 20 professional society meetings that were held between the staff and various commissioners. There were six ACMUI discussions that were held related to this. There were two full panel discussions, and there were four subcommittee meetings that were held with specific attention to diagnostic as well as therapeutic uses of radiation. There were two agreement state workshops that sought input on the revisions as well.

If we can go to Page 4, the role of the states was investigated, because currently there are 32 agreement states and only 18 NRC-regulated states, so it was felt it was very important to get their input as well. And this input came from the Organization of Agreement State, from the radiation officers, and there was a separate Part 35 Working Group that provided input into the process.

There was public input as well. There were 225 written comments -- this is Page 5. All the documents were available on the NRC web site. There were working group meetings that were held that were, again, open to the public and that public comment was solicited and acted on in an appropriate manner.

Page 6, the result is that we felt that overall the revised Part 35 regulations have provided some reduction in the regulatory burden for the stakeholders, although it was felt that this was much more so for the diagnostic community rather than the therapeutic community where the changes overall are not substantial in any way. But, again, that reflected the relative risk of the two radiation uses.

We felt that there was some elimination in unnecessary rules that had been present in the old regulations, and overall we felt that the prescriptiveness overall had been decreased, although, again, that there was quite a bit of reduction in nuclear medicine, probably not in the therapeutic modalities.

And we also feel that we're in a transition period in the sense that the Part 35 revision, if published and implemented in six months, will be the first step to dealing with overall revision and the use of radioactive materials for medical use. There were some issues that, you know, again, I think we have briefed the Commission. We had some differences with the Committee on medical event reporting, radiation to the unborn fetus as well as some issues related use of intravascular brachytherapy. And some of these issues were brought up before the Commission, and some of these were basically going to be ongoing issues in terms of emerging technology. Some of these other issues, the Committee I think had slightly different opinions from what the final rule reflected.

We also feel that it's very important in this transition that the guidance documents that are currently being worked on be provided to the user community, that implementing the rule in six months still leaves quite a bit of uncertainty as to how it's going to be implemented. This is true in the sense that the guidance documents serve as a template for which the user will be held to, plus the agreement states still have up to three years to become compliant with the revisions. And that will create a certain amount of uncertainty in the user community as well.

Those are my comments. I'll be happy to take any questions.

CHAIRMAN MESERVE: Why don't we hold the questions till to the end. We'll go through the briefings and then sweep through the questions at the end. But thank you.

DR. CERQUEIRA: Okay. Well, the next presentation is going to be on the implementation of 10 CFR Part 35 and the agreement states by Ruth McBurney.

MS. McBURNEY: Thank you. Good afternoon, Commissioners. As was mentioned earlier, the agreement states do represent most of the regulation of medical facilities; in fact, probably about 70 percent of the medical licensees are in agreement states. So it's important during the implementation of these rules that the states are involved.

From our perspective, I feel that the rulemaking process did involve agreement state staff in the Working Group and Steering Committee, and that was a very good thing. And throughout the process the states were involved. Also, it was a fair process that allowed for the input from all stakeholders.

There will be some implementation issues in the agreement states. As Dr. Cerqueira mentioned, the states have up to three years to implement the rules. Because it was a -- the states were involved in the rulemaking and also there was a parallel rulemaking going on through the Conference of Radiation Control Program directors to produce the suggested state regulations, which will be distributed to the states along with the Part 35.

Some of the rules are needed right now; in fact, some of the larger states have already implemented some of the rules regarding brachytherapy, the low dose rate and high dose rate brachytherapy and provisions for new technologies, because a lot of the newer technologies are being introduced into agreement states sooner than some of the Nuclear Regulatory Commission states.

And as a result, the scheduling of some of these rule changes will vary from state to state. As I mentioned, some of the states have already implemented parts of them that don't impact the compatibility issues but that are needed currently to address their needs. Some of the states will wait until nearly the three years are up in order to implement them, because some of the states need longer time. Their requirements are more onerous, and thus the rulemaking procedures take a little longer.

One of the more important areas for consistency that the ACMUI has addressed is the need for uniformity for the training and experience requirements for the MD authorized users, the physician users. The ACMUI recommends that NRC cooperate with the states in order to assure a more expedient uniformity in the requirements for the training experience for authorized users. There could be cross-boundary issues with physician training programs from state to state.

And, also, we recommend that the board approvals be done as soon as possible to facilitate the uniformity, because the board certification acceptance makes the approval of users a more efficient process.

We were also asked to address some of the things facing our various disciplines over the next few years. One of the things facing the states, as it is in the Nuclear Regulatory Commission, we're facing a maturing workforce, similar to that of the NRC. As our trained people that were trained back in the '60s and '70s reach retirement age, there aren't the people coming on board who have that same level of training. And attracting new staff at the salaries that states can offer is very difficult. So I'm not offering any new solutions to that issue, but just that the states and the NRC work together to address training and recruitment and retention issues. And a lot of it comes down to dollars. But the whole health physics community is facing the same workforce shortage and training shortage. Thank you.

DR. CERQUEIRA: Thank you very much, Ruth. This issue of shortage in the future is something that the Committee felt was very important. Our next three presentations will deal with specific areas where we anticipate with the aging baby boomers and the increased use of diagnostic and therapeutic techniques we're going to need more people. And the first part is going to be really on nuclear pharmacy related issues, and Sally Schwarz will be presenting.

MS. SCHWARZ: I want to continue along the lines that Ruth has just addressed is this issue essentially of worker shortages. I'm going to come at it from a little different direction. I'm interested in talking about the radiation safety issues that are involved with nuclear pharmacy, most recently the upswing in PET, which is positron emission tomography, and is accelerator-based isotope production.

So it's not under the regulation of the Nuclear Regulatory Commission but certainly influences the workers, because currently PET is developing technology and pharmacists are involved in working with mixed isotope produced byproduct material as well as accelerator-produced materials. And for centralized pharmacists, essentially handling PET isotopes or handling energies 511 keVs compared to more typical 100 to 300 range isotope energies. So what these pharmacists are facing essentially is the need to distribute their dose among more than themselves, essentially.

And we do have a problem with the number of pharmacists totally. It's essentially flat. There are other increased demands being placed on pharmacy in general, from every avenue -- the community, the hospital and nuclear pharmacy. So there is more need, and there really is not a tremendous increase. I would say, actually, it's just kind of a level field.

And some of the reasons for that are on Page 3. Essentially, the programs for pharmacist training have expanded from five years for the undergraduate degree to the six-year program, which is the Pharm D graduating classes now. So we've increased the length of education. And at that point, essentially, again there are these increased needs placed on the field as well. And in order to maintain ALARA, and that's as low as reasonably achievable, and typically has been looked at to try and maintain doses ten percent of the allowable federal hand and body doses. And when we're dealing with PET as an entity, the higher energy that we're dealing with, it's very difficult to comply with that ten percent ALARA. Ten percent is not regulated, it is just kind of an unwritten regulation that we try to keep ourselves within.

For PET, we're talking more in terms of 30 to 40 percent of the allowable doses for hands and body. And so that becomes an issue in that the NRC inspectors inspecting these facilities individuals working with both byproduct and accelerator-produced materials will be essentially viewed, need to keep in mind this exposure is not necessarily from unsafe practices, just that the energies that we're working with are significantly higher than previously used. And some facilities, you know, have very little byproduct and much more accelerator-produced materials on board.

The next is Slide 4. Essentially, as far as addressing the shortages for pharmacists, some professional pharmacy curriculums have allowed electives as far as the certification process for board certification of pharmacists, such that during the six-year professional program, you can take the required courses so that you can be didactic ready for then going out into the field and acquiring your hands-on training. But not all schools have allowed this ability. Purdue, as a university, has certainly allowed enough electives in these six-year programs so that the didactic education can be achieved.

As far as other issues, they're on Page 5. We can address the shortage. There are certificate programs available for this board certification process. I have listed three of the programs that are out in the community: Purdue, University of New Mexico, University of Arkansas. They have fairly large programs. There are other ways. The manufacturer, Syncor, for an example, has their own on-site training programs for their pharmacists that they hire, and this, again, is after the six-year program.

So on Page 6, if we look again to address the shortage, pharmacy has relied always on technicians, which are supervised

by the pharmacists, and there is specialization obviously needed for nuclear pharmacy technicians, and guidelines for nuclear pharmacy technicians were prepared by the APHA section on nuclear pharmacy practice in the year 2000. And they're currently working on certification programs for technicians through APHA.

One of the other issues that I'd like to just mention briefly, this is also in other fields as well, is the whole issue of mixed doses, not just PET and accelerator and byproduct materials, but also nuclear cardiology faces this mixed dose component dealing with x-ray and with gamma emitting or byproduct material. So these kinds of mixed doses become an issue that may possibly need to be addressed in terms of looking at the Part 20. Instead of using a deep dose as the effective dose, looking at the effective dose equivalent so that we could essentially combine exposures from more than one type of radioactive material.

DR. CERQUEIRA: Thank you, Sally. Our next presentation is going to be by Jeffrey Williamson on dealing with issues related to medical physicists, authorized medical physicists. Jeffrey?

DR. WILLIAMSON: Thank you for the opportunity to speak at this meeting. Could I have Page 2, please. What I'd like to talk about mainly are the training and experience requirements for the authorized medical physicist, or AMP, as defined in the new regulations.

First, let me say that I think the regulated community, in general, welcomes the concept of AMP. I think it's a great step forward in reconciling the regulatory point of view with clinical reality to realize that the physicist plays a much broader role in promoting the efficacy and safety of radiotherapy treatment than just calibrating cobalt 60 units. However, there is a major issue and conflict between the definition of qualified medical physicist used in the community and the concept of AMP.

If we go to Page 3, basically the community's definition of qualified medical physicist is having board certification by the American Board of Radiology or American Board of Medical Physics with appropriate continuing education requirements. Let me review for a moment the definition in 35.51 of authorized medical physicists. It reads that, "An AMP is one who is certified by a recognized board whose certification includes all of the requirements of Paragraph B." And then Paragraph B reads, "Or has a Master's degree, two years of training and experience under AMP, including various duties associated with high dose rate brachytherapy, cobalt 60 teletherapy and stereotactic radiosurgery, plus a preceptor statement."

Now, the board process is very similar in terms of the educational and experience requirements, at least a Master's degree and two to six years of experience, but it does not require specific experience with byproduct -- with specific byproduct technologies. It's emphasis is to assess the quality of judgment and knowledge base of the candidates to ensure that they are capable of independent clinical physics practice.

So this is the major problem. It appears, I think, almost certain that none of the boards in medical physics will be recognized as a pathway for becoming an authorized medical physicist under the new regulations.

If we go to Page 4, please. So what are the consequences of this largely, I think everyone acknowledges, is a mistake in the writing of the regulations? Well, first, there's a concern that it will marginalize board certification. It will reduce the incentive to complete the rigorous board certification route if it no longer has value in qualifying one to practice as an AMP. Bear in mind that unlike physicians there is not a uniform system of state licensure requirements that requires physicists otherwise to be certified, nor is there uniform treatment by hospital credentialing boards of the certification process.

Next slide, please, which is Page 5. So I think it could have the paradoxical effect of actually impacting negatively on public health. It could -- something to realize is that the board certification process really is the only accepted industry standard for defining competence in medical physics. And that's because we do not have a uniformly accepted system of training, like the residency training system that physicians have in different specialties. So it could exacerbate shortages of authorized medical physicists. For one thing, there are relatively few opportunities for cobalt 60 teletherapy or gamma stereotactic training.

So what are the remedies? These are listed on Page 6. Well, I think the short-term remedy -- one short-term remedy is to accept the language of the grandfathering clause, 35.57, literally. And it basically says, "All physicists mentioned or accredited as a teletherapy physicist on an agreement state or NRC license are hereby declared authorized medical physicist." And the ACMUI is on record recommending that the Commission accept that without qualification to create a pool of authorized medical physicists who could serve as preceptors.

The second thing we believe should be done is to in guidance space do what you can, instruct the staff to do what they can to make board certification useful. So one thing, for example, could be done is to say, all right, a board certified candidate to become an AMP only need show evidence of specified supplementary training with a specified modality. For example, in gamma stereotactic, the industry standard is to undergo a week's training by the vendor and visit another institution and participate in one or two cases at an institution with an accepted program. And that would be sufficient.

I think, obviously, the long-term solution is to initiate a rulemaking initiative which goes back to something approximating the old definition, which would say, "Be certified by one of the following boards, X, Y or Z, or comply with the following alternative pathway requirements," and then list the various educational and experience requirements. Thank you.

DR. CERQUEIRA: Thank you, Jeffrey.

DR. WILLIAMSON: I should mention one more thing. There are similar issues with the definition of authorized user as well. It may well turn out that board certification and radiation oncology may not qualify a physician to be an authorized user for high dose rate brachytherapy or gamma stereotactic.

DR. CERQUEIRA: Thank you. The next presentation is on board certification for radiation safety officers, and Dr. Richard Vetter will be doing the presentation.

DR. VETTER: Thank you. Thank you for the opportunity to be here. You will need to skip the next nine pages of Dr. Williamson's backup slides.

(Laughter.)

And you can go right to Slide 2, my Slide 2. I'd like to just briefly preface my remarks by saying that it is becoming apparent that there is a shortage of health physicists that is developing in this country. Back in the '50s and '60s and early '70s, there were numerous training programs around the country that were well supported, that had many radiological health fellowships and other fellowships supported by the Atomic Energy Commission at that time, the Department of Radiological Health and so forth. Those fellowships have dried up, and there was, at one point in time, considerable support for training programs. That support has dried up. And there are now, I have been told, approximately 100 health physicists in the pipeline in this country, and all those people who were trained in the '50s and '60s are about my age or older and will be retiring one of these days. And the profession is quite concerned about this shortage.

I'd like to address specifically one element of the regulations that may actually exacerbate that shortage for radiation safety officers. The current Part 35 requires that for someone to be qualified as a radiation safety officer they must be either certified by a board that is listed within the regulations there, specifically listed, specifically approved, or that person may meet certain training requirements -- 200 hours of training and experience and so forth -- and have one year of experience under the supervision of a radiation safety officer. So there is definitely -- there is very clearly an alternate pathway -- either board certified or meet certain training requirements.

On Page 3, I outline the current -- or the proposed Part 35, under which a person may become qualified as a radiation safety officer by either being certified by a specialty board or meeting training requirements and a preceptorship. The difference is there really is no alternative pathway here, because the certification route requires that the specialty board incorporate Parts B and C. So there is no alternate pathway. And, in fact, you don't need board certification to become a radiation safety officer; all you need is B and C. There is no incentive, for purposes of these regulations, to become certified.

I am personally aware of a broad scope medical licensee that is looking for a radiation safety officer today. They have a short list. The person at the top of the short list is a very well-qualified within the health physics community, certified health physicist, who works for a national accelerator laboratory. He does not work for a medical licensee. Number two on the list works for a DOE laboratory. Neither of those, under the proposed regulations, would be required. The university's job would be a lot easier because they could automatically eliminate the top two people on their list.

They would not be qualified under these regulations, because there actually is no separate certification pathway. And the reason there isn't is because the current certification bodies do not incorporate Parts B and C. Most of them require, of course, a degree in science, some of them even require a Master's degree in a specialty, but they do not require those specific hours of training, and they do not require a preceptorship. And the preceptorship is also another problem.

On Page 4, it lists some unintended consequences. This is really no one's fault. It's through this long process under which the revised Part 35 was generated. The NRC originally has proposed an accreditation procedure for the boards, and that obviously was going to be a rather large task for the NRC to accredit boards. And so as a result of their re-analysis and feedback from the general community, the new proposed Part 35 backed away from that and got us into the situation we are at today, where it's specialty board, not or training, but a specialty board and the specific training requirements.

This will result in an increased burden on the NRC, because they will not be able to simply accept someone who's certified by a board, because the boards don't meet the requirements. So that's no longer a pathway. They will have to examine the credentials of every person who wants to become a radiation safety officer.

This also, as Dr. Williamson mentioned earlier, marginalizes board certification. I think many people will become board certified anyway, because it's good for them, they want to rise to that level. But the regulations don't encourage it and in fact it's my personal belief and of course that of professional boards that we should do whatever we can to try to increase the competence of people who want to become radiation safety officers and encouraging board certification would do that.

This then also undermines an effective industry standard; that is, today you can become board certified -- if you are board certified, you can become a radiation safety officer. Tomorrow, when the new regulations become effective, you

will not be able to do that.

What are the remedies? Similar to what Dr. Williamson mentioned, a short-term remedy would simply be to accept health physics certification by the current boards who offer certification in health physics. Long-term, we simply need to look at some rulemaking simply to change "and" to "or," or it could be something that requires a little additional analysis that would in fact encourage people to become board certified.

Bottom line again, however, is that because of that unintended "and" instead of an "or," we actually are limiting the pool of people who are, under the regulations, qualified to be RSOs, and that in fact does create a shortage for us. Thank you very much.

DR. CERQUEIRA: Commissioner, we'll be happy to take any questions for any of the presentations that we've done.

CHAIRMAN MESERVE: Thank you very much for very helpful presentations. I realize that you've had to limit your time, and we very much appreciate your effort to do this.

I think, Commissioner McGaffigan, it's your turn to go first.

MR. McGAFFIGAN: Thank you for letting me know. I appreciate you all being here. I think the last time we met was actually in October of 1999, which is too long a period, but we were in limbo for much of this time with the Part 35 rule.

I want to go first to Mr. Williamson and Mr. Vetter or maybe it's really for Dr. Cerqueira. This issue that they're raising with the "and" and "or," I don't recall that, you know, being brought to our attention at all back in the '99 time frame. Is it one that just slipped past you and the staff as you were going through the process?

DR. CERQUEIRA: I think it is, but, Jeffrey, do you want to elucidate?

DR. WILLIAMSON: Yes. Well, there were a lot of shifts and changes.

MR. McGAFFIGAN: We put the thing out. I mean the frustration is that when we met in October of '99, my recollection -- Chairman Dicus was Chairman and we had put out the rule approximately July of that year and left it there for three months hoping that people would find line-in, line-out changes. We did make some changes ourselves in some of the areas that you talked about. But it had been sitting there, and, gosh, I was hoping that if there were "and's" that should be "or's" or vice versa, we would get that advice.

DR. WILLIAMSON: Well, the final rule was published more or less in this form or was widely available, and it should have been noticed. I think the oversight was not to realize that these alternative pathway requirements really did not reflect the board certification process as it exists now. I think everybody kind of assumed that this was a reasonably accurate rendition of the common prerequisite requirements for sitting for the boards.

It was complicated by the fact that there was a tendency, a philosophical approach here, which was to try to distill training and experience requirements to focus not so much on general clinical expertise but to identify the nucleus of health physics and safety issues that really defined the core minimum credentials to carry out the regulatory mandate. There was this philosophy to try to divide clinical competence from safety competence, which I think, in the end, was given up. And that's why a lot of this extra was put into that definition.

MR. McGAFFIGAN: Okay. Well, speaking as one commissioner, I'm sure we're going to try to work with you on this. I don't think it was our intent to have these unintended consequences. And it's amazing, my recollection back in '99 is that the one thing that almost everybody, including Carol Marcus, thought was good about our rule was the T&E requirement.

DR. WILLIAMSON: Well, you know, I think the regulated community and the staff of the NRC have to share the --

MR. McGAFFIGAN: This process has been so -- we tried to make it a very slow moving thing so we could get advice all the way through it.

I'm going to turn to Ms. McBurney next. We met in October of '99 and I went and read the transcript before the meeting. I was a little worried about these suggested state regulations. They were doing things, for example, recalling as I could read it, they were going to propose that the dose embryo fetus was the public dose, the 100 millirems, you guys were recommending five rem, that's what we adopted. And there were all sorts of other things. They wanted endocrinologists to have extra requirements compared to the current rule; we rejected that. Are those suggested state regulations in shape today, do you know? Or have they been presented to the states, and are they compatible with our rule now? Or are people still fighting some of these battles that that particular Committee seemed to be fighting at the time?

MS. McBURNEY: I'm not sure of the actual status. I think they are ready to go out to the states.

MR. McGAFFIGAN: For comment or for final --

MS. McBURNEY: If they've been signed off on by the federal agencies, then they would be ready to go out as final.

MR. McGAFFIGAN: I probably shouldn't be asking you; I should be asking Paul Lohaus --

MS. McBURNEY: Right. I'm not really sure myself.

MR. McGAFFIGAN: -- whether it's in good shape. I assume that they wouldn't -- if our rule is a certain way, they're going to --

MS. McBURNEY: That's right. It's going to have to meet the compatibility requirements.

DR. CERQUEIRA: It was set at level B, which means they have to be completely compliant, but they still have up to three years upon which to make a decision and respond. So for the user community, it's going to create some issues that would best be taken care of upfront, if possible.

MR. McGAFFIGAN: I do also note the Agreement State Organization isn't here, but speaking again as one commissioner, I did see the resolution that they passed last October in Sante Fe, and I do continue to believe that we're doing the right thing in having the T&E requirements be compatibility level B. I think somebody who's learning their -- getting educated at Georgetown shouldn't have to worry about whether they can practice at one of the Maryland suburban schools or vice versa. So I did think about it, and I come down on the other side. And I assume since the Commission as a whole was pretty united on that -- weren't we -- so I don't think you're going to get anything different there. But I do hope that those regulations are in good shape and they're compatible with ours now.

Ms. Schwarz, one of the issues that you mentioned was this issue of mixed doses and the doses from the higher keV gammas. You all are -- Mallinckrodt, at least, has got a very large presence in Europe as well.

MS. SCHWARZ: This is Washington University.

MR. McGAFFIGAN: Oh, okay. You're Washington University.

MS. SCHWARZ: The institute, right.

MR. McGAFFIGAN: Do you have --

DR. CERQUEIRA: Mallinckrodt endowed them.

MS. SCHWARZ: We were endowed.

MR. McGAFFIGAN: Okay. Mallinckrodt endowed you. Okay. You don't know --

MS. SCHWARZ: They are not supporting us.

MR. McGAFFIGAN: Do you have any idea how Mallinckrodt deals or how the European community deals with these issues? Because 40 percent of our occupational dose limit, which is what you said you'd get to when you deal with accelerator-produced isotopes, is about what the European limit is going to be. I mean their limit is now ten rem over five years, no more than five rem in a year.

And when the Mallinckrodt people talked to me at one point in the last year or so, they mentioned that it was the accelerator part of their operation which would be the most problematic in terms of meeting the European community standard, which I don't think has been adopted by every country, but it has been the standard. I think the Germans have now adopted it, for example, and the Spanish. But do you have any idea how they're coping with this, given that it's a -- that their medical practice has to be pretty similar to ours?

MS. SCHWARZ: I don't know for certain how they're handling it. I do know that the U.S. is probably in a different position than the European community, because I mean with this issue of freestanding PET centers, they've proliferated to a more rapid extent, I believe, in this country, not to say that they won't in that country. But I think what eventually, you know, we are moving to in this country too is change of operations of how we handle dose drawing and things like this. And, you know, we're on a learning curve, as I'm certain they are too, because PET has accelerated tremendously in the last several years, actually. So we're --

MR. McGAFFIGAN: We have apparently one -- I listen to on WTOP Radio as I'm driving in. There's one somewhere here on Rockville Pike that is trying to get -- they call it full body imaging or something, "Come in and get your heart and everything else checked out."

MS. SCHWARZ: Yes.

MR. McGAFFIGAN: You cannot -- it's advertised on the radio nowadays pretty broadly. It's pretty amazing stuff.

MS. SCHWARZ: Yes. I mean and I believe the technology will continue to grow, and it's just that as we're learning, we have to make adjustments in how we handle things, but that it is a higher energy, and even doing all that we can, we do still see higher doses.

MR. McGAFFIGAN: Ms. McBurney, one of the questions -- points you made was that the agreement states had to move forward with certain rules, because the technology is there. Does that say something about how quickly we're going to have to amend this rule to bring it -- I know there was some talk in the National Materials Working Group about this being an area where the states might take the lead in amending Part 35 to bring in some of the advanced technologies. Do you have any idea where that stands?

MS. McBURNEY: I think that the proposed rule on emerging technologies does leave enough flexibility --

MR. McGAFFIGAN: Right.

MS. McBURNEY: -- in the licensing process. But as we go forward, I think that perhaps some of the states can work with the NRC staff to develop for the rulemaking in some of these areas, on these combination units and that sort of thing.

MR. McGAFFIGAN: My understanding was we put that sort of placeholder so as to have flexibility.

MS. McBURNEY: Right.

MR. McGAFFIGAN: But then once something matured, we were going to move it into the rule itself. And it's that process of moving things into the rule itself that perhaps occasionally we will -- if a state has gone first and it has a decent model, maybe we should learn from that. Is that what you're basically proposing?

MS. McBURNEY: That's right. Some of the intervascular brachytherapy technologies are rapidly changing on how it's done.

MR. McGAFFIGAN: I'd imagine, just from the point of view of our own people who are in agreement states, that we have the District of Columbia, and I think Georgetown and Washington Hospital Center and all those guys think they're pretty good and probably are using most of these techniques. So I'm surprised we're not hearing from them that we need to move -- if the technology is matured, move into our rule fairly rapidly.

DR. WILLIAMSON: Well, I think one virtue of the way it's being handled in the new Part 35 is you can get a lot of practice writing licenses and license guidance, which you can adapt and change.

MR. McGAFFIGAN: Maybe it all emerges.

DR. WILLIAMSON: Then at some point it will emerge, and this will also serve as a model for the states, the first guidance that's written by NRC for licensing specific scope licenses to use these products.

MR. McGAFFIGAN: Okay. Mr. Chairman, that's all I had. Thank you.

CHAIRMAN MESERVE: Commissioner Merrifield?

MR. MERRIFIELD: Thank you, Mr. Chairman. The issue of Part 35 has been one that the Commission, I think, has spent an extraordinary amount of time on, as it should. And we managed to have felled quite a force in our effort to get here. I appreciate the very helpful comments today and the information that is provided. I'm particularly curious about the issues raised by Dr. Vetter and Dr. Williamson about some of the unintended consequences, and I intend, as a follow through on this meeting, to certainly, through my staff and through the staff of the Commission, to understand a little better from their standpoint, if in fact they agree with the analysis. Obviously, if it's taken at its face value, obviously it is troubling.

I am struck, however, with the positive comments about where we're going. I am always reminded that in Washington we use the old saw that we shall never let the perfect be the enemy of the good. And, overall, I think we're going in the right direction in that regard.

Mr. Chairman, I don't have any follow-up questions, given the fact it was a very concise and useful briefing. So I pass my questions. Thank you.

CHAIRMAN MESERVE: Thank you. I also just have a few brief comments and questions. Dr. Cerqueira, I know that you made mention in your comments about your request that you hope the user community would be involved in the development of the guidance. And let me -- this is a very major activity for us now in moving out in Part 35 to make sure that we get the wisdom of the user community involved in that.

And there are workshops that are planned, and we do anticipate that that will be a very public process, that some of the communities have raised some issues associated with this rule, and on behalf of the Commission, I have communicated with them and urged that they participate with us and with the staff in helping to develop guidance that in particular deals with diagnostic medical uses. And we very much welcome all of you to participate as well, and that things that we haven't cleaned up in the rule itself, I think there's a large number of things that we can fix in the guidance documents, and that's our intent to do that.

DR. CERQUEIRA: Commissioner, just one comment. The timeliness on this is kind of important also, and we obviously want to go through the process to get the stakeholder input, but at the same time, if we have the regulations published and don't have the guidance documents, it's going to create a certain amount of confusion, which is inevitable whenever you make these changes. And I guess my question is realistically can we get the guidance documents drafted, reviewed and finalized in six months?

CHAIRMAN MESERVE: Well, that's our hope. As you know, there was guidance documents that have been developed that have acknowledged inadequacies in them. And the idea, at least for the diagnostic medicine, was where we felt there was particular confusion, as to what the Commission intended, is to try to have a guidance document that is specific to the diagnostic application and to make clear that something that may not be as transparent in the rule as we would have hoped, that there are many areas where there are regulations that we did not intend to apply and others where perhaps there's more flexibility than had been perceived in the past.

DR. WILLIAMSON: I just wanted to make one comment about the therapeutic regulations. I would -- it's really not correct to say they're less prescriptive than the old ones. The 35.600 and 400 contained lots of detailed regulations. What's good about them is that they comply and are more similar to the standards of practice that we use now: American College of Radiology practice standards and AAPM Task Group reports. But I think there is a concern.

If this document is to lead to a performance-based regulatory system, this is going to be dependent upon how it's implemented and enforced. And if the inspectors go out there with the same kind of mindset that they've used in the past, it's going to be just like it was before, maybe slightly different technical requirements but the emphasis will be on whether you signed this or dated this and not on the quality of the program.

So I think just to make the general point that this new regulatory initiative will be performance based only to the extent that the worker force that implements it is trained, and there are appropriate guidance documents.

The second point is if it's going to take some months to prepare this guidance document and training documents and so forth, wouldn't it be reasonable to delay the publication of Part 35 by three months so at least the user community gets a few months of lead time to sort of get an idea of what the regulatory system is before they go ahead and implement it? I have this concern that on day 179 the guidance documents will be made available, and on day 180 it's a new world, new regulatory world, and nobody will know what's going on.

MR. McGAFFIGAN: Mr. Chairman, I don't think that's the -- the guidance documents, the changes we're talking making to them are relatively modest. I mean they do exist. They've gone through numerous drafts. We do have to make some changes. And I can't imagine we can't have them out within two months from now, so 30 days after we publish the rule. So I mean you'd have 150 days to have workshops, get it fixed up. I'm open, but this thing has been around for an awful long time.

DR. CERQUEIRA: Yes. I'd sort of second that also in the sense that, you know, we've had drafts of Part 35 revisions around for three plus years, and yet now we're still finding that there was some unintended meaning. So I think it would be more important to get it out and deal with some of these other issues as they come up.

CHAIRMAN MESERVE: Well, it is our -- I don't want to have -- leave any implication we're not going to address these issues. We're going to try to do them in as timely a fashion as possible. I think that the sense of the Commission has been that there are improvements in the revised Part 35. We'd like to make sure that we attain them, and we're going to work through the problems as we confront them.

But it does seem to me that none of us should expect that with the publication of Part 35 and with whatever effort that we make to issue the guidance that the battle is over. I mean this was a very complicated regulatory regime. There's learning on both sides that has to take place. There's training that has to take place. And I take your point that this is something that it is a work in progress, and we ought to approach it that way, and I think that we understand that.

MR. McGAFFIGAN: Mr. Chairman, I'd also mention, I know from my experience here there is at least one rule where we put it into effect and we discovered that we really couldn't put it into effect because there was a Catch-22, and I think we had some sort of enforcement discretion regime for some period of time. So there's all sorts of instruments available to us if there's some aspect of this rule that isn't quite ready for prime time 195 days from now, whatever, to deal with that.

MR. MERRIFIELD: I would say, Mr. Chairman, not to take your time, but we went through a similar issue associated with our inspection of the reactors. We changed our way of doing business, and part of that was associated with changing the way our inspectors did business. And I think the concern here is the implementation by our staff is only so good, and I think the Commission has demonstrated its reflection and attention to this issue, and that will continue.

CHAIRMAN MESERVE: And ACMUI's continue focusing on this issue is something that we would welcome as well.

DR. CERQUEIRA: We're committed to working with you on working through some of these problems that will inevitably come up. And I think you have the Committee's support on that.

CHAIRMAN MESERVE: Both Dr. Vetter and Dr. Williamson talked about aspects of our rule as to the board certification where we may have dropped the ball with regard to authorized medical physicists and radiation safety officers. Are there other categories where we've -- you haven't noticed as yet because you're not in those professions, and we need to look at these regulations as well? Do you know? I mean has anyone done a comprehensive examination of how we've done these certifications to make sure that we've caught all the places where there are possible areas where we've not appreciated that the existing certification requirements are ones that we haven't captured in the rule?

DR. CERQUEIRA: I think from the diagnostic authorized user physician category, most of the things are being dealt with in terms of board or training and experience. And perhaps Dr. Nag or Dr. Diamond would like to comment upon the radiation oncologist or the therapeutic applications.

MR. NAG: Subir Nag, Ohio State University, member of the ACMUI, radiation oncologist. I think one possible place where we may have some problems, and I'm not sure whether we will or not, is if you are a board certified radiation oncologist and you have requirements that you don't have a gamma knife in your center, if you are going to a center, you're board certified and your new center has a gamma knife or has HDR and you are not trained on HDR, whether you will be allowed to be an authorized user there or not. Another possible place where we may run into problems is the requirement if we are going to be using any unsealed isotope whether we will run into any problem or not. That is one possible place where we may have conflict. I haven't really seen the new document and how it will be applied in practice, so that perhaps may be made clear in the guidance document.

DR. CERQUEIRA: I think that's important because some of these areas I mean you have limited applications or a limited number of units out there. And what we tried to do with the rule was to have people have specific training in an area in which they were going to be using. And you can't require that of everybody, and yet you need to have a mechanism. I think the guidance documents may allow you the opportunity to tailor for these specific issues that have come up.

DR. WILLIAMSON: In the 35.600, which is the photon-emitting devices, it gives a definition of authorized user, which includes the same kind of logic: board certification that complies with Paragraph B or Paragraph B, and then it includes residency and so on. But in the experience that it describes that you have to have, it talks about checking treatment plans for high dose rate brachytherapy and writing prescriptions. So the clear implication is, is that that has to be an existing component of the training program, although the language is different enough that maybe there will be some way to weasel out of it.

The other change that's important is under the old regulations certification by the American Board of Radiology allowed one to be an authorized user for radiopharmaceutical treatments without qualification. And there is, I think, possibly some problem there. As we were talking about it before, it is not clear that the American Board of Radiology requires fixed number of cases that would comply that would allow radiation oncologists carte blanche who have certification to practice under the new regulation.

(END TAPE 1, SIDE A)

(BEGIN TAPE 1, SIDE B)

DR. WILLIAMSON: -- unsealed radiopharmaceutical and as a brachytherapy treatment source too.

CHAIRMAN MESERVE: Okay. Good. Thank you very much. Commissioner Dicus?

MR. DICUS: Thank you. It is a great advantage being the cleanup batter. You don't usually have quite as much going, particularly when there's been a very clear and precise presentation. Maybe I'll just make a couple of comments and one question to Ms. McBurney. Are the agreement states or I guess it would be CRCPD working on guidance or are they kind of waiting to what we get?

MS. McBURNEY: I am not sure, but I assume they're waiting on the NRC guidance.

MR. DICUS: Okay.

MS. McBURNEY: I don't think they're working on the guidance documents at this time.

MR. DICUS: All right. And to backup what's already been said, I know we have a great interest in getting our guidance out very quickly with the rule. We did step back to make some modifications based upon some concerns that were raised, tried to make this as clear and as good an implementation as we can, given the fact that we are, as the Chairman said, walking into a little bit of some new areas and are trying to deal with that accordingly.

We certainly don't want any unintended consequences. We hear what you're saying, and it's something we need to take a look at. We certainly will. I was a little bit relieved to hear you say, Dr. Williamson, that maybe you didn't -- you kind of missed it the first time around, didn't really understand the implementations. I think Dr. Vetter mentioned perhaps we did make a slight change, at least, in the one area. So something we need to look at a little bit more.

And let me, as a final comment, and it also backs up -- it comes off on something Commissioner Merrifield mentioned, when we did go to our new reactor oversight program, and we studied that for a quite a while, we recognized that it was a work in progress, that we would have to make modifications as we went along. But one of the concerns that was raised is will our resident inspectors, our regional inspectors, so forth, really be able to change how they had always done business? And did we have the kind of training program, the kind of oversight of our own staffs, our own management, that those changes would occur? And I was concerned about it. I had resident inspectors tell me they were concerned about what was their new job going to be? And also I had the industry expressing their concern.

We have been successful. Of course we still have a little bit of work to do, but our resident inspectors have been able to make the shifts. They are being able to deal with the new oversight process. Given the fact it is a work in progress and we are having to make some modifications from time to time, it is working. So I think we've got a track record on one side of the house of successfully doing this, and I think that message is loud and clear to the other side of the house to do the same thing. So just to pass that along. Thank you, Mr. Chairman.

MR. McGAFFIGAN: Mr. Chairman, could I -- there's just one question I forgot to ask. Dr. Cerqueira, do you have the medical specialties you need represented on the Board? We gave you an addition recently to the Board, and that was in response to some comment you had made to us. Are you now -- given what you see coming the next five years, are you now in reasonably good shape, in terms of the people you have on the Board?

DR. CERQUEIRA: I think we are. The addition of --

MR. McGAFFIGAN: The Committee?

DR. CERQUEIRA: -- an interventional cardiologist with intravascular brachytherapy I think will give us some input from a community that was not represented on the Board. I think some of the issues that were brought up about this mixed dosing is something that the Committee -- I see that as a problem, and I think that's something the Committee can deal with.

And a lot of these issues we've talked about relate to staffing and just availability of people, and that is going to be a big problem. I don't know how the Commission is going to be able to handle it, but it's something that we're going to make all of these rules so that we can use these radiation safely, but somehow we're going to need to get the manpower to be able to do it. Even some of Sally's concerns with people getting a lot of radiations and since there aren't enough radiopharmacists out there that work can be split up amongst different people. But I think the composition of the Committee at this point represents all the major stakeholders and should be able to deal adequately with the issues for the next three to five years.

MR. McGAFFIGAN: Mr. Chairman, I didn't intend to ask this, but the FDA must face the same issue. I mean they do machine exposures to radiation. There really is a concern. I don't know how we're going to deal with it, but we have to have -- we have a hard enough time with state salaries what they are having people out there capable of regulating these things is going to be a tremendous challenge, given the pay scales in the industry and then the pay scales offered by government. Maybe we need to find some really creative ways to deal with that, but I don't know what those are, other than oftentimes in the past people give higher pay for certain specialties in federal pay. NIH tends to have higher pay than the rest of government, et cetera. But selling that to a state legislature, the Department of Health, that may be the only way to go is that if you want us to be able to do our jobs, you have to pay us a little bit more and pay us a little bit more than some of the other folks in government.

DR. CERQUEIRA: But part of the problem is the training programs that used to exist for a lot of these specialties are not there anymore, they've closed down. And we're also getting a shift. People can make more money in a private practice, out-of-hospital setting doing less work than they do in a hospital. So hospitals are extremely hard hit by this. And paying people -- there just aren't enough people. You can have a $20,000 signing bonus and give a top salary and people are still not taking the position. It is something that's going to affect us. We're getting technologies that are being used more frequently for diagnosis and therapy, and people want it, patients need it, but we're not going to be able to provide it in the future to the people because of lack of manpower.

MR. McGAFFIGAN: It would be nice if these PET scan commercials that I hear on WTOP Radio as I drive to and from work admitted that the word "nuclear" was part of their -- was part of what they were selling. But you'd be hard-pressed to figure out there was any nuclear material involved listening to the advertisements.

DR. CERQUEIRA: And they've hired all the technologists from the hospitals and from the NIH. The NIH has had five technologist vacancies for a year, and they can't fill them.

MR. McGAFFIGAN: Is that right?

DR. CERQUEIRA: Yes.

CHAIRMAN MESERVE: Dr. Williamson?

DR. WILLIAMSON: Well, just to make a comment about the RSO. I think the shortage of health physicists and the fact that maybe many of those that exist can't be RSOs in major institutions is really a problem. The tradition focus of a radiation safety program is the RSO as a person who's kind of independent of the individual users and able to have an independent point of view and some power over them. And I'm afraid what will happen is there will be more of a tendency for clinical users, physicists and authorized users to become RSOs even in complex programs, and that will eliminate a lot of the independent oversight that exists. So, in a way, not having an independent certification organ for RSOs is short-sighted, and in the long run could erode the effectiveness of radiation safety programs.

CHAIRMAN MESERVE: Well, I'd like to thank all of the Committee members for -- excuse me, did you have something? There's a microphone over there. You might identify yourself for the transcript.

MR. NAG: Subir Nag, member of the ACMUI, radiation oncologist. I have a couple of questions to the Commissioners. One of the feeling that we have addressed at the ACMUI we know we are an advisory body. We sometimes feel that we make our recommendations, it goes to the NRC, and sometimes we don't get the feedback. Maybe you have the right to overlook or not take the advice, but we have spent a lot of time, and we do not know why some of these are not taken into account. We would like, if possible, to have feedback as to why those were not taken into account. I think some of us have frustrations in ACMUI, although I'm just a new member. That's some of the frustrations I've had. I don't know about the other members.

The other point I wish to make is that just like sometimes the wording of "and" and "or," like the ones for the medical physicists and for the RSO, there may be one similar one for interventional brachytherapy. And we, at the ACMUI, have not had the time yet to discuss the recent gain of the principal lessons of physicists or the authorized user, what some of those unintended consequences are. We are going to discuss hopefully some of that tomorrow. But some of these have been implemented somewhat quickly without taking into consideration what some of the consequences will be.

CHAIRMAN MESERVE: Thank you. You have another comment?

MR. DIAMOND: Thank you. My name is David Diamond. I'm a radiation oncologist, also on the Advisory Committee. I've been on the Committee for two years, so this is my first opportunity to meet you all, and we appreciate it.

I thought it would be useful to take a few moments to also give you a sense of some of the other issues that we've been discussing the past two years or so in our body, give you a sense of other things that are on the plate. One thing that you probably have a sense of is that there's an explosion in the use of radiopharmaceuticals, both for diagnostic and for therapeutic purposes.

My own particular feeling is that over the next three to five years in my particular area, which is the treatment of folks with cancer, is we're going to see an explosion in the usefulness of various modalities to target antibodies for cancer therapy, and even subsequent on the horizon these new technologies, which are known as nanogenerators, in which alpha-emitting particles are actually absorbed into cancer cells directly in an effort to go and cause cell kill. So there's an explosion of these new technologies, and as Commissioner McGaffigan pointed out, we're trying to keep up with some of these new technologies, and we welcome the fact that there's a Subpart 1000 that allows us some flexibility in how to keep a handle on it.

I'd also like to let you know that there are some other issues that we've been working on behind the scenes, so to speak. Firstly, the joint working group between the American College of Cardiology and the American Society for Therapeutic Radiation Oncology, also know by the acronym by ASTRO, has spent hundreds if not thousands of hours trying to resolve behind the scenes, so to speak, these issues regarding some of the friction with vascular brachytherapy. Vascular brachytherapy, for those of you who don't know, is the relatively new technology in which we use sources of radiation actually within part vessels to try and prevent restenosis after balloon angioplasty, and we believe that we have been very successful in working out a lot of these differences that heretofore had been a difficulty, and we look forward to continuing that relationship.

Another issue is that, unfortunately, as the sequela of September 11, there's been a lot of popular concerns regarding the terrible idea or the terrible possibility of some intentional release of radioactive materials, and I'd like you to know that the American Society for Therapeutic Radiation Oncology, or ASTRO, has been working with other agencies to help disseminate information to those of us in the medical fields to educate ourselves and just be informed God forbid that something terrible should happen. And, of course, there are a lot of resources available to us, such as REACTS, that have been very helpful in that.

So I just wanted to convey some of these senses to you. I know we didn't discuss them in detail as a full presentation, but I thought you may find that useful. Thank you.

CHAIRMAN MESERVE: I'd like to thank all of you for your comments. We very much value your advice and appreciate the time and effort that you put into advising us. And I realize that we've talked a large amount today, of course, about Part 35, and, as I think all of us have mentioned, we are all committed to making sure that's a success. And we would very much welcome your continuing oversight and comments to us in that area. With that, we're adjourned.

(Whereupon, the NRC briefing was concluded.)