

# **NUCLEAR REGULATORY COMMISSION**

Title: BRIEFING: MEETING WITH THE  
ADVISORY COMMITTEE ON THE  
MEDICAL USES OF ISOTOPES (ACMUI)

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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. MESERVE, 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.)

1 STAFF AND PRESENTERS:

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

3 KAREN CYR, ESQ., General Counsel

4 SALLY W. SCHWARZ, Nuclear Pharmacist

5 RUTH E. MCBURNEY, State Government Representative

6 SUBIR NAG

7 DR. RICHARD J. VETTER, Radiation Safety Officer

8 ANNETTE VIETTI-COOK, Secretary of the NRC

9 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

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1 and inspectors during the six-month date period  
2 preceding the effective of the revised rule. As both  
3 NRC and our licensees gain experience with the revised  
4 Part 35, we remain open to the possibility of future  
5 rule changes.

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

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

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

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

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

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

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

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

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

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

22 CHAIRMAN MESERVE: Thank you all for  
23 joining us.

24 DR. CERQUEIRA: It's our pleasure and what  
25 we've prepared for your today is a presentation

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1 dealing in part with the Part 35 revision process but  
2 also to try to identify for the Commission issues that  
3 we feel will be important in the next three to five  
4 years that will influence the medical use of isotopes.  
5 And so we'll go over our material, and we'll be happy  
6 to take any questions at any time from the  
7 commissioners.

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

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

23 Page 3, the process was an open process.  
24 There were seven public workshops that were held  
25 seeking input from members of the stakeholder

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1 community as well as the general public. There were  
2 20 professional society meetings that were held  
3 between the staff and various commissioners. There  
4 were six ACMUI discussions that were held related to  
5 this. There were two full panel discussions, and  
6 there were four subcommittee meetings that were held  
7 with specific attention to diagnostic as well as  
8 therapeutic uses of radiation. There were two  
9 agreement state workshops that sought input on the  
10 revisions as well.

11 If we can go to Page 4, the role of the  
12 states was investigated, because currently there are  
13 32 agreement states and only 18 NRC-regulated states,  
14 so it was felt it was very important to get their  
15 input as well. And this input came from the  
16 Organization of Agreement State, from the radiation  
17 officers, and there was a separate Part 35 Working  
18 Group that provided input into the process.

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

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

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

16                 And we also feel that we're in a  
17                 transition period in the sense that the Part 35  
18                 revision, if published and implemented in six months,  
19                 will be the first step to dealing with overall  
20                 revision and the use of radioactive materials for  
21                 medical use. There were some issues that, you know,  
22                 again, I think we have briefed the Commission. We had  
23                 some differences with the Committee on medical event  
24                 reporting, radiation to the unborn fetus as well as  
25                 some issues related use of intravascular

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1 brachytherapy. And some of these issues were brought  
2 up before the Commission, and some of these were  
3 basically going to be ongoing issues in terms of  
4 emerging technology. Some of these other issues, the  
5 Committee I think had slightly different opinions from  
6 what the final rule reflected.

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

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

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

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1 DR. CERQUEIRA: Okay. Well, the next  
2 presentation is going to be on the implementation of  
3 10 CFR Part 35 and the agreement states by Ruth  
4 McBurney.

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

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

18 There will be some implementation issues  
19 in the agreement states. As Dr. Cerqueira mentioned,  
20 the states have up to three years to implement the  
21 rules. Because it was a -- the states were involved  
22 in the rulemaking and also there was a parallel  
23 rulemaking going on through the Conference of  
24 Radiation Control Program directors to produce the

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1 suggested state regulations, which will be distributed  
2 to the states along with the Part 35.

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

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

21 One of the more important areas for  
22 consistency that the ACMUI has addressed is the need  
23 for uniformity for the training and experience  
24 requirements for the MD authorized users, the  
25 physician users. The ACMUI recommends that NRC

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1 cooperate with the states in order to assure a more  
2 expedient uniformity in the requirements for the  
3 training experience for authorized users. There could  
4 be cross-boundary issues with physician training  
5 programs from state to state.

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

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

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1 community is facing the same workforce shortage and  
2 training shortage. Thank you.

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

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

20 So it's not under the regulation of the  
21 Nuclear Regulatory Commission but certainly influences  
22 the workers, because currently PET is developing  
23 technology and pharmacists are involved in working  
24 with mixed isotope produced byproduct material as well  
25 as accelerator-produced materials. And for

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1 centralized pharmacists, essentially handling PET  
2 isotopes or handling energies 511 keVs compared to  
3 more typical 100 to 300 range isotope energies. So  
4 what these pharmacists are facing essentially is the  
5 need to distribute their dose among more than  
6 themselves, essentially.

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

14 And some of the reasons for that are on  
15 Page 3. Essentially, the programs for pharmacist  
16 training have expanded from five years for the  
17 undergraduate degree to the six-year program, which is  
18 the Pharm D graduating classes now. So we've  
19 increased the length of education. And at that point,  
20 essentially, again there are these increased needs  
21 placed on the field as well. And in order to maintain  
22 ALARA, and that's as low as reasonably achievable, and  
23 typically has been looked at to try and maintain doses  
24 ten percent of the allowable federal hand and body  
25 doses. And when we're dealing with PET as an entity,

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1 the higher energy that we're dealing with, it's very  
2 difficult to comply with that ten percent ALARA. Ten  
3 percent is not regulated, it is just kind of an  
4 unwritten regulation that we try to keep ourselves  
5 within.

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

18 The next is Slide 4. Essentially, as far  
19 as addressing the shortages for pharmacists, some  
20 professional pharmacy curriculums have allowed  
21 electives as far as the certification process for  
22 board certification of pharmacists, such that during  
23 the six-year professional program, you can take the  
24 required courses so that you can be didactic ready for  
25 then going out into the field and acquiring your

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1 hands-on training. But not all schools have allowed  
2 this ability. Purdue, as a university, has certainly  
3 allowed enough electives in these six-year programs so  
4 that the didactic education can be achieved.

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

16 So on Page 6, if we look again to address  
17 the shortage, pharmacy has relied always on  
18 technicians, which are supervised by the pharmacists,  
19 and there is specialization obviously needed for  
20 nuclear pharmacy technicians, and guidelines for  
21 nuclear pharmacy technicians were prepared by the APHA  
22 section on nuclear pharmacy practice in the year 2000.  
23 And they're currently working on certification  
24 programs for technicians through APHA.

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

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

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

24                 First, let me say that I think the  
25                 regulated community, in general, welcomes the concept

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1 of AMP. I think it's a great step forward in  
2 reconciling the regulatory point of view with clinical  
3 reality to realize that the physicist plays a much  
4 broader role in promoting the efficacy and safety of  
5 radiotherapy treatment than just calibrating cobalt 60  
6 units. However, there is a major issue and conflict  
7 between the definition of qualified medical physicist  
8 used in the community and the concept of AMP.

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

24 Now, the board process is very similar in  
25 terms of the educational and experience requirements,

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1 at least a Master's degree and two to six years of  
2 experience, but it does not require specific  
3 experience with byproduct -- with specific byproduct  
4 technologies. It's emphasis is to assess the quality  
5 of judgment and knowledge base of the candidates to  
6 ensure that they are capable of independent clinical  
7 physics practice.

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

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

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

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

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

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

21                 DR. CERQUEIRA: Thank you, Jeffrey.

22                 DR. WILLIAMSON: I should mention one more  
23                 thing. There are similar issues with the definition  
24                 of authorized user as well. It may well turn out that  
25                 board certification and radiation oncology may not

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1       qualify a physician to be an authorized user for high  
2       dose rate brachytherapy or gamma stereotactic.

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

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

10              (Laughter.)

11              And you can go right to Slide 2, my Slide  
12       2.   I'd like to just briefly preface my remarks by  
13       saying that it is becoming apparent that there is a  
14       shortage of health physicists that is developing in  
15       this country.   Back in the '50s and '60s and early  
16       '70s, there were numerous training programs around the  
17       country that were well supported, that had many  
18       radiological health fellowships and other fellowships  
19       supported by the Atomic Energy Commission at that  
20       time, the Department of Radiological Health and so  
21       forth.   Those fellowships have dried up, and there  
22       was, at one point in time, considerable support for  
23       training programs.   That support has dried up.   And  
24       there are now, I have been told, approximately 100  
25       health physicists in the pipeline in this country, and

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1 all those people who were trained in the '50s and '60s  
2 are about my age or older and will be retiring one of  
3 these days. And the profession is quite concerned  
4 about this shortage.

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

19 On Page 3, I outline the current -- or the  
20 proposed Part 35, under which a person may become  
21 qualified as a radiation safety officer by either  
22 being certified by a specialty board or meeting  
23 training requirements and a preceptorship. The  
24 difference is there really is no alternative pathway  
25 here, because the certification route requires that

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1 the specialty board incorporate Parts B and C. So  
2 there is no alternate pathway. And, in fact, you  
3 don't need board certification to become a radiation  
4 safety officer; all you need is B and C. There is no  
5 incentive, for purposes of these regulations, to  
6 become certified.

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

19 They would not be qualified under these  
20 regulations, because there actually is no separate  
21 certification pathway. And the reason there isn't is  
22 because the current certification bodies do not  
23 incorporate Parts B and C. Most of them require, of  
24 course, a degree in science, some of them even require  
25 a Master's degree in a specialty, but they do not

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1       require those specific hours of training, and they do  
2       not require a preceptorship. And the preceptorship is  
3       also another problem.

4               On Page 4, it lists some unintended  
5       consequences. This is really no one's fault. It's  
6       through this long process under which the revised Part  
7       35 was generated. The NRC originally has proposed an  
8       accreditation procedure for the boards, and that  
9       obviously was going to be a rather large task for the  
10      NRC to accredit boards. And so as a result of their  
11      re-analysis and feedback from the general community,  
12      the new proposed Part 35 backed away from that and got  
13      us into the situation we are at today, where it's  
14      specialty board, not or training, but a specialty  
15      board and the specific training requirements.

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

23             This also, as Dr. Williamson mentioned  
24      earlier, marginalizes board certification. I think  
25      many people will become board certified anyway,

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1 because it's good for them, they want to rise to that  
2 level. But the regulations don't encourage it and in  
3 fact it's my personal belief and of course that of  
4 professional boards that we should do whatever we can  
5 to try to increase the competence of people who want  
6 to become radiation safety officers and encouraging  
7 board certification would do that.

8 This then also undermines an effective  
9 industry standard; that is, today you can become board  
10 certified -- if you are board certified, you can  
11 become a radiation safety officer. Tomorrow, when the  
12 new regulations become effective, you will not be able  
13 to do that.

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

23 Bottom line again, however, is that  
24 because of that unintended "and" instead of an "or,"  
25 we actually are limiting the pool of people who are,

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1 under the regulations, qualified to be RSOs, and that  
2 in fact does create a shortage for us. Thank you very  
3 much.

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

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

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

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

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

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

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

5 MR. MCGAFFIGAN: We put the thing out. I  
6 mean the frustration is that when we met in October of  
7 '99, my recollection -- Chairman Dicus was Chairman  
8 and we had put out the rule approximately July of that  
9 year and left it there for three months hoping that  
10 people would find line-in, line-out changes. We did  
11 make some changes ourselves in some of the areas that  
12 you talked about. But it had been sitting there, and,  
13 gosh, I was hoping that if there were "and's" that  
14 should be "or's" or vice versa, we would get that  
15 advice.

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

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

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

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

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

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

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

21 MR. MCGAFFIGAN: For comment or for final  
22 --

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

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

3 MS. MCBURNEY: Right. I'm not really sure  
4 myself.

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

8 MS. MCBURNEY: That's right. It's going  
9 to have to meet the compatibility requirements.

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

16 MR. MCGAFFIGAN: I do also note the  
17 Agreement State Organization isn't here, but speaking  
18 again as one commissioner, I did see the resolution  
19 that they passed last October in Sante Fe, and I do  
20 continue to believe that we're doing the right thing  
21 in having the T&E requirements be compatibility level  
22 B. I think somebody who's learning their -- getting  
23 educated at Georgetown shouldn't have to worry about  
24 whether they can practice at one of the Maryland  
25 suburban schools or vice versa. So I did think about

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1       it, and I come down on the other side. And I assume  
2       since the Commission as a whole was pretty united on  
3       that -- weren't we -- so I don't think you're going to  
4       get anything different there. But I do hope that  
5       those regulations are in good shape and they're  
6       compatible with ours now.

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

12             MS. SCHWARZ:       This is Washington  
13      University.

14             MR. MCGAFFIGAN:    Oh, okay.     You're  
15      Washington University.

16             MS. SCHWARZ:    The institute, right.

17             MR. MCGAFFIGAN:   Do you have --

18             DR. CERQUEIRA:   Mallinckrodt endowed them.

19             MS. SCHWARZ:    We were endowed.

20             MR. MCGAFFIGAN:   Okay.     Mallinckrodt  
21      endowed you. Okay. You don't know --

22             MS. SCHWARZ:    They are not supporting us.

23             MR. MCGAFFIGAN:   Do you have any idea how  
24      Mallinckrodt deals or how the European community deals  
25      with these issues?     Because 40 percent of our

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1 occupational dose limit, which is what you said you'd  
2 get to when you deal with accelerator-produced  
3 isotopes, is about what the European limit is going to  
4 be. I mean their limit is now ten rem over five  
5 years, no more than five rem in a year.

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

17 MS. SCHWARZ: I don't know for certain how  
18 they're handling it. I do know that the U.S. is  
19 probably in a different position than the European  
20 community, because I mean with this issue of  
21 freestanding PET centers, they've proliferated to a  
22 more rapid extent, I believe, in this country, not to  
23 say that they won't in that country. But I think what  
24 eventually, you know, we are moving to in this country  
25 too is change of operations of how we handle dose

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1 drawing and things like this. And, you know, we're on  
2 a learning curve, as I'm certain they are too, because  
3 PET has accelerated tremendously in the last several  
4 years, actually. So we're --

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

11 MS. SCHWARZ: Yes.

12 MR. MCGAFFIGAN: You cannot -- it's  
13 advertised on the radio nowadays pretty broadly. It's  
14 pretty amazing stuff.

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

21 MR. MCGAFFIGAN: Ms. McBurney, one of the  
22 questions -- points you made was that the agreement  
23 states had to move forward with certain rules, because  
24 the technology is there. Does that say something  
25 about how quickly we're going to have to amend this

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1 rule to bring it -- I know there was some talk in the  
2 National Materials Working Group about this being an  
3 area where the states might take the lead in amending  
4 Part 35 to bring in some of the advanced technologies.  
5 Do you have any idea where that stands?

6 MS. MCBURNEY: I think that the proposed  
7 rule on emerging technologies does leave enough  
8 flexibility --

9 MR. MCGAFFIGAN: Right.

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

15 MR. MCGAFFIGAN: My understanding was we  
16 put that sort of placeholder so as to have  
17 flexibility.

18 MS. MCBURNEY: Right.

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

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

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

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

17 MR. McGAFFIGAN: Maybe it all emerges.

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

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

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1 CHAIRMAN MESERVE: Commissioner  
2 Merrifield?

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

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

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

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

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

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

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

24 DR. WILLIAMSON: I just wanted to make one  
25 comment about the therapeutic regulations. I would --

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1       it's really not correct to say they're less  
2       prescriptive than the old ones. The 35.600 and 400  
3       contained lots of detailed regulations. What's good  
4       about them is that they comply and are more similar to  
5       the standards of practice that we use now: American  
6       College of Radiology practice standards and AAPM Task  
7       Group reports. But I think there is a concern.

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

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

22             The second point is if it's going to take  
23      some months to prepare this guidance document and  
24      training documents and so forth, wouldn't it be  
25      reasonable to delay the publication of Part 35 by

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1 three months so at least the user community gets a few  
2 months of lead time to sort of get an idea of what the  
3 regulatory system is before they go ahead and  
4 implement it? I have this concern that on day 179 the  
5 guidance documents will be made available, and on day  
6 180 it's a new world, new regulatory world, and nobody  
7 will know what's going on.

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

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

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

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

19                 MR. McGAFFIGAN: Mr. Chairman, I'd also  
20                 mention, I know from my experience here there is at  
21                 least one rule where we put it into effect and we  
22                 discovered that we really couldn't put it into effect  
23                 because there was a Catch-22, and I think we had some  
24                 sort of enforcement discretion regime for some period  
25                 of time. So there's all sorts of instruments

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1       available to us if there's some aspect of this rule  
2       that isn't quite ready for prime time 195 days from  
3       now, whatever, to deal with that.

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

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

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

21             CHAIRMAN MESERVE:   Both Dr. Vetter and Dr.  
22      Williamson talked about aspects of our rule as to the  
23      board certification where we may have dropped the ball  
24      with regard to authorized medical physicists and  
25      radiation safety officers. Are there other categories

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1       where we've -- you haven't noticed as yet because  
2       you're not in those professions, and we need to look  
3       at these regulations as well? Do you know? I mean  
4       has anyone done a comprehensive examination of how  
5       we've done these certifications to make sure that  
6       we've caught all the places where there are possible  
7       areas where we've not appreciated that the existing  
8       certification requirements are ones that we haven't  
9       captured in the rule?

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

16               MR. NAG:       Subir Nag, Ohio State  
17       University, member of the ACMUI, radiation oncologist.  
18       I think one possible place where we may have some  
19       problems, and I'm not sure whether we will or not, is  
20       if you are a board certified radiation oncologist and  
21       you have requirements that you don't have a gamma  
22       knife in your center, if you are going to a center,  
23       you're board certified and your new center has a gamma  
24       knife or has HDR and you are not trained on HDR,  
25       whether you will be allowed to be an authorized user

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1       there or not. Another possible place where we may run  
2       into problems is the requirement if we are going to be  
3       using any unsealed isotope whether we will run into  
4       any problem or not. That is one possible place where  
5       we may have conflict. I haven't really seen the new  
6       document and how it will be applied in practice, so  
7       that perhaps may be made clear in the guidance  
8       document.

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

19              DR. WILLIAMSON: In the 35.600, which is  
20       the photon-emitting devices, it gives a definition of  
21       authorized user, which includes the same kind of  
22       logic:     board certification that complies with  
23       Paragraph B or Paragraph B, and then it includes  
24       residency and so on. But in the experience that it  
25       describes that you have to have, it talks about

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1       checking treatment plans for high dose rate  
2       brachytherapy and writing prescriptions. So the clear  
3       implication is, is that that has to be an existing  
4       component of the training program, although the  
5       language is different enough that maybe there will be  
6       some way to weasel out of it.

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

18               (END TAPE 1, SIDE A)

19               (BEGIN TAPE 1, SIDE B)

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

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

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

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

11                  MR. DICUS: Okay.

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

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

23                  We certainly don't want any unintended  
24 consequences. We hear what you're saying, and it's  
25 something we need to take a look at. We certainly

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1 will. I was a little bit relieved to hear you say,  
2 Dr. Williamson, that maybe you didn't -- you kind of  
3 missed it the first time around, didn't really  
4 understand the implementations. I think Dr. Vetter  
5 mentioned perhaps we did make a slight change, at  
6 least, in the one area. So something we need to look  
7 at a little bit more.

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

24 We have been successful. Of course we  
25 still have a little bit of work to do, but our

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1 resident inspectors have been able to make the shifts.  
2 They are being able to deal with the new oversight  
3 process. Given the fact it is a work in progress and  
4 we are having to make some modifications from time to  
5 time, it is working. So I think we've got a track  
6 record on one side of the house of successfully doing  
7 this, and I think that message is loud and clear to  
8 the other side of the house to do the same thing. So  
9 just to pass that along. Thank you, Mr. Chairman.

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

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

21 MR. MCGAFFIGAN: The Committee?

22 DR. CERQUEIRA: -- an interventional  
23 cardiologist with intravascular brachytherapy I think  
24 will give us some input from a community that was not  
25 represented on the Board. I think some of the issues

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1 that were brought up about this mixed dosing is  
2 something that the Committee -- I see that as a  
3 problem, and I think that's something the Committee  
4 can deal with.

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

20 MR. MCGAFFIGAN: Mr. Chairman, I didn't  
21 intend to ask this, but the FDA must face the same  
22 issue. I mean they do machine exposures to radiation.  
23 There really is a concern. I don't know how we're  
24 going to deal with it, but we have to have -- we have  
25 a hard enough time with state salaries what they are

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1       having people out there capable of regulating these  
2       things is going to be a tremendous challenge, given  
3       the pay scales in the industry and then the pay scales  
4       offered by government. Maybe we need to find some  
5       really creative ways to deal with that, but I don't  
6       know what those are, other than oftentimes in the past  
7       people give higher pay for certain specialties in  
8       federal pay. NIH tends to have higher pay than the  
9       rest of government, et cetera. But selling that to a  
10      state legislature, the Department of Health, that may  
11      be the only way to go is that if you want us to be  
12      able to do our jobs, you have to pay us a little bit  
13      more and pay us a little bit more than some of the  
14      other folks in government.

15               DR. CERQUEIRA: But part of the problem is  
16      the training programs that used to exist for a lot of  
17      these specialties are not there anymore, they've  
18      closed down. And we're also getting a shift. People  
19      can make more money in a private practice, out-of-  
20      hospital setting doing less work than they do in a  
21      hospital. So hospitals are extremely hard hit by  
22      this. And paying people -- there just aren't enough  
23      people. You can have a \$20,000 signing bonus and give  
24      a top salary and people are still not taking the  
25      position. It is something that's going to affect us.

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1 We're getting technologies that are being used more  
2 frequently for diagnosis and therapy, and people want  
3 it, patients need it, but we're not going to be able  
4 to provide it in the future to the people because of  
5 lack of manpower.

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

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

17 MR. MCGAFFIGAN: Is that right?

18 DR. CERQUEIRA: Yes.

19 CHAIRMAN MESERVE: Dr. Williamson?

20 DR. WILLIAMSON: Well, just to make a  
21 comment about the RSO. I think the shortage of health  
22 physicists and the fact that maybe many of those that  
23 exist can't be RSOs in major institutions is really a  
24 problem. The tradition focus of a radiation safety  
25 program is the RSO as a person who's kind of

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1 independent of the individual users and able to have  
2 an independent point of view and some power over them.  
3 And I'm afraid what will happen is there will be more  
4 of a tendency for clinical users, physicists and  
5 authorized users to become RSOs even in complex  
6 programs, and that will eliminate a lot of the  
7 independent oversight that exists. So, in a way, not  
8 having an independent certification organ for RSOs is  
9 short-sighted, and in the long run could erode the  
10 effectiveness of radiation safety programs.

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

15 MR. NAG: Subir Nag, member of the ACMUI,  
16 radiation oncologist. I have a couple of questions to  
17 the Commissioners. One of the feeling that we have  
18 addressed at the ACMUI we know we are an advisory  
19 body. We sometimes feel that we make our  
20 recommendations, it goes to the NRC, and sometimes we  
21 don't get the feedback. Maybe you have the right to  
22 overlook or not take the advice, but we have spent a  
23 lot of time, and we do not know why some of these are  
24 not taken into account. We would like, if possible,  
25 to have feedback as to why those were not taken into

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1 account. I think some of us have frustrations in  
2 ACMUI, although I'm just a new member. That's some of  
3 the frustrations I've had. I don't know about the  
4 other members.

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

17 CHAIRMAN MESERVE: Thank you. You have  
18 another comment?

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

24 I thought it would be useful to take a few  
25 moments to also give you a sense of some of the other

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1 issues that we've been discussing the past two years  
2 or so in our body, give you a sense of other things  
3 that are on the plate. One thing that you probably  
4 have a sense of is that there's an explosion in the  
5 use of radiopharmaceuticals, both for diagnostic and  
6 for therapeutic purposes.

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

22 I'd also like to let you know that there  
23 are some other issues that we've been working on  
24 behind the scenes, so to speak. Firstly, the joint  
25 working group between the American College of

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1 Cardiology and the American Society for Therapeutic  
2 Radiation Oncology, also know by the acronym by ASTRO,  
3 has spent hundreds if not thousands of hours trying to  
4 resolve behind the scenes, so to speak, these issues  
5 regarding some of the friction with vascular  
6 brachytherapy. Vascular brachytherapy, for those of  
7 you who don't know, is the relatively new technology  
8 in which we use sources of radiation actually within  
9 part vessels to try and prevent restenosis after  
10 balloon angioplasty, and we believe that we have been  
11 very successful in working out a lot of these  
12 differences that heretofore had been a difficulty, and  
13 we look forward to continuing that relationship.

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

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1       available to us, such as REACTS, that have been very  
2       helpful in that.

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

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

16              (Whereupon, the NRC briefing was  
17      concluded.)

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