

**UNITED STATES OF AMERICA**  
**NUCLEAR REGULATORY COMMISSION**

**Title:**           **MEETING WITH ACMUI AND DR. ROBERT  
ADLER ON RECOMMENDATIONS OF NAS  
REPORT ON REVIEW OF MEDICAL USE  
PROGRAM - PUBLIC MEETING**

**Location:**       **Rockville, Maryland**

**Date:**           **Friday, May 3, 1996**

**Pages:**          **1 - 60**

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UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

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MEETING WITH ACMUI AND DR. ROBERT ADLER  
ON RECOMMENDATIONS OF NAS REPORT ON  
REVIEW OF MEDICAL USE PROGRAM

- - -

PUBLIC MEETING

Nuclear Regulatory Commission  
One White Flint North  
Rockville, Maryland

Friday, May 3, 1996

The Commission met in open session, pursuant to  
notice, at 2:05 p.m., Shirley A. Jackson, Chairman,  
presiding.

COMMISSIONERS PRESENT:

- SHIRLEY A. JACKSON, Chairman of the Commission
- KENNETH C. ROGERS, Commissioner
- GRETA J. DICUS, Commissioner

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1 ACMUI MEMBERS PRESENT:

2 BARRY A. SIEGEL, Chairman

3 JUDITH ANNE STITT

4 JUDITH I. BROWN

5 DANIEL F. FLYNN

6 DENNIS P. SWANSON

7 JOHN GRAHAM

8 ROBERT M. QUILLIN

9 JEFFREY F. WILLIAMSON

10 LOUIS K. WAGNER

11 THERESA WALKUP

12 GEORGE MILLS

13 ALSO PRESENT:

14 ROBERT ADLER

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

1  
2 CHAIRMAN JACKSON: Good afternoon, ladies and  
3 gentlemen. The Commission would like to welcome members  
4 from the NRC's Advisory Committee on the Medical Uses of  
5 Isotopes as well as Dr. Robert Adler, who was a member of  
6 the National Academy of Sciences Committee for Review and  
7 Evaluation of the Medical Use Program of the Nuclear  
8 Regulatory Commission.

9 In July of 1993 the NRC requested that the  
10 National Academy of Sciences conduct a review and evaluation  
11 of the NRC's regulatory program for the medical use of  
12 byproduct material. At that time the National Academy of  
13 Sciences was asked to examine the broad policy issues which  
14 underlie the regulation of the medical uses of  
15 radioisotopes.

16 The Commission also was interested in an  
17 examination of the overall risk associated with the use of  
18 ionizing radiation in medicine.

19 Finally, the Commission wished to have the  
20 National Academy perform a critical assessment of the  
21 current framework for the regulation of the medical uses of  
22 byproduct material. The Commission asked that the National  
23 Academy make recommendations for an overall uniform national  
24 approach to the regulation of ionizing radiation in medical  
25 applications as well as appropriate criteria for measuring

1 the effectiveness of the regulatory program.

2 The Academy issued its report last December,  
3 including its recommendations, and it was briefed by the  
4 committee on February 27 of this year.

5 Today we will be hearing from our Advisory  
6 Committee on the Medical Uses of Isotopes on its views of  
7 the National Academy study and its recommendations. After  
8 the Committee has finished and we are finished with our  
9 questions, the Commission is also providing Dr. Adler with  
10 an opportunity to present his separate views on the National  
11 Academy study and its conclusions.

12 Before we begin, Commissioner Rogers, do you have  
13 anything to add?

14 COMMISSIONER ROGERS: Nothing at this time, thank  
15 you.

16 CHAIRMAN JACKSON: Commissioner Dicus.

17 COMMISSIONER DICUS: Nothing at this time.

18 CHAIRMAN JACKSON: Mr. Siegel, you may proceed.

19 DR. SIEGEL: Good afternoon. Let me begin by very  
20 briefly introducing the members of the ACMUI to you.

21 Beginning on my right is Mr. John Graham, who is a  
22 hospital administrator from St. Mary Hospital, part of the  
23 Beaumont System in Michigan.

24 Next, Dennis Swanson, a radio pharmacist from the  
25 University of Pittsburgh.

1 Dr. Daniel Flynn, a radiation oncologist, part at  
2 Mass General and part at Holy Family Hospital in  
3 Massachusetts.

4 Ms. Judith Brown, patient rights and care  
5 advocate.

6 Dr. Judith Stitt, a radiation oncologist from the  
7 University of Wisconsin and chairperson elect of this  
8 committee to succeed me.

9 Mr. Robert Quillin, Director of the Division of  
10 Radiation Control in the State of Colorado, and I guess  
11 chairman elect of the Organization of the Agreement States.

12 Dr. Jeffrey Williamson, a radiation oncology  
13 physicist from Washington University in Saint Louis.

14 Dr. Louis Wagner, a medical physicist from the  
15 University of Texas in Houston.

16 Theresa Walkup, radiation oncology dosimetrist  
17 from Mercy Hospital in Oklahoma City.

18 And Dr. George Mills, a nuclear medicine physician  
19 who is in the Center for Biologics Evaluation and Research  
20 at the Food and Drug Administration.

21 CHAIRMAN JACKSON: Would you tell me how you hope  
22 to structure your part of the discussion this afternoon?

23 DR. SIEGEL: I am going to make an initial part of  
24 the presentation with slides. I know you will interrupt as  
25 you see fit, and that is perfectly fine.

1           CHAIRMAN JACKSON: We will try to control  
2 ourselves.

3           [Laughter.]

4           DR. SIEGEL: Then Mr. Quillin is going to show one  
5 slide after I finish mine, and Dr. Williamson is going to  
6 show a few slides thereafter. Wherever Professor Adler fits  
7 in logically is fine with us.

8           If I can have the first slide, please.

9           [Slide.]

10          DR. SIEGEL: I want to begin by saying that the  
11 ACMUI did not attempt in its analysis of this situation to  
12 recreate its own version of an IOM report. We didn't  
13 believe that was our charge. Moreover, we didn't really  
14 have the time to do so. Rather, what we have done is  
15 reacted to the report to feed into your own internal process  
16 of analysis of the report. So in a way it's either an  
17 agreement or a disagreement with various components of the  
18 report, and we will try to articulate our reasons for so  
19 doing.

20          We approached the process with some apprehension,  
21 because we felt that second-guessing an expert committee of  
22 the Institute of Medicine was perhaps a thankless job, but  
23 on the other hand, I think we felt reasonably comfortable  
24 that our accumulated experience as your experts and, for  
25 many of us, terms on this committee of nearly six years gave

1 us a substantial insight into the problems that the IOM  
2 addressed and in fact many of the things that the IOM said  
3 are things that we have said repetitively at our meetings  
4 and have said in prior briefings of the Commission.

5 If I can have the next slide, please.

6 [Slide.]

7 DR. SIEGEL: In general, I think the ACMUI comes  
8 down as being in agreement with the principles that underlie  
9 the IOM report. As you will see, we differ primarily with  
10 regard to some mechanistic details.

11 The IOM advice, as I just said a moment ago, is  
12 really quite similar overall to the advice that the ACMUI  
13 has been giving the Commission for the last six years. I  
14 used the word "complicity" in this slide, but the fact that  
15 we have participated in rules and helping you formulate  
16 those rules doesn't mean we agreed that those rules were  
17 necessary. In a way, we were doing damage control to try to  
18 make the rules as acceptable as reasonably achievable  
19 through our input even though we frankly often thought the  
20 rules were not needed at all.

21 Next slide, please.

22 [Slide.]

23 DR. SIEGEL: Over the course of the last six years  
24 we have developed in our discussions several principles that  
25 we believe should guide the regulatory reform relating to

1 medical radiation use and presented some of these in part at  
2 the last Commission briefing. Let me briefly go through  
3 them.

4 First, it is an established fact that the NRC's  
5 responsibility for byproduct radioactive material use in  
6 medicine really is only a small fraction of all radiation  
7 use in medicine. As you know, the IOM report quotes 10  
8 percent. I think at our last briefing we estimated that,  
9 depending on how you cook the numbers, it might be as little  
10 as 3 percent. So there is some concern that the tail is  
11 wagging the dog. Therefore, wanting to have a broader  
12 picture is certainly appropriate, and that is exactly what  
13 the IOM was charged with looking at.

14 Second, we have held all along that the risks of  
15 medical use of ionizing radiation from byproduct material  
16 are absolutely identical to those from other sources of  
17 ionizing radiation used in medicine, and this regulatory  
18 scheme is an anomaly created by the Atomic Energy Act. I  
19 think we all recognize that.

20 CHAIRMAN JACKSON: Let me stop you. I said I  
21 would try to control myself, and I will. As you go along,  
22 it would be helpful, particularly relative to the second  
23 bullet, if you could talk about databases that exist that  
24 would help support or not the conclusion that the relative  
25 risks are all the same.

1 DR. SIEGEL: I can't cite a specific database at  
2 the moment. We have talked at many committee meetings about  
3 the kinds of events that have occurred with accelerator  
4 produced teletherapy versus the kind of things that occur  
5 with cobalt 60 teletherapy, and the expert opinion of the  
6 practitioners on the committee is that the problems are  
7 essentially identical.

8 CHAIRMAN JACKSON: But a database does exist?

9 DR. SIEGEL: I think a database exists that is as  
10 good as the database that is available for regulating  
11 byproduct material. I think the medical literature has  
12 information in it about the frequency of certain types of  
13 events. I didn't bring it with me, but there is a very  
14 comprehensive study conducted by the School of Public Health  
15 at Harvard that looks at errors in medicine and looks at the  
16 implications for malpractice from those errors.

17 CHAIRMAN JACKSON: Relative to this particular  
18 area?

19 DR. SIEGEL: There is a reference in that report  
20 to the frequency of events.

21 CHAIRMAN JACKSON: If you could provide that to  
22 the Commission, it would be helpful.

23 DR. SIEGEL: I could. There is actually a series  
24 of articles in a book, and I can get you those references.

25 Next slide, please.

1 [Slide.]

2 DR. SIEGEL: I know some data has been presented  
3 to the Commission in the past. We also believe that the  
4 risks to the public, to workers and to patients from the  
5 medical uses of ionizing radiation are really quite similar  
6 to the risks encountered during the daily provision of  
7 medical care in other ways. Just a few examples.

8 The risks to workers from being around byproduct  
9 material in a way pale in comparison to the risks from  
10 needle sticks and transmission of HIV and hepatitis viruses;  
11 the environmental risks from working in an area where  
12 chemotherapy agents are being prepared for injection; known  
13 carcinogens require tight environmental airborne control  
14 very similar to working with potentially airborne  
15 radionuclides.

16 The risks to the general public are also similar.  
17 You can think in terms of the problems that uncontrolled,  
18 unregulated use of antibiotics in the practice of medicine  
19 have created by creating multi-drug resistant bacteria that  
20 have caused and have the potential to cause serious  
21 epidemics in our country.

22 When we look at the frequency of events related to  
23 radiation use in medicine and compare them with the kinds of  
24 problems that we see in the rest of medicine, we are really  
25 struck not by the problem but by the remarkable safety

1 record of radiation use in medicine.

2 COMMISSIONER ROGERS: Let me just stop you there,  
3 though.

4 DR. SIEGEL: Yes, sir.

5 COMMISSIONER ROGERS: That isn't what this  
6 statement says. This says they are similar.

7 DR. SIEGEL: The risks are similar.

8 COMMISSIONER ROGERS: I thought what you just  
9 finished saying is they are a lot less with the nuclear  
10 medicine than many other fields of medicine.

11 DR. SIEGEL: Correct. For nuclear medicine the  
12 risks are less. For radiation oncology the risks are  
13 similar.

14 COMMISSIONER ROGERS: I think there is a point  
15 here, and that is this. Whether we are making a statement  
16 of fact or a statement of should be, there is a difference.  
17 If in fact the risks from the uses of ionizing radiation are  
18 a lot less than risks from other medical practices, then  
19 this doesn't quite fit. One might interpret it that  
20 therefore perhaps we have margin for increasing the risk  
21 from the use of ionizing radiation because it's already a  
22 lot lower than other areas of medical practice.

23 This is supposed to be a statement of principles.  
24 If it's a statement of principles, then those are some  
25 guides rather than simply statements of fact. If this is

1 simply a statement of fact that, well, they're all about the  
2 same, that is one thing, but if it's a statement that  
3 regardless of whether in fact the current situation is that  
4 the uses of ionizing radiation are a lot less risky than  
5 other medical practices, if you interpret that as a should  
6 be, that's a statement that one might relax with respect to  
7 safety concerns with respect to ionizing radiation.

8 I think there is an important point here as to  
9 really what you are talking about.

10 DR. SIEGEL: I think the quantitative data  
11 available to fine tune that question to the extent you are  
12 trying to get me to fine tune it probably are not available.

13 COMMISSIONER ROGERS: It's a question of what you  
14 have in mind.

15 DR. SIEGEL: I can conceive of circumstances where  
16 nuclear medicine uses can be as risky as uses of other types  
17 of therapy. The vast majority of practices in nuclear  
18 medicine are really exceedingly low risk. In radiation  
19 oncology the potential for harm is considerably greater and  
20 similar to the kinds of risks that one encounters with  
21 general anesthesia, the kinds of risks one encounters with  
22 surgery.

23 I think you can't lump all of radiation medicine  
24 together under a single umbrella. Bad metaphor. I  
25 apologize. But overall there is nothing about the use of

1 ionizing radiation in medicine, and more specifically, the  
2 use of byproduct material in medicine, that would warrant,  
3 in our opinion, a regulatory structure for its use that is  
4 many degrees more stringent than the use of surgery,  
5 anesthesia, antibiotics, other types of drugs, and the  
6 general practice of medicine. As you well know, that has  
7 been an overarching concern that the ACMUI has expressed on  
8 many occasions.

9 COMMISSIONER ROGERS: I know it is, and I know  
10 that is an issue here. That is why I am bringing it out,  
11 because I think there is a point here that has to be  
12 understood as to what your point of view is.

13 I don't want to hold everything up in our  
14 discussion here today on this particular point, but I think  
15 there is a point and I think it ought to be sharpened up,  
16 and that is whether in fact because for most uses of  
17 ionizing radiation in medicine the risk is a lot less than  
18 other areas that one then could interpret this as room for a  
19 degree of less concern and therefore less regulation.

20 DR. SIEGEL: We agree completely.

21 COMMISSIONER ROGERS: I think it would be good if  
22 you said it that way then. Then I think there is an issue  
23 that one can debate.

24 DR. SIEGEL: It is more difficult to say it that  
25 explicitly, because I think we all agree that the database

1 is not as good as we would like it to be. In our  
2 unequivocal expert opinion as practicing physicians and  
3 others aligned with health care, we can tell you that the  
4 risks are no worse, and therefore the regulatory scheme that  
5 is in place that is clearly more onerous does not appear to  
6 us justified.

7           Which is what I've just said in the next bullet.  
8 This clearly is a matter of opinion, because we haven't  
9 asked everybody, but I think it is safe to say that the  
10 regulated community, most of the members on this committee,  
11 view the NRC's medical use program as intrusive to the  
12 practice of medicine, burdensome in terms of the  
13 prescriptive and recordkeeping requirements, and not  
14 justified by proper cost-benefit analyses that really link  
15 it to the level of risk.

16           That's a problem, because the failure to have  
17 buy-in by the regulated community, which in this case is  
18 very limited, leads to a regulatory environment that you  
19 know better than we is not an optimal one. Whether this is  
20 tied in every case specifically to the regulations  
21 themselves or to the way those regulations are enforced is  
22 also an issue that is potentially open to some discussion.

23           CHAIRMAN JACKSON: Will you be addressing that  
24 distinction?

25           DR. SIEGEL: To some extent.

1 CHAIRMAN JACKSON: I think that's an important  
2 distinction to be addressed.

3 DR. SIEGEL: Correct. To some extent.

4 Next slide, please.

5 [Slide.]

6 CHAIRMAN JACKSON: Let me say the following. You  
7 might think about it in real time, doing some parallel  
8 processing as you go along, because in the end I think it  
9 has to be squarely addressed.

10 DR. SIEGEL: I will try. Maybe the committee will  
11 think in parallel process while I'm talking. I'm pretty  
12 good at multitasking but not necessarily while I'm making a  
13 presentation.

14 CHAIRMAN JACKSON: I have to do it all the time.

15 [Laughter.]

16 DR. SIEGEL: I know. I do if I get a chance to  
17 pause, and I will.

18 Based on the foregoing principles, I think this  
19 committee believes that the regulation of medical uses of  
20 ionizing radiation certainly should be uniform, rationally  
21 based on risk, and shouldn't be tied to the source of the  
22 radiation. Back to the anomaly of the Atomic Energy Act.

23 The committee also has said several times before  
24 that we think the responsibility for regulation of medical  
25 use of ionizing radiation should rest with an entity that

1 deals with medicine as its business rather than with the  
2 narrower focus of just radiation as its business. The  
3 primary reason for that is simply because then those risks  
4 can be looked at relative to all other medical risks with a  
5 higher level of expertise and, moreover, within an  
6 understanding of the constraints on the costs of delivering  
7 health care in the United States, which the NRC has no  
8 obligation to pay attention to. I'm sure you do, but you  
9 are not obligated to. The Department of Health and Human  
10 Services is indeed obligated to.

11 Next slide, please.

12 [Slide.]

13 DR. SIEGEL: The next series of slides include  
14 text in italics that represent the IOM recommendations and  
15 in Roman face our reaction to the IOM recommendations.

16 The IOM preferred alternative, as you know, was  
17 what they labeled Alternative D, which was a system  
18 essentially run by the states but with federal guidance of  
19 varying degrees.

20 When we discussed this in depth at our last  
21 meeting, we probably would characterize ourselves as more  
22 Hamiltonian than the IOM Committee. They were far more  
23 Jeffersonian.

24 We believe that a greater level of federal  
25 oversight of state programs is necessary, with some

1 mechanism, for example linkage to Medicare reimbursement ala  
2 the Mammography Quality Standards Act and the way that has  
3 been implemented, to ensure two things.

4 One, that states and users will comply, because we  
5 share your concerns. We don't believe in a completely  
6 unregulated system. And to ensure that there will be  
7 greater uniformity of state programs.

8 We are indeed concerned that some states will have  
9 very little incentive to put a significant program in place  
10 and are just as concerned that some states will put a  
11 Draconian program in place, and we think that the  
12 practitioners of the United States ought to be able to  
13 experience a more or less level playing field.

14 Next slide.

15 [Slide.]

16 DR. SIEGEL: IOM Recommendation A1 recommends to  
17 Congress that it eliminate all aspects of your medical use  
18 program.

19 ACMUI effectively agrees with this recommendation  
20 insofar as we think that the responsibility should be  
21 transferred to DHHS, but we entirely recognize, and are not  
22 prepared to propose a mechanism, how complicated this will  
23 be for Congress to achieve, how much reluctance there will  
24 be to do this, but in an ideal world we would entirely agree  
25 that this is what we would recommend as well.

1 Next slide.

2 [Slide.]

3 DR. SIEGEL: IOM Recommendation A2 says that  
4 Congress should direct the Secretary to do a variety of  
5 activities. If you can just quickly go through slides 9 and  
6 10 as well.

7 [Slides.]

8 DR. SIEGEL: These are encouraging activities of  
9 the CRCPD and encouraging the suggested state regulations,  
10 and then a variety of other things to help the states.

11 We can now skip over to slide 11.

12 [Slide.]

13 DR. SIEGEL: Basically, because of the fact that  
14 the ACMUI believes in a more direct level of federal  
15 oversight than the IOM did, we don't wholly endorse  
16 Recommendation A2 but believe that DHHS' activities, if they  
17 were to get this responsibility, should encompass items (c)  
18 through (h) of the IOM report. We are essentially not  
19 endorsing items (a) and (b) because we are not putting as  
20 much faith in the CRCBD and the suggested state regulations  
21 as the mechanism for creating the regulatory structure.

22 Next slide.

23 [Slide.]

24 DR. SIEGEL: One of the reasons we take this  
25 approach in part is because we think that a centralized

1 authority for rulemaking is more likely to achieve this  
2 goal. We mentioned a moment ago that some states have  
3 inadequate rules and other states have excessively  
4 burdensome rules. We also had a concern, based on what we  
5 were able to learn and what our agreement state members on  
6 the committee could tell us, about the effectiveness of the  
7 CRCPD and the openness of the CRCPD as a mechanism for  
8 developing regulations since it is not subject to the  
9 Administrative Procedure Act, and then the processes in the  
10 50 states to adopt those regulations are variably subject to  
11 different levels of public scrutiny. We just felt  
12 uncomfortable that this was an efficient mechanism for  
13 achieving a level of uniformity that we believe is  
14 important.

15 COMMISSIONER DICUS: I want to step in here with a  
16 question. The issue here with the second bullet, I think  
17 it's something that I brought up in a previous briefing, the  
18 fact that there is a great deal of variability now in  
19 programs. What I really want to address is the top bullet  
20 together with some other statements that related to it.

21 Is it fair to say that what you are basically  
22 saying the outcome of the recommendation might be to prevent  
23 state programs from having some flexibility? Is that going  
24 to be an outcome of this?

25 DR. SIEGEL: I don't want to make any

1 constitutional law comments because I'm not a constitutional  
2 lawyer. I'm a physician. I don't think we would want  
3 flexibility done away with entirely. I think the ability to  
4 be creative and innovative makes sense. I think we  
5 certainly would like to achieve at least some level of  
6 uniformity. We certainly would not want 50 different  
7 versions of Part 20. That would be disruptive. We  
8 certainly would not want widely diverging versions of Part  
9 35. We think some level of uniformity is appropriate. We  
10 recognize that local needs still dictate the ability to have  
11 local variation.

12 That is sort of an ambiguous answer, but I think  
13 it reflects properly the sense of the committee. If I read  
14 the committee correctly, and I think I did, at our last  
15 meeting there were concerns on both ends of the pole, that  
16 some states just wouldn't do the job at all and that other  
17 states would get carried away.

18 We believe, as a later slide points out, that if  
19 you get the best minds together in a central place along  
20 with the best advisory committee in a central place, you  
21 have a better chance of achieving the right balance than if  
22 you let 50 states go off and do it on their own.

23 CHAIRMAN JACKSON: Have you received any feedback  
24 or input from the states themselves relative to their  
25 willingness or ability to take on the added responsibilities

1 implied in this?

2 DR. SIEGEL: We certainly have had feedback from  
3 Mr. Quillin.

4 CHAIRMAN JACKSON: I know you have. I am sure  
5 Mr. Quillin has heard me raise this kind of question before.  
6 I think we kind of left it on the table before. Any kind of  
7 comprehensive input.

8 DR. SIEGEL: No, and we don't feel that we were  
9 charged with the responsibility of surveying the states. We  
10 have seen the summary comments, that quick summary that  
11 Dr. Holahan put together recently, and are not at all  
12 surprised by the diversity of the comments and the  
13 reluctance of many states to want anything to do with the  
14 responsibility the IOM wish to give it. In a way, that was  
15 much our concern as well.

16 Next slide, please.

17 [Slide.]

18 DR. SIEGEL: IOM Recommendation B1 says the NRC  
19 should immediately relax the provisions relating to the  
20 quality management program and misadministration reporting.

21 ACMUI concurs with that, and in fact we think the  
22 IOM is echoing something we have been saying for a number of  
23 years. We officially went on record to recommend that the  
24 NRC not promulgate the quality management rule. We have  
25 discussed with the Commission on several occasions our grave

1 concerns with the way misadministration reporting is  
2 undertaken, its perceived purposes, and the patient  
3 notification requirements.

4 Next slide.

5 [Slide.]

6 DR. SIEGEL: That highlights the point I just  
7 made, namely, that we see that interface as most severely  
8 intruding into the practice of medicine and getting beyond  
9 the third medical policy statement.

10 Next slide.

11 [Slide.]

12 DR. SIEGEL: Regarding IOM Recommendation B2, that  
13 you all initiate formal steps under the APA to revoke Part  
14 35 if Congress doesn't act, we weren't quite so sanguine as  
15 the IOM that that would happen.

16 [Slide.]

17 DR. SIEGEL: We were skeptical that you could do  
18 that legally, or that you would do that. We thought  
19 therefore if the full force of the IOM recommendations were  
20 to go down that it really was going to require congressional  
21 action.

22 I want to emphasize this point, that if Congress  
23 does not act, we are prepared to help you all rebuild Part  
24 35 from the ground up by a thorough and critical assessment  
25 of the risks of medical use of ionizing radiation in order

1 to help you determine what level of regulation is necessary.

2 I know that it has been on your agenda to re-look  
3 at Part 35 for sometime. I also know that you intend to  
4 have us in the loop. I just wish to emphasize how very much  
5 we want to be in the loop right from the beginning and  
6 really help you accomplish this job, if that is what it  
7 comes to as part of this overall activity.

8 Next slide, please.

9 [Slide.]

10 DR. SIEGEL: In that regard, if you retain your  
11 current statutory authority, we think the following points  
12 regarding Part 35 are essential.

13 As we have discussed on many, many occasions,  
14 training and experience for medical authorized users needs  
15 to be completely reevaluated, to get you out of the turf war  
16 if nothing else. We have generally focused in the past on  
17 radiation safety to the general public and workers as the  
18 primary focus for training experience, but I think this is a  
19 wide open issue that should be thoroughly debated publicly  
20 and thoroughly reviewed by you all and by the ACMUI.

21 As just stated, that the quality management rule  
22 be eliminated.

23 We also think that the procedural components of  
24 ALARA probably should be eliminated. We agree with the  
25 philosophy of ALARA but frankly in medical institutions find

1 that ALARA becomes a mechanism to lower the maximum  
2 permissible doses by a factor of ten, generates large  
3 amounts of paperwork and very little actual improvement in  
4 the long run. So although we subscribe to the principle, we  
5 think that the approach that is built into the license  
6 conditions should be substantially lightened up.

7 COMMISSIONER ROGERS: Before you leave that slide,  
8 could you say a few words on what you really have in mind  
9 when you say "while continuing to encourage these  
10 principles"? How does a regulator encourage?

11 DR. SIEGEL: I'm not exactly sure how you convert  
12 that into regulatory language. You build it into the  
13 overall safety program.

14 Which should we talk about, ALARA?

15 COMMISSIONER ROGERS: ALARA is the one I'd be  
16 happy to focus on, because I think that is a terribly  
17 important concept. Pick either one if you want. What do  
18 you really have in mind when you suggest that a regulatory  
19 agency should continue to encourage these principles? That  
20 is something we have to wrestle with all the time. We are  
21 very good at discouraging; we are not very good at  
22 encouraging. We don't have much to offer. How do we  
23 encourage?

24 DR. SIEGEL: This may get back to a point we made  
25 at a briefing some years ago, Commissioner Rogers, where we

1 talked about -- and this will get to your question to some  
2 extent -- the issue of whether you ensure quality by  
3 inspection and enforcement and thereby impose the burdens of  
4 excessive recordkeeping and highly prescriptive procedures  
5 on the good actors as well as the bad actors, or whether you  
6 develop a regulatory schema that has a substantial  
7 educational component to try to raise the level of  
8 performance of the bad actors while letting the good actors  
9 continue to do the good job by the mechanism they have  
10 crafted.

11 Our general perception is that the NRC's  
12 regulatory schema, although wanting to subscribe to the  
13 second idea, doesn't come out that way in practice. There  
14 is excessive attention to the paper trail and to minutia,  
15 and the people who really run excellent programs and who  
16 could do with substantial less of a paper trail and much  
17 less effort than NRC regulations require are forced to adopt  
18 those practices because you all felt that they were  
19 necessary for the bad actors.

20 I think there is a way to encourage ALARA  
21 principles and encourage quality management, which we will  
22 all tell you that we are stuck with as part of our medical  
23 practices by the JCAHO and by our own hospital managers.  
24 Quality management also relates to cost reduction now in the  
25 total health care environment and being able to compete

1 effectively for the managed care dollar. We have to prove  
2 that we have got quality and that we have good outcomes.

3 This is built into medicine. I do think that  
4 there are ways to do it, without being able to give you  
5 exact details right now, by educating and elevating rather  
6 than by pushing us all down to a common level.

7 COMMISSIONER ROGERS: I don't want to belabor the  
8 point, but ALARA is one of the tools which we found we can  
9 use to help to move us away from a more prescriptive  
10 approach in our regulatory activities in other areas. That  
11 is why I focused my attention on your view that you want to  
12 eliminate ALARA and you also want us to be less  
13 prescriptive, and to me those are not necessarily consistent  
14 positions. But it depends on what you have in mind.

15 DR. SIEGEL: Lou, did you have a comment?

16 MR. WAGNER: I have a question for Commissioner  
17 Rogers. You made a very interesting statement. Could you  
18 give us some examples of how you found that principle to  
19 help reduce the regulatory burden through ALARA?

20 COMMISSIONER ROGERS: Yes, because it says that  
21 the interpretation of how to get as low as reasonably  
22 achievable will be determined by each individual licensee as  
23 they try to get there. I'm speaking more from my own point  
24 of view. It is not necessarily exactly how things work at  
25 the Commission. My own point of view has been that by use

1 of the ALARA concept one asks a licensee to develop a  
2 program to achieve as low as reasonably achievable, but you  
3 do not hold them accountable for a particular end point  
4 result. They do the best they can and they demonstrate to  
5 you that they have a reasonable approach to trying to do  
6 that. Licensee A and licensee B may wind up at very  
7 different end points but still have reasonable programs for  
8 doing the best they can that take us well below what we  
9 would necessarily require as a regulatory limit for  
10 everybody.

11 We certainly have seen that with respect to  
12 nuclear reactors. There is no question that the air  
13 emissions from nuclear reactors are far below what we would  
14 have put in place after much argumentation and debate as a  
15 requirement. Allowing licensees to do the very best they  
16 can has allowed those emissions to be driven much lower than  
17 we probably would have achieved if we had a requirement.

18 MR. WAGNER: I guess I would question if you have  
19 any examples in medicine where this is the case. I think if  
20 you look at most of the badge reports from all the  
21 facilities and all the people who work in our facilities,  
22 the people who work with radiation in medicine for the most  
23 part have very low readings, always well below the 1/10th  
24 limit.

25 I don't see how imposing ALARA as a regulation

1 improves on the fact that we already have such a low limit.  
2 What it does to us is it makes us write prescriptive rules  
3 for ourselves delineating what we are going to do in order  
4 to achieve ALARA, and if we don't do something that is  
5 written in those rules, when we get inspected we are cited  
6 for not doing that.

7 COMMISSIONER ROGERS: I'm not going to respond.  
8 I'm just going to say okay.

9 MR. SWANSON: Barry.

10 DR. SIEGEL: Yes, Dennis.

11 MR. SWANSON: If I may make a comment. You asked  
12 how you can encourage a principle such as ALARA. The NRC is  
13 in a fortunate position that you see multiple programs. I  
14 am certain that you see good programs that are doing good  
15 things to achieve ALARA concepts. It has always been  
16 interesting to me that the NRC very readily publishes the  
17 names and problems that they identify but they never publish  
18 and identify the people that are doing good things. One way  
19 that you could very much encourage ALARA principles is to  
20 share those good concepts with us.

21 CHAIRMAN JACKSON: I think that the NRC does have  
22 a mechanism, and again it's operative more in reactor space  
23 than it traditionally has been in the space you represent,  
24 of endorsing standards or methodologies for doing things as  
25 opposed to broadly promulgating good practices. That is

1 something I think we feel is best left to those who are  
2 practitioners, but I think there are enabling mechanisms. I  
3 don't know at this point the extent to which they are  
4 operative in this arena, but I don't know that we are going  
5 to promulgate good practices, that these are the good guys  
6 and these are the bad guys.

7 DR. SIEGEL: Next slide.

8 [Slide.]

9 DR. SIEGEL: Continuing in this theme of Part 35,  
10 we think your event reporting requirements should be revised  
11 and in fact would actually encourage lowering some of the  
12 thresholds for reporting. We really share with you a belief  
13 in the need for legitimate data gathering so that you can  
14 build a database, because we think the centralized national  
15 perspective is the best way to have an early warning system  
16 that something is going wrong, and individual facilities,  
17 even individual states are going to have a much more  
18 difficult time achieving that.

19 What we want is to have that kind of reporting  
20 uncoupled from the kind of bad vibes that the regulated  
21 community has from the current misadministration rule and  
22 the patient notification and the reporting there that  
23 typically results in rapid inspection, punitive action, and  
24 in fact we believe potentially discourages reporting,  
25 potentially could lead to problems. We think this should be

1 as open a system as possible to maximize the flow of  
2 information to the NRC or to the DHHS or whoever it is who  
3 has this responsibility.

4 We also think if we were to help you rebuild Part  
5 35 that most of the requirements, or many of the  
6 requirements, relating to diagnostic nuclear medicine would  
7 simply evaporate. Molybdenum checks on technician  
8 generators at least daily, or every elution checks, are a  
9 holdover from technology that long since has bypassed that  
10 rule; remeasuring doses in dose calibrators that have  
11 already been measured at a commercial radio pharmacy. There  
12 are rules that make work that don't add to safety. I think  
13 we could help you analyze those.

14 CHAIRMAN JACKSON: Why do you feel that patient  
15 notification requirements should be eliminated?

16 DR. SIEGEL: Because we feel that the NRC turns a  
17 medical event that is already handled adequately by  
18 professional standards into one that becomes inherently  
19 legalistic. I think it was the last briefing we did where  
20 we discussed that at great length. It takes a relatively  
21 straightforward medical situation where a bad event has  
22 occurred and where in fact the standard of care is to inform  
23 the patient and now turns it into a situation where the NRC  
24 gets in the loop, and all of a sudden it becomes an arm's  
25 length interaction with the NRC and with the patient, and

1 frankly that kind of adversarial attitude that creeps into  
2 these events messes them up medically.

3 Next slide.

4 [Slide.]

5 DR. SIEGEL: IOM Recommendation B3. We agree that  
6 this is logical. We don't think that the NRC regulated  
7 states should be bearing the total cost of paying for the  
8 regulations that are shared by the agreement states. I know  
9 when the IOM briefed you you raised concern about how you  
10 were going to charge the agreement states for that. I  
11 haven't got a clue.

12 CHAIRMAN JACKSON: We don't either.

13 DR. SIEGEL: I know. Maybe Congress will have a  
14 mechanism for figuring out how it should be done.

15 Next slide.

16 [Slide.]

17 DR. SIEGEL: Recommendations C1 and C2 related to  
18 the CRCPD incorporating Part 35 and that all the state  
19 legislatures do their thing to create these regulations.

20 [Slide.]

21 DR. SIEGEL: The next slide indicates that because  
22 of the fact that we favor a more directly managed federal  
23 approach than the IOM did that we don't really subscribe to  
24 Recommendations C1 and C2, and also, since we don't think  
25 that Part 35 is right as rain right now, we wouldn't want to

1 transfer it wholesale to the suggested state regulations.  
2 We think it needs to be rebuilt from scratch.

3 Next slide.

4 [Slide.]

5 DR. SIEGEL: This is kind of an apple pie and  
6 motherhood recommendation about using good science, and it's  
7 pretty hard to argue with using good science to formulate  
8 regulations.

9 [Slide.]

10 DR. SIEGEL: Our only concern here is that we  
11 think it should be centralized for the reason already  
12 stated. The chances you can get the right people together  
13 in the room to do the job and the chance that you can get  
14 the right advisory committee together are probably best at  
15 the federal level. The active input by the regulated  
16 community seems to work better, in most of our opinions, at  
17 the federal level than at the state level. Those are the  
18 primary reasons for that.

19 At this point let me stop speaking for a moment  
20 and let Mr. Quillin say a few words about the states'  
21 perspective, and then when he is done, Dr. Williamson is  
22 going to say a few words about approaches to building a new  
23 medical use regulatory program.

24 I should point out that Dr. Williamson, who is a  
25 new member of the committee -- in fact, I think he just

1 became official this week -- has had substantial experience  
2 working with professional organizations in crafting practice  
3 standards in radiation oncology. So I felt he was uniquely  
4 qualified to make these recommendations.

5           Although we discussed many of these  
6 recommendations at our last meeting, we have not achieved a  
7 complete committee consensus on the points he will make. So  
8 some of them represent his own opinions, and perhaps he can  
9 identify some of those as he goes.

10           Bob is next.

11           MR. QUILLIN: Can I have the next slide, please.

12           [Slide.]

13           MR. QUILLIN: I just wanted to make a few comments  
14 and I want to predicate it by saying I'm not here as a  
15 representative of the CRCPD or the Organization of Agreement  
16 States. I am not speaking for those organizations today but  
17 as a member of this committee.

18           The IOM report made certain assumptions. One  
19 assumption was that states would be either an agreement  
20 state or whatever they would be called under this HHS  
21 umbrella. As data has already shown in the review of the  
22 report, four states have written in and indicated that they  
23 cannot or will not, unless they add more carrots, take on  
24 this kind of responsibility. So there is real problem with  
25 the hypothesis that all states will willingly accept this

1 responsibility.

2           The second item was that the CRCPD would take a  
3 much greater rôle in coordinating the states in developing  
4 and passing regulations or suggested regulations.

5           The CRCPD has a number of strengths and it has a  
6 number of weaknesses. It's a great consensus building  
7 organization. It is also, as many organizations are right  
8 now, suffering financial problems. The Food and Drug  
9 Administration, as I understand it, is cutting back their  
10 financial support for the organization. So the CRCPD has  
11 some fundamental problems that it has to face as to how to  
12 continue its operations under a reduced budgetary situation.

13           Finally, as has been mentioned previously, states  
14 are always going to be independent one way or another.  
15 Sometimes that's good and sometimes that's not good. They  
16 are innovative in many ways, but they will express their  
17 independence. That has to be assumed. I think there was a  
18 perspective in the IOM report that states would sort of  
19 willingly go along with the standardized program on a  
20 national basis. States are going to be different. They  
21 will not necessarily accept this responsibility. Even if  
22 they do accept the responsibility, there are going to be  
23 differences from state to state.

24           CHAIRMAN JACKSON: Thank you.

25           MR. WILLIAMSON: Like Mr. Quillin, I guess I would

1 like to say that these also represent my views as a  
2 committee member and not any of the other organizations that  
3 I am involved with.

4 I guess what I would like to do is outline some  
5 basic elements of an alterative regulatory paradigm.

6 Slide 25, please.

7 [Slide.]

8 MR. WILLIAMSON: I guess there are three parts.  
9 One, if you are going to start over and rebuild Part 35.  
10 Whether or not is in this agency or some other, I think  
11 maybe there are three elements to look at.

12 One is to assess what is the essential purpose or  
13 goals.

14 I think the second is to identify what are the  
15 essential practice standards that are to be promulgated by  
16 the system.

17 The third, of course, and perhaps the most  
18 troubling aspect of the existing system, is to come up with  
19 an enforcement process that works to achieve the goals.

20 I think this proposal could actually have a very  
21 positive benefit for the entire field of radiation medicine  
22 and avoid some of the criticisms that many of us make in the  
23 regulated community, namely, that the existing system is  
24 intrusive, expensive, and may be only marginally effective  
25 from our point of view.

1           Could I have the next slide, please.

2           [Slide.]

3           MR. WILLIAMSON: I would submit to you that a  
4 reasonable goal is promotion of professional practice  
5 standards defined and selected by the regulated community as  
6 essential to good practice of radiation medicine. This view  
7 assumes that most radiation medicine is practiced at an  
8 adequate level of quality and safety already and that the  
9 principal task of the regulatory system is to go after the  
10 bad apples, that small fraction of practitioners located  
11 down in the lower end of the quality spectrum, and bring  
12 them closer to the mean.

13           Hopefully a new system would be erected that will  
14 minimize the burden of those meeting the standards and I  
15 think exploit the quality improvement mechanisms that have  
16 already been so successful in promoting safe and quality  
17 health care delivery within our respective subspecialties.

18           CHAIRMAN JACKSON: Let me stop you for a minute.  
19 You talk about the use of standards as defined by the  
20 regulatory community. The regulatory community has  
21 different organizations that represent the interests of that  
22 community. Those organization that represent those  
23 interests can have different views of what are appropriate  
24 standards. How does one then bring those differences into a  
25 regulatory framework that makes sense?

1 MR. WILLIAMSON: I was going to make a suggestion.  
2 If we can go to slide 28.

3 [Slide.]

4 MR. WILLIAMSON: My definition really devolves to  
5 the selection. It basically amounts to developing an  
6 inventory of what are essential practice standards and then  
7 making a decision which of those are to be incorporated in a  
8 regulatory framework and which are best left outside.

9 My proposal would be to develop a collaboration  
10 and assemble representatives of the various involved groups  
11 who are deeply involved already in articulating and  
12 promoting standards of practice -- I have listed some of the  
13 organizations up here -- and see if a consensus within each  
14 of these subspecialties can be built. These are the people  
15 that really understand the sort of quality assurance glue  
16 that holds the field together.

17 I think this would be an opportunity to get a  
18 level of expertise and create a not only practical but  
19 useful vehicle for promoting quality. I think if somebody  
20 standing outside does it, they are less likely to appreciate  
21 the dynamics that really drive it.

22 DR. SIEGEL: One might imagine something like an  
23 NIH consensus development conference serving as the  
24 mechanism to develop an expert opinion on what constitutes a  
25 set of standards for performing brachytherapy safely. That

1 mechanism that NIH has used repetitively is highly effective  
2 for coming up very quickly with a set of recommendations  
3 about what is the standard of care at the present time, what  
4 are the unanswered questions, where do we need more data. I  
5 think that is an approach that NRC might consider using in  
6 the future.

7 CHAIRMAN JACKSON: One aspect of the way NRC and  
8 regulatory bodies develop regulations has to do with input  
9 from the various affected parties, including the regulated  
10 community. This approach seems to suggest a primacy of the  
11 perspectives of the regulated community relative to perhaps  
12 other stakeholders. Can you give me some sense of the  
13 rationale and the justification for that?

14 MR. WILLIAMSON: I will certainly try. Yes, I  
15 certainly am endorsing a larger role for the regulated  
16 community in developing standards.

17 CHAIRMAN JACKSON: It's not so much the  
18 development of them but having them be the embodiment of the  
19 regulatory framework. That's really what I'm talking about.

20 MR. WILLIAMSON: You want the regulatory framework  
21 to be effective, I assume, and to really promote patient  
22 quality. When you get into the area of quality of health  
23 care delivery, I think as regulators and nuclear reactor  
24 experts and health physicists, you have kind of gone beyond  
25 the purview of your expertise and ability to do this well.

1           I guess what I am saying is, if you want a system,  
2 especially in the area of technical quality assurance  
3 standards and clinical quality assurance standards, if we  
4 get into that, it would be well to have more involvement of  
5 that community.

6           CHAIRMAN JACKSON: Are you saying that those who  
7 are regulated should set the standards by which they are  
8 regulated?

9           MR. WILLIAMSON: Essentially, yes. I am saying  
10 that is the way to build upon the mechanisms that already  
11 have resulted in a high level of quality.

12          DR. SIEGEL: In general, I think it's safe to say  
13 that NRC regulations in this area have lagged behind  
14 standards of care that were already put in place with new  
15 technologies by the professional organizations that  
16 recognize the problem and develop standards of practice.

17          I think a key point that I am sure you understand  
18 but which is worth emphasizing is that unlike other  
19 organizations that you might be wanting to put into the same  
20 bailiwick that you might view as a trade organization trying  
21 to minimize the regulatory burden as its sole objective, the  
22 professional organizations we are referring to are  
23 organizations of professionals, and in this case medical  
24 professionals, whose first order of business is to maximize  
25 the welfare of their patients.

1           The standards of practice that we develop are not  
2 based on what can we do to keep the government out of our  
3 faces; they are based on what do we need to do to deliver  
4 the best possible patient care. I think if you understand  
5 those practice standards coming from that purview, then it  
6 makes them easier to swallow as the starting point of a  
7 regulatory framework.

8           CHAIRMAN JACKSON: Ms. Brown, you presumably  
9 represent patient rights and are an advocate in that regard.  
10 Is there a comment you might make?

11           MS. BROWN: I buy what Barry is saying to the  
12 extent that I know the members of this committee and  
13 probably the prominent ones in the associations that  
14 represent the regulated community, but the larger part of me  
15 is worried about the professionals who don't have patient  
16 care as their be all and end all and are on the other end of  
17 the bell-shaped curve.

18           MR. WILLIAMSON: That is exactly what I am trying  
19 to make this proposal targeted to.

20           Slide 29, please.

21           [Slide.]

22           MR. WILLIAMSON: I think the enforcement process  
23 is key. In many respects, especially in the area of  
24 personnel and public safety, I think standards have a great  
25 overlap between the proposed system and what is in place

1 now. What I am suggesting for enforcement is basically an  
2 accreditation system. Every institution or practice in  
3 radiation medicine would be reviewed and site visited by a  
4 team of appropriate medical professionals. I don't think in  
5 isolation or totally independent of the regulatory agency,  
6 but as sort of the experts to filter through and look at all  
7 aspects of the practice and make a determination whether in  
8 large part does this practice adhere to the minimum  
9 standards of practice that have been chosen to be regulatory  
10 end points.

11 I think the idea would be it's pass or fail. If  
12 you pass for an allotted period of time, you are certified  
13 to practice your subspecialty. If you fail, you have to  
14 come up with a remedial program and implement it to bring  
15 your practice up to the standards.

16 [Slide.]

17 MR. WILLIAMSON: I think the goal here is to  
18 identify exactly what Ms. Brown was talking about, that  
19 percentage of practices that are way down on the lower end  
20 of the tail and don't have, I think, the welfare of the  
21 patient as their primary aim. I think perhaps by this  
22 system the group of people that we all want to target and  
23 bring into the mainstream of modern medical practice could  
24 be achieved and the burden on the rest of us lessened, and  
25 at the same time your program would increase in

1 effectiveness because you are meshing it in a consistent,  
2 coherent way with the quality assurance mechanisms that  
3 already exist in these fields and are endorsed by all the  
4 professional bodies involved as practice standards.

5 CHAIRMAN JACKSON: With respect to your suggested  
6 enforcement process, you speak of using relevant clinical  
7 professionals as reviewers. What does relevant mean?

8 MR. WILLIAMSON: I think for a radiation oncology  
9 practice it would mean using radiation oncologists and  
10 medical physicists, perhaps. For a nuclear medicine  
11 facility, I'm not an expert in that, but I would presume a  
12 board certified nuclear medicine physician and perhaps a  
13 nuclear pharmacist, if appropriate. It would depend on the  
14 area, but peer review is the point.

15 MR. FLYNN: I'm involved in the American College  
16 of Radiology practice accreditation program for radiation  
17 oncology. For the practice assessment portion of that  
18 program, as opposed to the standard writing part of the  
19 program, we review radiation oncology practices to see if  
20 they would meet the standards for accreditation. I'm  
21 chairman of the pass/fail subcommittee.

22 I would say of over 100 practices we have surveyed  
23 in five years 12 did not meet the standard. And those are  
24 not the 12 that are setting the standards. It's those who  
25 practice high quality radiation oncology that are setting

1 the standards. Of those 12, over half have improved their  
2 program to a degree. It may have taken them several years  
3 to reapply and then be accredited, but there are still some  
4 out there who have not been.

5 I think that's a good example how the system can  
6 work, especially in an era now where you have managed care,  
7 where insurers are looking for those health care providers  
8 who in trying to contain costs of delivering health care  
9 don't sacrifice quality. So more and more we are seeing  
10 that insurance companies are requiring the health care  
11 provider who is trying to sign a contract with the insurer  
12 have some outside method of accreditation to demonstrate the  
13 quality of their practice.

14 CHAIRMAN JACKSON: Thank you.

15 Commissioner Rogers, do you have questions.

16 COMMISSIONER ROGERS: Just on this one, to begin  
17 with. Why do you think it hasn't happened? This doesn't  
18 seem like an unreasonable approach tool to try to present  
19 something to NRC that represents the best thoughts of the  
20 professional community. We certainly hear from organized  
21 professional groups in other areas that we regulate.

22 I'm a little puzzled when I look at this to try to  
23 understand why it hasn't happened so far. It does seem as  
24 if it's a kind of obvious way to proceed. All good ideas  
25 seem obvious and we all believe that we thought of them

1 ourselves after somebody else has told us about them.

2 We've had a running problem here with the  
3 regulated community in the medical area for years and years.  
4 It has been going on for decades almost, I guess. Why do  
5 you think that an approach such as this hasn't been already  
6 attempted? Or has it?

7 DR. SIEGEL: It certainly has been attempted in  
8 areas outside of byproduct material.

9 COMMISSIONER ROGERS: We've been battling over  
10 this business of NRC being the regulator and not  
11 understanding what it is regulating and not paying  
12 sufficient attention to the concerns of the professionals.  
13 All right. Here we were. Here are the organizations. What  
14 was missing? Did it need another organization to assemble  
15 these, to call everybody together to try to do this? Why  
16 didn't it happen?

17 DR. SIEGEL: I can suggest a couple of possible  
18 reasons and then let anybody else chime in. One is the 3  
19 percent or 10 percent perception, which is, this is a small  
20 fraction of total use and why mess with it? We're doing  
21 just fine for the other 95 percent. That's one possibility.

22 Another possibility is, I think, considerable  
23 concern that there is not much reception for the approach  
24 and a lot of effort to put it together without much  
25 opportunity to make it fly. I can't prove that, but it is

1 not clear to me that the NRC would have welcomed such an  
2 approach with open arms.

3 I think that if you thought that this kind of an  
4 approach was a good idea, if it were NRC driven, you would  
5 accomplish getting those organizations together to come with  
6 logical proposals to you much better than if you simply let  
7 them go about their own devices.

8 MR. WILLIAMSON: One other suggested reason is, I  
9 think over the last few years there has really been an  
10 ingrowth of NRC regulatory activity in the domain that has  
11 been largely patient care with the institution of the  
12 quality management rule, what seems to me subjectively to be  
13 more adversarial and severe and nitpicky enforcement since  
14 some of the incidents that have occurred in the early 1990s  
15 and the bad publicity in the Plain Dealer. I think actually  
16 NRC scrutiny in the radiation oncology community has been  
17 greatly enhanced, and that is one reason perhaps we why we  
18 are reacting more and presenting more proposals.

19 CHAIRMAN JACKSON: Dr. Stitt, you wanted to make a  
20 comment?

21 DR. STITT: Yes, thank you. It is entirely  
22 possible that the sort of talking we are doing today could  
23 be a type of catalyst. There are certainly in the American  
24 College of Radiology standards that have recently been  
25 reviewed for high dose brachytherapy, for low dose

1 brachytherapy. There is the accreditation review that  
2 Dr. Flynn referred to of those standards. If those things  
3 could be linked with the regulatory agency, it might be a  
4 way to look at these issues.

5 MR. QUILLIN: I would just like to point out that  
6 there has been a lack of a mechanism to bring this consensus  
7 about. There has been no initiator to this process. NIH  
8 has not sponsored a conference, for example, to bring all  
9 these groups together to try to come up with a consensus  
10 position in this area. So there has never been the push to  
11 get this done.

12 COMMISSIONER ROGERS: There is something a little  
13 perplexing here, I find, in the reaction of the states so  
14 far to this. If in fact all of the regulation of nuclear  
15 medicine outside of the use of Atomic Energy Act materials  
16 is under the states now, and if we are only dealing with  
17 something like 10 or less percent of the total practice, why  
18 is this such a terrible burden to be taken on? All right,  
19 it's a little bit more, but why is this something that  
20 states would feel so concerned about taking on if they have  
21 90 to 97 percent of the action already under their purview?

22 MR. QUILLIN: At the present time there is one, I  
23 think soon to become two, states that have no radiation  
24 programs at all, Wyoming and Montana. So there are two  
25 states which basically don't have any program in this area

1 at all. There are other states that don't have the  
2 resources. Here is a federal agency that is doing it. If  
3 the state were to take it on, it becomes a federal mandate,  
4 which is a no-no.

5 COMMISSIONER ROGERS: We understand the unfunded  
6 federal mandates argument. But how big is that burden?

7 MR. QUILLIN: There are some states that are so  
8 small. Why do it for a dozen licensees, for example? Under  
9 the present system of being an agreement state you have to  
10 go through a process of becoming an agreement state; you  
11 have to keep your regulations up. It's an expensive  
12 business if you have a very small group of customers to  
13 support it. So it's not something that you are going to  
14 break even on.

15 CHAIRMAN JACKSON: Commissioner Dicus?

16 COMMISSIONER DICUS: No.

17 CHAIRMAN JACKSON: Commissioner Rogers?

18 COMMISSIONER ROGERS: Let me just simply say first  
19 that I think your committee did an excellent job. When I  
20 read your comments and your suggestions and so on, it seemed  
21 to me that you really had given a lot of thought. I  
22 appreciate that very much.

23 I hope my remarks and questions haven't appeared  
24 to be antagonistic, but we are trying to get at something  
25 here and there is only one way to do it that I know of, and

1 that's ask questions.

2 I think that you have really worked very hard to  
3 sharpen up the issues here and to present in a very  
4 professional way some suggestions. You looked at some  
5 alternatives: if something doesn't work, well, there is  
6 another way that may have to be followed.

7 None of us know what Congress is going to do. If  
8 all of our actions are predicated upon the assumption that  
9 they are going to take a particular action and they don't,  
10 then what do we do?

11 The very willingness of this committee to step  
12 forward and say, well, if that doesn't happen, we are ready  
13 to help you and work with you, I really appreciated that  
14 very much. I know you have always been helpful, but I think  
15 stepping forward that way is significant, because that's  
16 where we may be. Who knows?

17 I felt that you really have been giving us a lot  
18 of useful thought here, and I appreciate it.

19 CHAIRMAN JACKSON: The meeting is not over. If  
20 you don't mind parting the waters so we can hear from  
21 Dr. Adler. I will thank you at the end.

22 DR. ADLER: My name is Bob Adler. I regret that I  
23 wasn't here at the last meeting you had to discuss the IOM  
24 report, but I didn't get notice of that meeting, which was a  
25 Tuesday, until 4:30 the Friday before, and I have a life and

1 couldn't reschedule.

2 [Laughter.]

3 DR. ADLER: I do apologize, but I thank you very  
4 much for inviting me. I don't have very much to say.

5 I must say that I have been enchanted by the views  
6 that we have just heard. I was sitting in the chair, saying  
7 that I wish I had been with these guys instead of with the  
8 IOM.

9 [Laughter.]

10 DR. ADLER: You have copies of my separate  
11 statement and I believe you have copies of my February 27  
12 letter to the Commission about the report, which was written  
13 in unbelievable haste. I just want to add a few thoughts.  
14 I will run through them quickly, and then any questions and  
15 comments you have I'll be delighted to answer.

16 As a starting point, I want to hasten if not leap  
17 to point out that I claim no particular expertise in the  
18 arena of nuclear medicine. In fact, in the months since the  
19 last meeting of the IOM Committee I think I've forgotten  
20 most of the terminology that I picked up over the two years  
21 of the study.

22 As even a casual perusal of the report will show,  
23 the points of contention were not particularly scientific.  
24 They were policy, philosophy, and those are areas where I do  
25 have some expertise, especially with respect to regulatory

1 policy and philosophy.

2 I also want to say that, at least for me, serving  
3 on the IOM Committee was not a pleasant experience,  
4 especially once it became clear that I did not share my  
5 colleagues' views regarding the report. This is probably a  
6 terrible metaphor to use, but I would liken it to being  
7 treated by a proctologist with poor depth perception.

8 [Laughter.]

9 DR. ADLER: I do apologize for that.

10 That is to say, I think it is possible to disagree  
11 without being disagreeable, and while some of my colleagues  
12 were terrific -- I can't say all of them were -- I should  
13 also add that the IOM staff was terrific and nothing that I  
14 have to say is directed to them.

15 With respect to the report, the first point I  
16 would make is something that is implicit in the report but  
17 not stated explicitly, and I think that since it's good news  
18 it ought to be touted.

19 CHAIRMAN JACKSON: You can turn up the volume.

20 [Laughter.]

21 DR. ADLER: That is that we did look at the events  
22 that prompted the convening of the IOM. We looked at the  
23 radiation incident in Indiana, Pennsylvania. We went over  
24 the materials that were presented to Senator Glenn. We had  
25 extensive discussion.

1           And as best I can recall, I didn't hear a single  
2 voice of dissent, saying, oh yeah, the NRC, what a bunch of  
3 goofballs; they are too timid; they are not doing an  
4 effective job. To the contrary, I heard the exact opposite:  
5 you are doing an excellent job in protecting the public.

6           The concern of the IOM members was you do too good  
7 a job. That is, you achieve wonderful ends but at too high  
8 a cost. That is a highly debatable point upon which  
9 reasonable people can differ, and I am sure that you are  
10 getting some views today that differ with that as well.

11           It does seem to me that in this age of, as Tom  
12 Lehrer says, universal brouhaha, failing to state that the  
13 NRC does an effective job in its regulatory efforts  
14 constitutes a major flaw in the report, and also, at least  
15 upon reflection, shows me some of the mind-set of some of  
16 the members of the committee.

17           I want to comment on two broad themes of the  
18 report that you have heard discussed today.

19           The first is that you are a burdensome, costly and  
20 unduly prescriptive set of regulators.

21           The second is that a combination of federal  
22 direction, state regulation and private professional  
23 guidance can provide an equal, or if not equal, at least a  
24 far more cost-effective measure of protection to the public  
25 from the hazards of nuclear medicine.

1           Those propositions may be true, but I don't find  
2           convincing evidence in the report to document those  
3           assertions.

4           I base my conclusions on the evidence that was  
5           presented in the report, the discussions that the committee  
6           had, the site visits I made, conversations with individuals  
7           who were connected with the IOM who made many, many more  
8           site visits than I did, and I honestly cannot say that I  
9           found evidence that the NRC regulation was unduly  
10          burdensome. I could characterize some of it as nitpicky, as  
11          annoying, as frustrating, but burdensome is not a term that  
12          I would use to describe NRC regulation.

13          You may be a burdensome body, but I didn't see  
14          evidence of it, and I would urge you, in the event you are  
15          not sure about whether you are an unduly prescriptive and  
16          burdensome body, to listen to folks on the Advisory  
17          Committee here and to talk to people in the regulated  
18          community and to try to come up with evidence one way or the  
19          other about the real life impact of your regulations.

20          It is true that when you are dealing with a group  
21          of extremely sophisticated and educated and well intentioned  
22          professionals, especially medical professionals, that there  
23          is a different approach that they take. There is a high  
24          degree of deference that I would extend to them. I would  
25          extend to them a high degree of discretion, because we as a

1 society hand that to them in order that we may be made  
2 healthy.

3 Taking all of that into account, looking at the  
4 rules that I've heard most complained about, that is, the QM  
5 rule and the misadministration rule, when I look at those,  
6 in all honesty I say you've got to be kidding if you call  
7 those burdensome. They may be annoying. I would be  
8 delighted to hear evidence to suggest that they are  
9 burdensome, but that is not a term I would use.

10 With respect to abolishing the NRC's medical use  
11 program and leaving it to the states and the medical  
12 societies to handle, I join with the folks who were here in  
13 their observation about the states. Some states do an  
14 absolutely terrific job. Some states may do a better job  
15 than the NRC. I haven't seen evidence of that. But some  
16 states clearly don't.

17 I can't remember the gentleman who said it, but I  
18 did agree with it. You could have states that end up, for a  
19 variety reasons, some of them political and not substantive,  
20 imposing more Draconian, more onerous regulation than the  
21 NRC does. Having observed state government, having observed  
22 local government, having worked in both, frankly, and the  
23 federal government, I think that the federal government in  
24 terms of regulation often is more rational and often is more  
25 moderate than state regulation.

1           I do have to address the point about the lack of  
2 uniformity in the regulation of ionizing radiation today.  
3 If there is one thing I got hammered with time and time  
4 again in the meetings, that was it. I think that is a  
5 legitimate concern. But I would also add that a regulatory  
6 inconsistency tells me there is an inconsistency. It  
7 doesn't tell me that you do it wrong and the states do it  
8 right. What it tells me is there is an inconsistency.

9           I remain to be convinced that repealing NRC  
10 authority, for example, would lead to greater uniformity.  
11 What you have now is some federal uniformity, and then with  
12 respect to the non-byproduct ionizing radiation, you've got  
13 a whole patchwork quilt of regulation. If you were to  
14 abolish NRC regulation, I don't know which way it would go,  
15 and I'm not certain it would move in the direction of more  
16 uniformity. It might, but it might not.

17           If we, by the way, are to have regulation of  
18 nuclear medicine -- this is a point that I think we all  
19 share, and I'm sure I will be corrected if it's not. I  
20 don't hear anybody saying don't regulate nuclear medicine  
21 -- then the critical question is, how do we do it best, in  
22 the most rational and cost-effective manner?

23           In all honesty, it shouldn't matter whether the  
24 NRC does it, whether the states do it, or whether some  
25 combination of professional societies and anybody else does

1 it as long as it is done in a rational and cost-effective  
2 way. My problem is I have yet to see evidence to document  
3 that you do it in a bad way. You may do it in a bad way,  
4 but as I read and reread the reports and have gone over my  
5 notes from meetings, I remain to be convinced that you do  
6 such a terrible job.

7 I guess I have one last point, and I will wax a  
8 tiny bit philosophical. Regulatory policy of the sort that  
9 we are talking about, you would wish it were rocket science,  
10 but on the other hand, if it were crystal clear and  
11 mechanical, then we wouldn't need you, and we wouldn't need  
12 to pay you the big bucks that we do --

13 CHAIRMAN JACKSON: Excuse me.

14 [Laughter.]

15 DR. ADLER: I'm a professor. Trust me.

16 -- to make these terribly difficult judgment  
17 calls, because the judgment calls, and this is not new, are  
18 not just science. They are values; they are philosophy,  
19 they are projections. When you talk about a linear dose  
20 threshold versus no threshold judgment call, you are not  
21 talking science. What you are talking about is moving  
22 beyond the realm of science into policy.

23 I think it is critical that there be constant  
24 consultation between you and the people you work with and  
25 you regulate. The Advisory Committee, I must say again how

1 impressed I am with how thoughtful they are and how  
2 reasonable and concerned they are. I will just say it  
3 again. I wish I had worked with you guys and not with the  
4 IOM.

5 CHAIRMAN JACKSON: Thank you, Dr. Adler.

6 Do you have any questions, Commissioner Rogers?

7 COMMISSIONER ROGERS: Just one. What interaction  
8 was there from your point of view with the IOM Committee,  
9 the agreement and non-agreement states, and the regulated  
10 community on the conclusions in the report? To what extent  
11 did the states get an opportunity to weigh in on that?

12 DR. ADLER: They certainly were heard from, as you  
13 know. There were hearings held where they came in and  
14 spoke. There was certainly a lot of consultation back and  
15 forth, but once the report starts being written, then there  
16 is no consultation outside of the committee itself except  
17 with IOM members.

18 I think at a certain point we just moved into  
19 drafting the report. I guess to some extent I am precluded  
20 from talking about, well, you should have seen what this  
21 draft said, but it is amazing that the report ended up being  
22 as balanced as it was. In my judgment, it really didn't  
23 start out nearly as balanced as it is. But I do think that  
24 some degree of skepticism is due the report.

25 COMMISSIONER ROGERS: Let me just say that I know

1 that you were a minority.

2 DR. ADLER: Of one.

3 COMMISSIONER ROGERS: Of whatever, and I know it's  
4 difficult to be in that position. That is not a comfortable  
5 position to be in. I know that you are not speaking for the  
6 majority or the whole committee, but I do think it is  
7 important that we hear from you. I am personally very  
8 pleased that you have been able to be here today to answer  
9 our questions and to give us your observations. I think  
10 that is very valuable in trying to provide a balanced  
11 assessment of the work of the committee. I thank you very  
12 much for being here.

13 CHAIRMAN JACKSON: Commissioner Dicus?

14 COMMISSIONER DICUS: No questions.

15 CHAIRMAN JACKSON: Commissioner Rogers always  
16 waxes philosophical. I thank you for coming and taking the  
17 time. I would also like to thank the committee. It is  
18 clear that you have devoted a lot of thought to the issues  
19 and trying to think through the various aspects.

20 This whole issue of the NRC's regulatory role in  
21 the medical uses of byproduct materials is not a simple one  
22 to be dealt with. It is probably why the earlier Commission  
23 said let your committee study it. But now we are going to  
24 have to bite the bullet and work it through and come to a  
25 decision.

1           It strikes me that these meetings, the comments of  
2 our advisory committee and your comments have clearly  
3 sharpened the focus, and it strikes me that we have three  
4 things we have to deal with.

5           One is the issue of the transfer of regulatory  
6 authority somewhere else and whether that is a good idea or  
7 not and whether what exists is so useless or egregious or  
8 burdensome or costly that it would justify that. There is  
9 at the heart of it a policy issue as to what constitutes  
10 good regulation in that area and what degree.

11           The second aspect has to do with change in the  
12 regulations themselves and to what degree that gets at the  
13 heart of what we are talking about.

14           The final has to do with the administration of  
15 regulations or the implementation of regulations.

16           All of these are joined in getting at what you,  
17 Dr. Adler, called the issue of having rational,  
18 cost-effective regulation and what the committee was  
19 speaking to.

20           I thank the committee and I thank you for helping  
21 to sharpen that focus and to make it clear. Dr. Siegel, I  
22 think your committee obviously spent a large amount of time  
23 talking about and grappling with these issues.

24           So we are going to give serious consideration to  
25 the input of all of you to our deliberations. I think it is

1 also clear that because it is a policy decision we also need  
2 input from others and other stakeholders in the process.  
3 Nonetheless, this is an important piece of our decision  
4 making, and as such the Commission appreciates all of your  
5 efforts.

6 If there is nothing more, this meeting is  
7 adjourned.

8 DR. SIEGEL: Chairman Jackson, if I could make one  
9 more brief statement.

10 CHAIRMAN JACKSON: Please.

11 DR. SIEGEL: This is almost certainly the last  
12 commission meeting that I will be at as Chairman of ACMUI.  
13 My chairmanship expires in September. I want to thank you  
14 and your predecessors for giving this committee an  
15 opportunity to participate in the process. I greatly  
16 appreciate this opportunity. I hope our efforts have helped  
17 the NRC.

18 CHAIRMAN JACKSON: The microphone is off, and I  
19 would like this to be part of the record.

20 I think your committee has provided a valuable  
21 service to the Commission in its deliberations. However,  
22 your chairmanship of the committee has helped to move that  
23 along.

24 If the Chairman speaks, the microphone comes on.

25 [Laughter.]

1           CHAIRMAN JACKSON: Again, I think it is important  
2 if we have an advisory committee that we hear from that  
3 advisory committee. I think it's important that we have as  
4 broad-based a discussion as we can, but we are going to  
5 track this to closure this time one way or the other. Thank  
6 you.

7           COMMISSIONER ROGERS: Since I've probably had the  
8 opportunity to see Dr. Siegel in action for longer than  
9 anybody else has had that privilege, I really think you have  
10 done a super job as the chairman and member of this  
11 committee. I know the number of difficult issues that have  
12 come up from time to time. I think the way that you with  
13 very good grace and an even hand have dealt with some very  
14 tough situations that popped up has just been exemplary. I  
15 think you are going to be a very tough act to follow.

16           DR. SIEGEL: Thank you.

17           CHAIRMAN JACKSON: Again, thank you. We are  
18 adjourned.

19           [Whereupon at 3:35 p.m. the meeting was  
20 adjourned.]

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CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: MEETING WITH ACMUI AND DR. ROBERT  
ADLER ON RECOMMENDATIONS OF NAS REPORT  
ON REVIEW OF MEDICAL USE PROGRAM -  
PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Friday, May 3, 1996

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Michael Paulus

Reporter: Michael Paulus

# **ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES**

- **Commentary on the Report of the IOM Committee for Review and Evaluation of the Medical Use Program of the Nuclear Regulatory Commission**
- **“Radiation in Medicine: A Need for Regulatory Reform”**

## **General ACMUI Perspective**

- **Overall, ACMUI is in agreement with the fundamental principles of IOM report.**
- **IOM advice is quite similar to ACMUI advice for the last 6 years.**
- **ACMUI “complicity” in rule-making does not necessarily mean it thought rules were necessary.**

## **Principles That Should Guide Regulatory Reform**

- **Medical use of ionizing radiation from byproduct RAM is a small fraction of all medical use of radiation: i.e., NRC's responsibility is very limited.**
- **Risks of medical uses of ionizing radiation from byproduct RAM are no different than risks of medical uses of ionizing radiation from other sources.**

# **Principles That Should Guide Regulatory Reform**

- **Risks to public, workers, and patients from medical uses of ionizing radiation are similar to other risks associated with provision of medical care.**
- **NRC medical use regulatory program (which sets the tone for all medical radiation regulation) is widely viewed as intrusive, excessively burdensome, and not justified by level of risk.**

## **Principles That Should Guide Regulatory Reform**

- **Regulation of medical uses of ionizing radiation should be uniform and rationally based on risk. It should be independent of source of radiation.**
- **Responsibility for regulation of medical use of ionizing radiation should reside with an entity that has regulation of MEDICINE as its primary responsibility.**

## **IOM Preferred Alternative**

- ***Alternative D—Federal Guidance***
- **ACMUI favors a greater level of Federal oversight of state programs, with a mechanism (e.g., linkage to Medicare reimbursement) to ensure compliance of the states and users AND to ensure greater uniformity of state programs.**

## **IOM Recommendation A1**

- ***That Congress eliminate all aspects of the NRC's Medical Use Program, 10 CFR Part 35, and those regulatory activities conducted under 10 CFR Part 20 that are applicable to medical uses.***
- **ACMUI effectively agrees with this recommendation.**

## **IOM Recommendation A2**

- ***That Congress direct the Secretary of DHHS to support, coordinate, and encourage the following activities involving regulation of all ionizing radiation in medicine:***

## **IOM Recommendation A2 (cont.)**

- a. supporting the operation of the Conference on Radiation Control Program Directors (CRCPD);***
- b. providing a venue for the review and evaluation of Suggested State Regulations for Control of Radiation (SSRCR);***
- c. assisting states in implementation of their regulations;***
- d. aiding in assessment of the effectiveness of state programs through the collection and analysis of data;***

## **IOM Recommendation A2 (cont.)**

- e. helping develop survey methods by which the rate of adverse events for a wide range of procedures and devices might be measured;***
- f. monitoring the effects of deregulation;***
- g. enhancing training and standards for health care personnel; and***
- h. investigating future significant radiation medicine incidents.***

## **IOM Recommendation A2 (cont.)**

- **ACMUI favors more-direct Federal oversight, rather than just guidance of state activities, by DHHS.**
- **ACMUI agrees that DHHS activities should encompass items (c) through (h) of IOM Recommendation A2.**

## **IOM Recommendation A2 (cont.)**

- **A centralized authority for rule-making is more likely to ensure that some states do not have inadequate rules while others have excessively burdensome rules.**
- **ACMUI questions the effectiveness or openness of CRCPD as a venue for developing regulations.**

## **IOM Recommendation B1**

- *The NRC should immediately relax enforcement of 10 CFR 35.32 and 35.33 through its present mechanisms.*
- **ACMUI entirely concurs. This IOM recommendation echoes the prior ACMUI recommendations not to promulgate the Quality Management (QM) Rule and to eliminate misadministration reporting and patient notification requirements.**

## **IOM Recommendation B1**

- **As previously noted by ACMUI, this IOM recommendation addresses fundamental concerns with NRC's intrusion into the practice of medicine and its approach to implementation and enforcement of its regulations.**

## **IOM Recommendation B2**

- ***That NRC initiate formal steps under the Administrative Procedure Act to revoke Part 35 in its entirety, if Congress fails to act within two years in response to the two recommendations to Congress stated above.***

## **IOM Recommendation B2 (cont.)**

- **ACMUI skeptical that NRC could (or would) take this action precisely as stated by IOM; congressional action is essential.**
- **If Congress does not act, ACMUI is prepared to help NRC rebuild Part 35 by a thorough and critical assessment of the risks of medical uses of ionizing radiation in order to determine what level of regulation is necessary.**

## **IOM Recommendation B2 (cont.)**

- **If NRC retains its current statutory authority, ACMUI believes several major revisions of Part 35 are essential.**
  1. **Complete re-evaluation of training and experience requirements for authorized users (with focus on radiation safety to general public and workers).**
  2. **Elimination of ALARA and QM rules as regulatory requirements (while continuing to encourage these principles).**

## **IOM Recommendation B2 (cont.)**

- 3. Revision of event reporting requirements (may even need to lower certain reporting thresholds because of legitimate need to gather more information about undesirable events with potential safety significance in order to build a useful database). Such reporting must be treated in a non-punitive manner, and the patient notification requirements should be eliminated.**
- 4. Deletion of most requirements relating to diagnostic nuclear medicine.**

## **IOM Recommendation B3**

- *That the NRC separate the costs of formulating regulations from the cost of administering those regulations.*
- **ACMUI agrees that this is logical and equitable if current regulatory structure remains intact.**

## **IOM Recommendations C1 and C2**

- ***That the CRCPD incorporate into its SSRCR any relevant concepts from 10 CFR Part 35 that are not already integrated in those suggested regulations.***
- ***That all state legislatures enact enabling legislation to incorporate the regulation of reactor-generated byproducts into existing state regulatory programs.***

## **IOM Recommendations C1 and C2**

- **ACMUI favors an approach that is more directly managed by a Federal authority with responsibility for medicine as its principal venue (i.e., DHHS).**
- **ACMUI favors a complete re-assessment of regulations, rather than a wholesale transfer of Part 35 to the SSRCR.**

## **IOM Recommendation C3**

- ***That the CRCPD and the states continually reevaluate their regulations and procedures pertaining to radiation medicine to ensure congruence with evolving scientific understanding of radiation bioeffects and to be in accord with advances in knowledge regarding benefits and risks related to medical and biomedical research uses of ionizing radiation in medicine.***

## **IOM Recommendation C3**

- **ACMUI agrees that such periodic review of regulations and their scientific basis is essential, but favors centralizing the process at the Federal level:**
  - **more likely to get the best scientific experts as regulators and as advisors for one Federal effort than for 50 state efforts**
  - **mechanisms in place for active input by the regulated community**

# **NAS/IOM REPORT A STATE PERSPECTIVE**

- **All states will not be agreement states**
- **With all its strengths, the CRCPD also has weaknesses**
- **States will always be independent**

# **Medical Use Program Elements**

- **Essential purpose: Goals, mandate and scope**
  - What is special about radiation medicine compared with other specialties?
- **Practice standards**
  - Ask the regulated community what is essential.
- **Enforcement process**
  - Build upon existing processes for promoting quality healthcare.

# **Rational Regulatory Program Goals/Scope**

- **Promote essential professional practice standards as defined by the regulated community.**
  - **Minimize burden and intrusiveness on those meeting the standards.**
  - **Accept documentation, training, and quality improvement standards of the regulated community.**
  - **Abandon preoccupation with isolated incidents.**

# **Regulatory Program Constraints**

- **Base regulatory imposition of practice standard on risk vs. benefit assessment.**
- **Recognize that regulatory endpoints should be integrated into a single QA program serving many other goals.**
  - **Appropriateness of selected treatment**
  - **Experience, training, and competence of caregivers**
  - **Accuracy and optimality of treatment**

# **Practice Standards**

- **Develop collaboration with professional organizations (ACR, AAPM, SNM, etc.).**
- **Develop inventory of essential practice standards for each subspecialty.**
  - **Safety standards for public and staff**
  - **Essential resources: equipment, credentialed staff**
  - **QA standards essential to patient safety?**

# **Enforcement**

- **Enforcement process guidelines**
  - **Inspections: function like an accreditation site visit**
  - **Use relevant clinical professionals as reviewers**
  - **Emphasize staff credentialing and program's adherence to practice standards, not isolated errors or omissions**
  - **Decouple misadventure reporting from patient reporting and punishing institution**

# **Enforcement/Accreditation Standards**

- **Goal: bring sub-standard practices into mainstream without burdening others**
- **'Calibrate' inspection process against random sample of practices to ensure reasonableness**
- **Models to study:**
  - **ACR accreditation programs**
  - **Mammography Quality Standards Act**