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

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MEETING WITH ACMUI AND DR. ROBERT ADLER

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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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ACMUI MEMBERS PRESENT:

BARRY A. SIEGEL, Chairman

JUDITH ANNE STITT

JUDITH I. BROWN

DANIEL F. FLYNN

DENNIS P. SWANSON

JOHN GRAHAM

ROBERT M. QUILLIN

JEFFREY F. WILLIAMSON

LOUIS K. WAGNER

THERESA WALKUP

GEORGE MILLS

ALSO PRESENT:

ROBERT ADLER

P R O C E E D I N G S

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

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

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

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

the effectiveness of the regulatory program.

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

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

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

COMMISSIONER ROGERS: Nothing at this time, thank you.

CHAIRMAN JACKSON: Commissioner Dicus.

COMMISSIONER DICUS: Nothing at this time.

CHAIRMAN JACKSON: Mr. Siegel, you may proceed.

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

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

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

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

Ms. Judith Brown, patient rights and care advocate.

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

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

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

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

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

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

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

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

CHAIRMAN JACKSON: We will try to control ourselves.

[Laughter.]

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

If I can have the first slide, please.

[Slide.]

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

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

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

If I can have the next slide, please.

[Slide.]

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

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

Next slide, please.

[Slide.]

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

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

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

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

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

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

CHAIRMAN JACKSON: But a database does exist?

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

CHAIRMAN JACKSON: Relative to this particular area?

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

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

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

Next slide, please.

[Slide.]

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

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

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

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

record of radiation use in medicine.

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

DR. SIEGEL: Yes, sir.

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

DR. SIEGEL: The risks are similar.

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. SIEGEL: We agree completely.

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

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

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

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

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

CHAIRMAN JACKSON: Will you be addressing that distinction?

DR. SIEGEL: To some extent.

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

DR. SIEGEL: Correct. To some extent.

Next slide, please.

[Slide.]

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

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

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

[Laughter.]

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

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

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

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

Next slide, please.

[Slide.]

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

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

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

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

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

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

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

Next slide.

[Slide.]

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

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

Next slide.

[Slide.]

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

[Slides.]

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

We can now skip over to slide 11.

[Slide.]

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

Next slide.

[Slide.]

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

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

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

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

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

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

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

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

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

implied in this?

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

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

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

Next slide, please.

[Slide.]

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

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

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

Next slide.

[Slide.]

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

Next slide.

[Slide.]

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

[Slide.]

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

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

to help you determine what level of regulation is necessary.

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

Next slide, please.

[Slide.]

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

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

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

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

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

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

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

Which should we talk about, ALARA?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I don't see how imposing ALARA as a regulation

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

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

MR. SWANSON: Barry.

DR. SIEGEL: Yes, Dennis.

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

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

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

DR. SIEGEL: Next slide.

[Slide.]

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

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

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

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

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

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

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

Next slide.

[Slide.]

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

CHAIRMAN JACKSON: We don't either.

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

Next slide.

[Slide.]

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

[Slide.]

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

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

Next slide.

[Slide.]

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

[Slide.]

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

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

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

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

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

Bob is next.

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

[Slide.]

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

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

responsibility.

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

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

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

CHAIRMAN JACKSON: Thank you.

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

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

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

Slide 25, please.

[Slide.]

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

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

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

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

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

Could I have the next slide, please.

[Slide.]

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

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

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

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

[Slide.]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Slide 29, please.

[Slide.]

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

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

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

[Slide.]

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

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

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

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

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

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

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

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

CHAIRMAN JACKSON: Thank you.

Commissioner Rogers, do you have questions.

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

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

ourselves after somebody else has told us about them.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN JACKSON: Commissioner Dicus?

COMMISSIONER DICUS: No.

CHAIRMAN JACKSON: Commissioner Rogers?

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

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

that's ask questions.

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

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

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

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

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

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

couldn't reschedule.

[Laughter.]

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

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

[Laughter.]

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

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

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

policy and philosophy.

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

[Laughter.]

DR. ADLER: I do apologize for that.

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

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

CHAIRMAN JACKSON: You can turn up the volume.

[Laughter.]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN JACKSON: Excuse me.

[Laughter.]

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

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

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

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

CHAIRMAN JACKSON: Thank you, Dr. Adler.

Do you have any questions, Commissioner Rogers?

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

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

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

COMMISSIONER ROGERS: Let me just say that I know

that you were a minority.

DR. ADLER: Of one.

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

CHAIRMAN JACKSON: Commissioner Dicus?

COMMISSIONER DICUS: No questions.

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

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

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

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

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

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

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

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

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

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

If there is nothing more, this meeting is adjourned.

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

CHAIRMAN JACKSON: Please.

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

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

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

If the Chairman speaks, the microphone comes on.

[Laughter.]

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

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

DR. SIEGEL: Thank you.

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

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

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 it 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 reasonablenss
- Models to study:
  - ACR accreditation programs
  - Mammography Quality Standards Act