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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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MEETING

ADVISORY COMMITTEE ON MEDICAL

USES OF ISOTOPES

(ACMUI)

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WEDNESDAY

FEBRUARY 21, 1996

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ROCKVILLE, MARYLAND

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The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, T2B3, 11545 Rockville Pike, at 8:30 a.m., Barry A. Siegel, Chairman, presiding.

COMMITTEE MEMBERS:

BARRY A. SIEGEL, Chairman

DANIEL S. BERMAN, Member

JUDITH I. BROWN, Member

DANIEL F. FLYNN, Member

A. ERIC JONES, Member

ROBERT M. QUILLIN, Member

COMMITTEE MEMBERS:(CONTINUED)

JUDITH ANNE STITT, Member

DENNIS P. SWANSON, Member

LOUIS K. WAGNER, Member

THERESA WALKUP, Member

JEFFREY F. WILLIAMSON, Member

ACMUI STAFF PRESENT:

LARRY W. CAMPER,
Designated Federal Officer

DR. PATRICIA HOLAHAN

ALSO PRESENT:

DR. DONALD A. COOL

SHAWN GOOGINS

KATE LOUISE GOTTFRIED

DICK GROSS

MARK SELIKSON

HUGH THOMPSON

JOHN VILLFORTH

A G E N D A

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

(8:40 a.m.)

MR. CAMPER: In the interest of time and trying to stay on schedule the Chairman has asked if we could get started, so I'm going to start to proceed and do that. Are you on the record? Okay.

Good morning, ladies and gentlemen, I am pleased to welcome you to Rockville, Maryland and to the NRC headquarters for this public meeting of our advisory committee on the medical uses of isotopes

I am Larry Camper, I am the Chief of the Medical Academic and Commercial Safety Branch, and I have been designated Federal Official for this advisory committee meeting.

This meeting is an announced meeting of the advisory committee, and it's being held in accordance with the rules and regulations of the General Services Administration and the Nuclear Regulatory Commission. This meeting was announced in the Federal Register on the 26th of January 1996 and on the 15th of February 1996. That notice stated that the meeting will begin at 8:30 a.m., and we are slightly late.

The function of the advisory committee is to advise the NRC staff on issues and questions that arise on the medical use of byproduct material. The committee provides counsel to the staff but does not determine or direct the

actual decisions of the staff or the Commission. The NRC solicits the opinions of counsel and values the opinions of this committee very much. Staff requests that the committee reach a consensus, if possible, on the various issues that will be discussed to day, but also values stated minority or dissenting opinions. We ask that you, if you could, please clearly articulate those dissenting opinions as we discuss the specific agenda items.

The agenda for this special meeting of the ACMUI will focus primarily upon the considered deliberations of the National Academy of Sciences Institute of Medicine Committee for the review and evaluation of the medical use program of the Nuclear Regulatory Commission. The deliberations of this committee are contained in the report entitled "Radiation in medicine, a need for regulatory reform."

In addition to the NAS report the ACMUI will also discuss two other significant issues. First, a proposed rulemaking entitled "Reporting requirements for unauthorized use of licensed radioactive material." And secondly, "Staff action items resulting from resent internal contamination incidents."

As part of their preparation for this meeting I have reviewed the agenda from member's finance and employment interest. I have not identified any conflicts that based upon the very general nature of the discussion that we're going to

have during this meeting. Therefore, I see no need for any individual member of the committee to recuse themselves from the discussion. However, if during the course of our business you determine that you may have some conflict, please state that for the record and recuse yourself from that particular aspect of the discussion.

I would like to take this opportunity to introduce the members of the committee for the benefit of the public in attendance. Starting to my extreme left we have Dr. Jeffrey Williamson. And we have Theresa Walkup next to him.

Dr. Williamson and Ms. Walkup are new members of the committee. They have been approved by the Commission for seating on the committee. They are still undergoing the formality of document review and presentation of backgrounds, etcetera, which is currently under review by the agency.

They will participate in the discussions today. Unfortunately in view of their current status, they cannot vote on consensus building, but they can take an active role in participating in the discussions. And we welcome you and we encourage you to take an active part.

I would like to comment with regards to Dr. Jeffrey Williamson, for the physics community I am quite proud to say that Dr. Williamson recognizes a reinstatement of a second medical physicist position on the committee, and he brings to bear a considerable amount of expertise particularly

in the areas of brachytherapy and high dose rate remote after-loading. So we're glad to have you aboard.

Next is Dr. Wagner, Louis Wagner, who is also a medical physicist on the committee.

Dr. Dennis Swanson is our radiopharmacist.

Dr. Judith Stitt representing radiation oncology and therapy.

Mr. Robert Quillin representing State's regulator's perspective. He's with the State of Colorado.

Next, sitting at the table today, is Dr. Patricia Holahan who is currently the acting section leader for the medical and academic section filling in for Dr. Piccone, who is here. Josie is back in the audience. Josie is currently on a rotational assignment dealing with the agency strategic assessment activities and so she's doing a higher calling at the moment in time, and Trisha is filling in for us.

Of course to my left is the esteemed Chairman, Dr. Barry Siegel.

To my right representing the FDA is Dr. Eric Jones.

Next we have Ms. Judith Brown representing patients rights and consumer advocacy concerns.

And finally, Dr. Dan Berman who is our cardiologist representing, he's also a nuclear medicine practitioner, but he's representing the cardiologist

activities on the committee.

With that introduction I have one or two administrative comments for the benefit of the public and is welcome the public here. It's good to see the attendance and the interest.

To my rear, out the doors at the end of the hallway you'll find rest rooms. The men is on the left, the ladies is on the right. We also have a cafeteria on the first floor which has a full assortment of goodies. They have coffee and other things you might like. So please help yourself to them.

So with that as a background I would then turn the meeting over to Dr. Siegel to chair.

CHAIRMAN SIEGEL: Thank you. The esteemed chairman is under the weather so you'll hear my cough as a constant accompaniment of the day's sound effects.

We have a lot of business. The Federal Register announcement for this meeting solicited written commentary for members of the public but did not specifically budget time for a commentary for members of the public. However, as per our usual practice, at the Chair's discretion members of the public may be allowed to make statements at varying times during our discussion, points of information.

We also have a specific request from the American College of Nuclear Physicians, Society of Nuclear Medicine to

make a statement, if time permits, but they wish to do so tomorrow. And so we will until tomorrow morning on that.

And, if other members of the public wish to make statements, they should let me know so that I can figure out whether or not we have the time to do it.

This is one of the few meetings of the ACMUI that I have come to with almost no clue how we are going to proceed during the course of the day. I personally have a philosophy of chairing a committee that the chairman should be about 98 percent certain what's going to happen when he or she comes into a committee meeting. And at Washington University where I chair the radioactive research committee I actually prepare the minutes before the meeting and all I do is leave the votes blank. Occasionally I have to change something in the minutes, and I do, but I have always done all my homework.

In this case I found it very difficult to anticipate how we're going to structure this discussion and what we're going to conclude. I have some reticence even about whether we should be in a position to second guess an esteemed panel of the National Academy of Sciences and Institute of Medicine, but nonetheless we are being asked to do so in part because I asked that we have the opportunity to do so, and that's part of the reason we're here.

And so with those few introductory comments let me introduce Don Cool who is going to give us a brief overview

and hopefully help us understand why we're second guessing the National Academy.

DR. COOL: Thank you, Barry.

Good morning everyone. Let me first welcome you all to Washington. And I particularly welcome our new members. This is your first time here.

And you are correct, Barry. In fact in this meeting I also am not exactly sure where we may be headed in this particular process. You can think of the whole possible range of quotes, you know, an old Chinese proverb "May you live in interesting times." And certainly we are at this point living in some very interesting times with a lot of things which are moving the whole regulatory program not only in medicine but in a variety or areas in the whole materials regulation area around. Almost as if we were pieces of the continental plate and we're having some grinding on the edges and there's a lot of friction going on and there's occasionally these sudden bursts of release, something suddenly slips and everyone seems to go sort of ballistic over some period of time.

Don't take that analogy too far, but there are a lot of different things that are going on right now. And what I want to do here for the next couple of minutes is just sort of to outline for the committee some of the kinds of activities that are going on within the commission and give

you some idea to the extent that I can do so about the directions that the staff may be proceeding, some of the possibilities for how the NRC may look at this report. What I can tell you is unfortunately limited because some of those decisions have not yet been made, and then to go ahead and lead us into the discussion on the report.

So the first thing I want to do, I'm going to throw up one overhead, if I can get that to work. It appears that it's going to. My belief in mechanical types of things, transportation kinds of things has been severly jolted this weekend. You need to know that I am one of the people who in fact rides the MARC rail trains every day,a nd of course MARC rail proved on Friday that it's perfectly capable of messing things up.

The airlines over the last couple of days have proved perfectly capable of messing a number of things up, as most of you have experienced, when an airline ran off the end of the runway and proceeded to shut down National for a little while.

All of those give us sort of little hints and tidbits and reminders that as much as we would like to neatly craft and organize and box and control in detail everything that we would like to do and have everything neatly scripted out and have all of our nice little plans firmly in place, that occasionally things do not work out the way that we would

like them to.

A year and a half or so ago we went to the National Academy of Sciences Institute of Medicine. What we were asking them to do was to take a look at the medical program. There were a number of issues that were being raised. Certainly there was a lot of comment, pro and con, more con than pro for the most part, with regards to the program that was going on within the NRC at the time.

We asked them to take a look at the overall risks, both in the use of Atomic Energy Act, AEA, types of materials and all of those things which are not covered by the Commission, which in fact is, as the National Academy has pointed out, a significantly larger chunk of the overall amount of treatment that goes on here in the United States, to try and take an examination of some of the policy issues and implications that would underlie the regulation either by the NRC or by states or other authorities and bodies, and to do a critical assessment of the framework of regulation and to see if they could provide some recommendations for either continuing the program, alternatives to program or otherwise. You all have copies of the pre-publication draft which the National Academy released in December.

This afternoon we will have representatives from the Institute of Medicine, National Academy who will be here and provide an overview of the report, the process they went

through and be able to answer questions and engage in a discussion, so I am not going to attempt to second guess or otherwise represent where they may be. But rather to talk about what we now need to do as a result of the fact that we have this piece of information in front of us.

What we were looking for was some recommendations on how to try and achieve uniform national approach to the regulation of ionizing radiation in medicine. Clearly recognizing that we have only one small portion of that particular approach and how to try and harmonize. That's one the favorite words running around the agency here and there is "Risk harmonization regulation," "harmonization." We can try and get to a more harmonized approach to the system. What kind of criteria there might be for measuring the effectiveness of the programs that are out there.

The National Academy has presented us with a report. They have prepared a number of recommendations. And in a moment or two Dr. Holahan is going to walk you through what those recommendations were, just so that we're starting from the same script. It's a very interesting set of recommendations. I don't know exactly what each of you at this point may believe in terms of agreement or disagreement, nor am I asking you to tell me at this point, that's part of one of the things that we need to go through is to see where we stand with regards to agreement or disagreement.

On the other hand I do not see us here as a second guessing or a re-evaluation of what the National Academy has done. We have impact now this marker which is sitting out here and we need to determine how to proceed.

In talking with our chairman before the meeting, he asked can you give me some idea of what the staff is going to do with this report? And very frankly, I wish I could tell you that. Because I wish there was a nice simple answer that I could tell you the staff is going to proceed to do X, Y, Z, Q and W in that particular order. Unfortunately that is not the case, there are at least three separate distinct possibilities for directions in which the staff could proceed here.

The staff in fact has a proposal in front of the Commission for the Commission to consider. That is still subject to Commission consideration, and they have not made a decision on that. But basically the range of approaches ranges from the possibility the Commission can tell the staff go forward, do good, do exactly what NAS said, extract the NRC from the medical program.

In which case a particular set of actions would need to be done in order to execute that kind of approach. If that were the case, what would be extremely useful to me and my staff, who then have to carry forward that particular sword and execute that particular kind of downsizing, is how to move

from what are actually relatively broad sweeping recommendations, do this, do this, do this in terms of broad outcomes.

Translate that back into how do I get there from here, how do I actually achieve the kind of goals that we are looking for, uniform regulatory approach, even transition, some transition period, some continuity of approaches, if the Commission were to more or less unilaterally start to proceed down the road as in fact the National Academy has suggested in at least one of its recommendations.

There are at least two other possible routes that the Commission could proceed in. One is that the Commission could use a more participatory process to try and develop that new regulatory approach, the next layer below the recommendations. The Commission has in fact a number of mechanisms for working with agreement states, non agreement states, the public, in developing policies and regulations.

Examples of enhanced participatory types of rulemaking where public workshops or otherwise are used to try and elicit a wide variety of feedbacks, get a lot of different kinds of groups involved who may not have had an opportunity to suggest where the pitfalls are and the kinds of approaches to moving the NRC perhaps away from the level of regulation that we have had right now.

The Commission has available to us a group or an

approach which is now known as an operational committee, you can put that in quotes if you'd like, which allows us to work in a committee format with agreement states for the federal organizations and in fact perhaps with non agreement state through representation such as the Conference and Radiation Control Program Directors to have a committee provide the staff and the Commission with discussion and recommendations for that more detailed level of implementation, how to get from here to there.

We have another possible route, and that is in fact to give the entire consideration at this point to an ongoing activity within the Commission which has been called strategic assessment. The Commission has underway at this time a broad sweeping re-examination of what we do as an agency to fulfil our mandate under the Atomic Energy Act and how we go about doing that. Where we'll place our resources, the kinds of resources, going back to the basic fundamental, what do we need to do, what are we required to do, what is the best approach to doing it.

Dr. Piccone, whom you are used to seeing this chair here is in fact one of the people who is detailed to that particular effort over the next several months.

And another possibility which the Commission could pursue is to ask the group which is doing that overall examination of the entire regulatory program, extending well

beyond medical to take the medical piece of the program, in particular the recommendations of the National Academy, as part of its effort and to fold it into the overall recommendations which that group is supposed to provide the Commission.

Each of those have distinctly different time frames. If the Commission were to say staff, go ye forward an get us out now, we would be in a relatively quick time frame where we would be looking for things that we could proceed to start doing relatively quickly to begin an extraction process.

If you were to proceed in a strategic assessment kind of approach, the current schedule has some recommendations due to the Commission in the May time frame with some discussions, perhaps some focus groups or other public interactions in the June, July types of time frames, and some final considerations by perhaps August of this year, a relatively fast ambitious schedule.

If you were to pursue an operational committee type of approach with agreement states, other federal agencies, if you were to pursue interactions through public workshops or otherwise, that would have yet a slightly longer time frame due to the necessity to set up the committee, have them meet and plan and have opportunities for those workshops and public input. So that might be a pattern which would move

us on into perhaps the November, December type of time frame.

So that is to give you a sort of broad view of the possibilities. So where does that leave us here, given that we are in sort of late February. We have a report in hand, we have a set of recommendations.

I think that this committee can give both the staff and the Commission some input with regard to the pros and cons of possible approaches, the pros and cons or need for additional interactions that may be necessary to implement the kinds of recommendations that the National Academy has made.

Certainly a view with whether or not the committee agrees or disagrees and why will be of value to everyone concerned. Without attempting to second guess or otherwise the academy, but some of the recommendations can be viewed in some sense as being at least parallel, perhaps even in conflict, somebody go off and do this such as the congressional, and if they don't then you go do this other sort of thing, which if you tried to do both of those simultaneously could get you into a strange sort of juxtaposition of activities. You know, so how might the staff look at trying to balance out some of the different kinds of recommendations and considering timing.

And then what I think is most important for myself and the staff right now is the considerations of taking those broad recommendations, go do this, do this and do this,

which are stated in terms of outcomes, and have your views, thoughts, approaches, comments with regards as to how to actually do that translation from a regulatory program which exists, codified in 10 CFR, to something which would implement that kind of approach, if you assumed that the Commission were to pursue implementation of at least some of the recommendations because there is a large gap in between there.

I cannot wave any sort of magic wand and NRC is out of medical. Some rulemaking is going to be necessary, some changes in guidance, changes in inspection procedures. And for each one of those things there is going to have to be some corresponding changes that will be necessary in other portions of the regulatory community. Agreement states picking up additional things, agreement states or perhaps non agreement states obtaining additional authorities, questions with regards to control for federal facilities for which states under their current jurisdiction in fact have no jurisdiction in particular locations in areas. So there are number of those kinds of implementation questions, the next tier down which are particularly critical for us to attempt to move forward in whatever process.

And that kind of information will be useful irrespective of whether the Commission tells me tomorrow go extract us, or whether the Commission says have the strategic assessment group do it, in which case the strategic assessment

group will need this kind of information in order to craft their recommendations. Or as input to any kind of operational committee or public workshops which would enable us to get a larger expansion of views.

So that in brief is the kinds of things that are going on within the approach and the directions which the Commission may proceed. Certainly we are going to do something with it. I would expect the decision with regards to a course of action to be made within the next couple of weeks. The National Academy briefs the Commission next Tuesday. And I would expect that there will probably be a decision by the Commission, and we are in fact now, for those of you who haven't been following, we do have a Commission again with the appointment of Greta Dicus as Commissioner, we're back to normal operations of vote and consensus process within the Commission, and some direction of the staff as to how to proceed forward.

Let's put this in a little bit of context of some of the other geologic plates that happen to be moving around at the time. There is considerable ongoing discussion about what should happen with materials regulation programs as a whole. This is in fact only a subset of them and perhaps a more broad question of should agreement states have all of the control in materials areas. Should the Commission be pushing for all states to be agreement states. Playing over on the

edge of this, perhaps it's the drumming marching the beat, is the question of fees and costs and some of those associated things which vary considerably. The questions of who was responsible for generating this sort of underlying regulatory program and who is perhaps the right group to do that.

Then there is the ever present question of what do we do with the last event? You know, we have already talked some and I know the ACMUI is already on record as requesting the staff to be cautious and careful in response to the contamination events which happened last year at the National Institutes of Health and the Massachusetts Institute of Technology.

The staff now has the findings of the incident investigation team for the Massachusetts Institute of Technology. I believe the committee was provided with a copy of that report. The staff has a series of actions which have been directed by the executive director for operations to look at issues associated with control of material associated with securities and material, associated with the responsibilities and authorities of radiation safety officers, and a variety of other things which deal with large materials programs.

They came about in the context of a large research program. But if I look at the kinds of licensees that I have and I look at the people around this room, what kind of license do you operate under? You operate under a

broad scope license. And that is exactly the kind of licensee that tripped this particular trigger, got everyone all wound up.

As with any event, people tend to have their reactions do some sort of loop where they greatly exceed probably the level that they should react to and, if everything were to work real nice, they would loop back to whatever the appropriate response level was.

Now, unfortunately you might all know the biological systems sort of, if we're really lucky, have a damping function to that point. We need to try and figure out where that is.

I'm providing this kind of background to the committee mostly to ask you to keep in mind the fact that there are things besides the National Academy report in terms of the overall materials program, in terms of several particular events which the Commission and the staff are also going to need to factor into and explain to someone or multiple someones, our friends down on the Hill as well as a number of others in terms of the kind of approach which considers all of those options together for regulatory forum.

That concludes the things that I wanted to outline for you. I will leave it to you, Barry, as to whether you would like Dr. Holahan to walk you through the recommendations or whether you would like to have some give

and take initially before we get into that.

CHAIRMAN SIEGEL: I'm loose. Does anyone have any specific quest ions for Don while he's here?

All right, why don't we do just what's scheduled. And Trish, why don't you walk us through the National Academy of Sciences' recommendations.

I think that Don just made a very important point and that is we should think about how our institutions and how practices in the real world will function if the NRC simply somehow got out of the medical business but the NRC was still in the overall materials business. Would much really have changed in the final analysis?

And so the notion that you just raised about the NRC somehow extracting itself from the whole materials program and essentially forcing all states or encouraging all states to become agreement states actually is the model that fits best with the recommended National Academy of Sciences' approach.

So that's where I think we should keep that in mind when we talk about predominantly medical issues, that we should try to extend our thinking to materials issues overall.

Go ahead.

DR. HOLAHAN: Okay, and thank you.

I'm not going to try and go through the details of the report. As Dr. Cool mentioned the Institute of

Medicine will be this afternoon and they will probably go through more of the specific details.

One of the things I did want to outline though is they looked at seven different alternatives for the regulation of medical use program. And their preferred alternative was briefly to give the regulatory authority over the medical uses to the states and rely on the states to expand their existing programs, their existing radiation control programs, that are currently applied to NOARM to include byproduct as well.

One of the provisos in the report that only licensed users will have access to byproduct material. And then the report also identifies a federal agency other than NRC to exercise the leadership role in the radiation safety community. And such a federal agency would assist in developing recommended state laws and regulation, provide a leadership role, act as an information clearing house, and distribute resources for training and research.

So that's basically a summary of their preferred alternative, and I'm sure they'll give you more details this afternoon.

To implement this preferred alternative, they came up with eight recommendations, two of which were directed to Congress, three to NRC, and three to the states and CRCPD, the Conference for Radiation Control Program Directors.

What I'd like to do is just sort of step you

through the recommendations and then sort of let you know a little bit as to where we are and what we're currently doing.

The first recommendation is that Congress eliminate all aspects of NRC's medical use program that includes Part 35 and the regulatory activities that are conducted under Part 20 that are applicable to medical uses, the aspects relating to occupational workers and members of the public.

MEMBER WAGNER: Trish, may I ask a question?

DR. HOLAHAN: Yes.

MEMBER WAGNER: In regard to the application of this, I'd just like to understand the NRC's point of view about the application here. My reading and understanding is that it applies to medical uses both in research and at research institutions as well as in hospitals and with patients?

DR. HOLAHAN: Yes, my reading of the report is that it does indicate that it also applies to biomedical research, as I read through the report, in addition to the direct medical uses.

CHAIRMAN SIEGEL: But just by comment, it's pretty vague on that. I kept trying to read that one point very carefully and I don't know whether biomedical research means that the NRC should have nothing to do with the materials uses in medical institutions or whether it means

that the NRC shouldn't be involved with human uses of byproduct material or radioactive material. And I just thought the report was unfortunately more than a little ambiguous about that.

DR. HOLAHAN: Yes, they did not define what they meant by biomedical research, whether or not they were considering non human research as well.

Okay, the second recommendation to Congress was that Congress should direct the Secretary of Health and Human Services to support, coordinate and encourage the following activities involving regulation, and that includes supporting the operation of the conference of radiation control program directors; providing a mechanism or a venue for the review and evaluation of suggested state regulations for control of radiation which currently the CRCPD does put out for regulation of ionizing radiation; assisting states in implementation of their regulations; aiding in the assessment of the effectiveness of state programs through the collection and analysis of data. And this where I had indicated before in terms of an information clearing house.

Helping develop survey methods by which the rate of adverse events for a wide range of procedures and devices could be measured; the error rates or rates of adverse events; monitoring the effects of deregulation; enhancing the training and standards for all health care personnel; and also

investigating future significant radiation medicine incidents. So those were the two recommendations directed to Congress.

The next three recommendations were directed to NRC. Based on reading through the recommendations it appears that they believe Congress would take action within two years. The first recommendation is that NRC should immediately relax enforcement of 10 CFR 3532 and 3533 through its present mechanisms. And as you're probably all aware, that's the quality management role, and the reporting and notification of misadministration.

Secondly, the committee recommends that the NRC initiate formal steps under it's Administrative Procedures Act to revoke Part 35 in its entirety, and basically pull itself out of the regulation of the medical uses of byproduct material. This is if Congress fails to act within two years, which is why I indicated that they are assuming, or it appears that they are assuming, that Congress may act within two years.

Finally, their third recommendation to NRC is that NRC separate the cost of formulating regulations from the cost of administering those regulations. In effect that again from a review of the report, that the development of regulations applies to all licensees including those in agreement states, whereas actual inspection and enforcement applies only to the NRC licensees. So they are recommending

that we separate those costs out.

The final three recommendations are to the CRCPD first of all, and then two to the state legislatures. First of all, they recommend that the CRCPD look at Part 35 and incorporate those aspects of Part 35 that they believe are relevant into their suggested state regulations for control of radiation.

Secondly, that all state legislatures, that includes the agreement states and non agreement states, enact enabling legislation to incorporate byproduct material or reactor generator material into their existing state regulatory programs for non byproduct material.

And the final recommendation is that the CRCPD and the states together re-evaluate their regulations and procedures pertaining to radiation medicine. And, if you think back to recommendation A2, this was to be done in working with HHS in terms of evaluating effectiveness of regulations and deregulation.

Okay, what we have done to date and I'll sort of give you a little bit, Dr. Cool sort had walked through some of the issues, but we did publish a Federal Register notice on January 22nd seeking public comment, noticing that we had received a copy of the report and seeking public comment on the report.

In addition, copies of the report were provided

to the governors of all 50 states plus the Territories and District of Columbia, and also to all the radiation control programs for all states. And we have requested comments on the expected impacts to those states.

Additionally, we have provided copies to all the federal agencies that are mentioned in the report including HHS, DOT, EPA, the Department of Defense and their respective Department of the Army, Navy and Air Force, Department of Veterans Affairs, and OSHA. And then copies of the report have been provided to the Congressional Oversight Committee and yourselves, and also all the regions.

As Dr. Cool mentioned there will be a Commission briefing next week by some of the committee members of the Institute of Medicine, and that's scheduled for next Tuesday.

We have also done a preliminary review of the report, and as such we have identified several issues for your discussion which you all should have in your briefing books. And just for the public I'm just going to walk through those issues and then I'll turn it over to the committee to walk through, if they like.

Okay, the first one is I outlined what the IOM's preferred alternative was. It's does the ACMUI agree with the preferred alternative and the eight recommendations that they've come to propose to implement.

Also, do the bases or rationale that is used in

the report actually support their conclusions that they have reached to come up with this preferred alternative.

I can put these all back up, if you'd like, as you walk through them.

The second one, Appendix L of the report includes a dissenting opinion. The committee did not reach full agreement and so there is a separate appendix on the dissenting opinion by one of the committee members. And what we're looking for is your comment on the rationale that he outlined in that appendix.

As I outlined before, recommendation B2 indicates that, if Congress fails to act, that we pursue withdrawal through the Administrative Procedures Act. Now, in order to do that Section 81 of the Atomic Energy Act does allow certain uses to be exempt from the requirements for a license. However, such action does require a prior finding by NRC that it would not unconstitute an unreasonable risk to the common defense and security and to the health and safety of the public.

And a question to the committee is, on what scientific basis might NRC make such a finding that there is no unreasonable risk and pursue such a withdrawal.

Also within the report it indicates that there is a lack of data in terms of adverse events both in other areas of radiation medicine as well as other areas of medicine. And

again how does support making such a finding in Section 81. Would that type of data be essential in determining the effectiveness of the regulatory program.

One of the recommendations to the committee was to assess the effectiveness of a regulatory program, and they did make a statement in there that they did not address that recommendation.

Also then we would need to do a rulemaking to revoke Part 35 and how best could NRC proceed to do a regulatory analysis to support the rulemaking.

If NRC could not make findings or Congress did not enact legislation and NRC retained its current statutory authority, does the committee have any recommendations to what necessary revisions should be made to Part 35.

If NRC were to withdraw from the aspect of patient safety based on a finding that adequate protection of patients was provided, what revisions should then be made to Part 35 to provide adequate protection of occupational workers and members of the public.

I mentioned earlier that recommendation B2 again suggested that NRC revoke Part 35 in its entirety through it's Administrative Procedures Act. However, unlike the recommendations A1 and A2 this recommendation does not address a federal guidance role in any way. And the question is, is how could uniformity be achieved under this recommendation if

no federal agency is identified to provide a guidance or a leadership role. Is this a necessary aspect of their recommendations.

Okay, again, if Congress enacted legislation or to findings in Section 81 were made, the necessary findings were made in Section 81, and NRC statutory authority for medical use was deleted in its entirely and the states were to assume this authority, what action should be taken and by whom to insure a smooth transition and that there are no regulatory gaps.

Again, we have recommendations that are sort of to the bottom line recommendations as to where we should be, the question is how do we get there, if the recommendations were accepted as is.

Another issue to be address is what approach could be used to assure uniform protection of patients in the light of differences or potential differences and state priorities in terms of funding, industry pressure and consumer interest. How best can uniformity be assured for patient protection.

Again, in recommendation B1 the committee recommended that NRC withdraw or immediately relax enforcement of 3532 and 3533, the quality management rule and reporting of misadministration.

Within the report, as I read the report, it also

included monitoring as part of the enforcement. Some of the questions then to the committee is what, if any, are the conceptual problems or the basis for the quality management role. Could NRC modify the implementation of the QM rule without losing the basic concepts. And what would be the basis for NRC or the rationale to discontinue inspection of the rule without revocation of the rule.

Furthermore, what is the basis for the necessity for relaxation, for the immediate action rather than going through a rulemaking process or take action as part of the overall recommendations.

And finally a question again to the committee is, if NRC were to follow these recommendations, what follow-up action should NRC take in the event of a misadministration that results in either a serious injury or even possibly death.

Another issue that the committee focused on was the lack of data, as I mentioned before, in terms of adverse events. And the committee urged NRC to continue to cooperate with FDA, has provided the MOU to obtain data on devices and drugs as well as biological processes, or rather products, I'm sorry.

And the committee also determined that there was a need for improved databases on the actual incidents of adverse events and misadministration. Again both in radiation

medicine and in other aspects of medicine.

How can we go about achieving the improved data collection, what is the need for these databases. And if NRC was to remove itself from the medical use area, why should NRC continue to gather such data on user errors, drugs and biological products to share with FDA. Now, if NRC continued as the committee recommends in the role of regulating the manufacturer and production, then there would still be some interest in the sealed sources and device reviews and therefore there may be some information on devices, but in other areas is there a need to collect information on user errors and drugs.

Finally, the last two questions or issues relate more to the state's implementation and how the states could provide uniformity. One of the notes in the report was that the committee could find no real evidence to suggest that state regulation is not working well or that all radiation medicine should be subject to federal regulation, but they did note that despite attempts at federal coordination the regulation of other sources, non byproduct sources, is fragmented.

So is there evidence or what is the evidence really that state regulation is working well in all states or working well in some specific states.

And finally will the states uniformly adopt,

voluntarily adopt, the CRCPD's suggested state regulations in the absence of any real compelling mandate placed on either CRCPD or the states.

The report did indicate that NRC would continue to license again the manufacturing distribution and production, and therefore all users must be licensed to receive material. But will this provide the uniformity that is being requested, or that the NRC was seeking recommendations on.

And as an example, in the recently passed mammography law, Congress provided a compelling reason in that facilities -- or there would be no reimbursement unless the facilities had enacted the -- unless they were certified.

So these are some of the issues that we sort of put on the table for discussion by the committee, and unless you have any specific questions I'll leave it to the committee.

CHAIRMAN SIEGEL: Just a few non controversial questions.

DR. HOLAHAN: Yes.

CHAIRMAN SIEGEL: Which also put us at risk of breaking the NAS's legs before they get a chance to talk to the Commission, which is another interesting problem. If we conclude that the report is badly flawed, it's interesting that we will have gone on record before they have actually

made a Commission briefing. And I don't know what the risks of our doing that are, but it's something we should keep in mind as we go through this.

Let me make a few comments before we start here because I really still have not got a clue on how we ought to structure this discussion. But as I read this report a few principles came across that actually I think are the same principals that we have discussed on a number of occasions and that we have presented to the Commission on a number of occasions, and that as you know I carried to the National Academy of Sciences on our behalf when I made a presentation at one of their meetings. And those principals really are as follows:

First of all that the Nuclear Regulatory Commission as an anomaly of the law of the land has responsibility for regulating only a small part of ionizing radiation use in medicine. And it just happened that way because that's the way thing occurred. The focus at the time that the Atomic Energy Act was passed was on nuclear reactors and bombs and the focus was not on the rest of ionizing radiation use.

During the process of fostering the peaceful uses of atomic energy, the Atomic Energy Commission got itself into the business of fostering medical research, fostering medical applications and simultaneously developed a regulatory

program, but their statutory authority only extended to byproduct material or, if we had any reasons to use source material or special nuclear material in medicine, I guess their authority would extend to that level.

So it's only a small part and it's an anomaly of a law that is now almost 50 years old or 40 years old at least as amended. That's number one.

Number two, we all have agreed repetitively that the risks from ionizing radiation that derives by byproduct material is not unique by comparison with ionizing radiation that derives from NOARM or ionizing radiation that is machine produced, 140 KEV photon has the same capacity for ionizing whether it comes from NOARM or byproduct material or an x-ray generating machine. It doesn't make any difference, the risks are identical.

Number three, the risks of ionizing radiation use in medicine are not intrinsically greater than the risks of other things that occur in medicine. We've talked about the risk of surgery, the risks of chemotherapy. And although one might narrowly focus that on the risks to patients, and that certainly is the most logical focus when you talk about the risks of things that occur in medicine, there are public health and occupational safety implications of the rest of medicine.

We worry about the disposal of things that are

contaminated with radioactive materials in hospital settings because they're radioactive when in fact the biological hazards associated with things that were contaminated by a patient make the radiation risks pale by comparison.

We worry about the risk because of releases to the general public or releases of radioactive material into waste streams and into the atmosphere, but the public health risk of the emergence of things like multiply drug resistance streptococcus pheumoniae, and I'll spell that for you later, or the pneumococcus for those of you who don't know the correct current terminology, make the kinds of risks that we deal with with radiation also seem relatively small by comparison. Now, the public health implications of resistant bacteria and unregulated antibiotic use over the last 50 years are pretty substantial.

Consequently, based on those tenets, this committee has been on record repetitively of saying that the regulation of ionizing radiation in medicine should be conducted under some uniform set of regulations that affect all sources of ionizing radiation whether that's housed within a federal agency or whether that is somehow distributed to the states to do individually since the states, one could argue and the National Academy of Sciences has argued, are doing the lion's share of the work now.

And a second portion of our recommendation is

that whoever has responsibility for that should not have the narrowly focused vision provided by the Atomic Energy Act or some radiation control act, but should have a more broadly focused vision relating to medicine as a whole so that the tradeoffs between an extra dollar's worth of regulatory expense in ionizing radiation can be made against a dollar's less regulatory effort devoted to controlling the misuse of antibiotics, to take the example that I just took.

And I think that has been our principal that we've talked about half a dozen times, at least twice to the Commission and at least half a dozen or a dozen times at these meetings, and we've been pretty consistent in reaching those conclusions.

So we need, I think if we try to remember those principals it will help us try to understand whether our past thinking is consistent with the National Academy of Sciences' thinking. That's number one.

Number two, there is a thread that runs through the NAS report and a thread that we've talked about before and that is this issue of would ionizing radiation use in medicine be as safe as it is were it not for the NRC having regulated it to the hilt for the last 40 years. And I know Judith has raised that question repetitively. And I am reminded a little bit of the story of, I guess it's the man on the train riding through some country who has a amulet around his neck, and the

passenger next to him asks him why do you wear that amulet and he says it's to ward off tigers. And the response is, but there are no tigers in this country, and the answer is, the amulet is working.

And so in a way I think you can, one can-- I once challenged Chairman Selin to suggest that what we really needed was a randomized controlled trial where we deregulated ionizing radiation use in half the country and continued to regulate it in the other half, and then really try to find out whether the events that we are so concerned about or that the NRC is so concerned about are really occurring at the noise level as we as practitioners have suggested repetitively or whether the NRC intervention has really had the beneficial effect that the NRC wishes to repetitively pat itself on the back and say see, we're doing great and it's because we're here.

And a corollary to that is, Trish just said, well what would happen when we get the next serious misadministration that results in injury or death. And I think the one thing we need to remember is we certainly don't want to continue to have government by yo-yo. And reacting to the last bad event is not an intelligent way to govern. Unfortunately it is the way the government appears to work in the United States. And I don't know whether all the words we can shed on that are going to do much, but we should try to

remember that principal when we respond to the NRC.

Now, does anybody want to counter anything I just said as principals that I believe we have generally established and usually reached a consensus on before we go any further.

Lou?

MEMBER WAGNER: Barry, one issue I think was brought up by the RSNA in the report, and I took note of their dissention with the idea that the regulation should be under one agency for the use of radiation in medicine. They recommended or they suggested that there are entirely different risks associated with radiation which is introduced into a patient versus radiation that is machine produced. And they didn't feel that the regulation would be appropriate to be monitored by a single agency. And I just wanted to make note of that in the report.

And I think there are some important issues, although the risk of ionizing radiation are the same no matter where it comes from in terms of irradiating the body, the method of how it is introduced is entirely different in those two things and there are some very significant issues in terms of the potential risks of how it might be introduced.

CHAIRMAN SIEGEL: I'm not sure I agree with you. I mean that's the RSNA's viewpoint from the viewpoint of their constituents and the turf that they are choosing to protect.

I would actually argue that the more, the larger the component of this that is regulated by a single entity or in a single fashion, the more likelihood it is that the regulated community has an opportunity to have its voice heard.

And one problem in the past has been is that the nuclear medicine community and the radiation oncology community relative to radiology as a whole is a relatively small segment and lacks the clout, if you want to use that sort of nasty word, to have it's viewpoint be heard and get the full light of day.

So, well in fact I've made the argument on a couple of occasions that, if we applied an NRC-like regulatory schema to all of medicine, that having a couple of hundred thousand doctors involved and all the pharmacists and everything else would insure that the process would achieve some greater level of balance than it has when it's only the NRC dealing with byproduct material with a relatively small constituency of regulated, members in the regulated community, that don't have a lot of clout in the final analysis, that can't get Congress to change it for them because they just don't carry enough weight.

So I understand the RSNA's viewpoint, but yes sure machines are different, machines don't pollute the streams and the air, but the overall radiation safety issues

in the final analysis can be broken down to trying to understand what the risks are and then trying to create a set of regulations.

I mean teletherapy is currently NRC regulated and it's a form of machine produced. And so I don't know that I'm swayed by the RSNA's argument.

Lou?

MEMBER WAGNER: May I just make one other comment though. I think the focus that we should try to look for is on why the system is broke, what are the mechanisms which caused it to be broke. The issue here in regard to internally administer radiation or externally administer radiation, I have a little bit of experience with from my state because it appears to me in my state much of the regulations that come down for machine-generated radiation are just simply transferred from what the NRC recommends through internal administration. And that doesn't work. It simply doesn't apply all the time, and we're constantly fighting with the state because of the inapplicability in that area.

And I think there's a lot of issues like that which are going to be very difficult to deal with in this committee and in the future with regard to these recommendations that are important for us to address.

CHAIRMAN SIEGEL: Dennis?

MEMBER SWANSON: I think one other principal that

in fact this committee is embodied in is that there needs to be active involvement of the regulated community in the development and evaluation of regulation. And certainly we've seen a very positive approach on the NRC's part in recent years in that regard. But I think it's critical that that be one of the principals of however this is regulated. And in fact I think that's one the big areas where it got broke.

CHAIRMAN SIEGEL: Lou?

MEMBER WAGNER: Yes. I think we still have to focus on the idea of where it got broke. And I liked Dennis' comment a lot. One of the factors that I didn't see in the report, which maybe we also ought to think about, is the fact that they did allude at least in the report to the fact that the expertise in medicine to the NRC was grossly lacking within the NRC. Now, the NRC seeks recommendations from the medical community as with this committee regarding its recommendations and things, but there is actually no clout of medical expertise within the NRC itself in making and describing and enforcing the regulations.

So I think that Dennis' comment is very good. I don't see within this IOM report recommendations as to how to solve that aspect of the problem that I think we agree was broke.

CHAIRMAN SIEGEL: Jeff, do you have a comment?

MEMBER WILLIAMSON: Well, yes. I guess the

thoughts that I've had trying to read this report are in a slightly different direction. I do want to say regarding medical use, I really agree with your enunciation of the set of principals. So I suppose in my mind I find it helpful to distinguish kind of three levels maybe of regulation that we might think about.

I mean there are first of all, I suppose some general practices which are applicable to all forms of ionizing radiation, and they pertain I think largely towards minimizing the epidemiological risk of exposures of large groups of people.

So I'm thinking of regulations that would identify maximum permissible exposures to the general public, to occupationally exposed workers regardless of whether they're working with byproduct material electronically-generated x-rays, whether it be in medicine or nuclear reactors or wherever. So they're sort of core of basic safety standards which, you know, maybe in my view it would be better to have a uniform set of standards across the country rather than one state allow 100 sievert per year, millisievert per year, occupational exposure and another adheres to something else. That's sort of confusing.

I suppose the second level of regulation then would maybe pertain to the specific properties of radioactive materials as opposed to electronically-generated sources of

ionizing radiation. Namely those that when the machine is turned off go away versus those where there is some lingering presence, and that does present some different issues regarding if a source is lost or false from a controlled state and unintentionally exposes some group of people.

So there are then maybe rules and standards regarding the transportation of sources, shielding requirements, requirements on record keeping so sources don't get lost and mislaid, and so on and so forth. And that again is an issue that it seems to me totally independent of whether it's medical use or some other kind of use.

And then finally I think we come to medical use. And I really think a lot of what has inflamed the regulated community is recent attempts by NRC to get into the issue of managing quality of the treatment of patients. And I think that any kind of sort of regulatory approach that's going to focus on what seemed to clinical practitioners to be sometimes very superficial aspects of the treatment without taking sort of global view is just doomed to fail.

Either, you know, you have to come with some sort of a system that encourages and fits in with sort of the global management of the patient, and that's going to focus not just identify the patient in two ways, but is this the proper thing to be doing for this patient with this clinical presentation.

And even as physicists, you know, I have my role in checking that, but NRC doesn't recognize that as having any importance at all, you know. They're focused on relatively remote and low probability events.

And I really don't -- I guess I find it difficult to see how a prescriptive system can do that. It seems some sort of a more set of standards or evaluations or something.

But I think it's sort of the third level, maybe if we distinguish between these three levels of what's needed, maybe it would be a little easier to structure our discussion. Because it seems most of the points that resonate with me in the National Academy of Sciences report pertain to the issues and controversies surrounding the sort of third level, that is the involvement of regulatory agencies in the delivery and monitoring of treatment to patients as distinguished from the issue of safety to practitioners and members of the public.

CHAIRMAN SIEGEL: Good.

Any other comments before we continue?

Donald?

DR. COOL: I'd like to take just a moment. I was very interested by a couple of the comments here. I remind the committee in this discussion that one of the things we were looking for when we originally went out to obtain these recommendations was to get some view of how to get a uniform consistent national viewpoint.

And, Barry, you make a very interesting comment a minute ago about the effectiveness of a single entity and the voice that individual groups would have versus a variety of entities which might be out there, which is in fact the present situation now.

One of the questions that has bothered me personally about this process, about the recommendations and otherwise, is how you obtain any sort of uniform consistency as I move from one place to another. Particularly given a recommendation which would appear to fragment the responsibility in 50 different ways. Or how to obtain some consistency given that 50 individual organization states plus some Territories and otherwise.

Looking then at the different levels, because you do have a couple of different levels. One of the questions that we were attempting to ask here was the difference in levels. I think if we were to hold a long discussion we would all agree that everything that had been done in the past was by no means perfect. I will be the first to tell you that. And I am not here today in an attempt to defend any particular program. There are some things that I think personally I would significantly change even if the regulatory authority were to remain with the Commission.

If I step back out of the role of director of industrial nuclear safety, what I would like to see achieved

is a uniform consistent approach which has the right kind of focus on the right kinds of issues, issues associated with protection of physicians, nurses, those who are going to be occupationally exposed because they are using this material and they are using it for some particular purpose. In that sense you are not really any different from a lot of the other groups. The folks that walk into the power plant every day are receiving occupational exposure because they're attempting to work with radioactive material to achieve some end that happens to be a different end.

The same sort of thing happens with a radiographer or a mammographer, those who would run in a radiator, those who run a research reactor, those who prepare radiopharmaceutical. All of those are obtaining risks or accepting risks because they are working with a material to produce some particular product or value or information.

Secondly there is a general charge towards protection of the public. And one of the issues to be derived here, one of the issues which may in fact be critical in a decision of how to proceed overall is what you mean when you say public. Because there is no single public necessarily when you go out there. When I say public do I mean the patient. Certainly he is a member of the public, eh's not an occupational worker.

But that's very different from the person sitting

in the cafeteria who is probably very different from the husband, wife, significant other, kids and otherwise of the person being treated who may yet be different from the person whose house sits across the street. And the relative ambitions and approaches that we take to provide protection for those different groups.

So there are a couple of issues that you've laid out on the table that I hope you'll be able to explore a little bit more. But the consistency approach and how to achieve that, and irrespective of where that's located, it may well not be within the NRC because of the limitations that, Barry, as you've rightly pointed out, AEA gives us a very little box in which to play.

But I would hope that in going and solving the problem we would just not succeed in moving the box around.

CHAIRMAN SIEGEL: Agreed.

Lou?

MEMBER WAGNER: I was just going to ask some questions because I'm a little confused about this idea of consistency.

What we have now in place, the NRC comes up with its recommendations. Now, agreement states have to follow them. But agreement states can deviate form them as long as they're more restrictive, which in many cases they are. So we don't have a total uniformity of regulations across the board

in the first place simply because that's in force. In my state we have more restrictive rules in some cases than what the NRC has.

CHAIRMAN SIEGEL: Let me interrupt for just a second.

MEMBER WAGNER: Yes.

CHAIRMAN SIEGEL: That level of consistency though only applies to byproduct material.

MEMBER WAGNER: Of course, but then my state does what many other states do is take those rules and apply a narrative.

Of course, and the way things would work within the IOM's recommendations is that you would have a federal agency which would make recommendations for uniformity, and the states would have the option in that case of adopting or not adopting them so that instead of being more restrictive, they could be less restrictive if they wanted to. That's the only one difference that I see in all these recommendations.

But otherwise we don't have uniformity completely today because we have some places that are more strict than others.

MR. CAMPER: A comment on that, Lou.

It's an interesting comment, and I find some of Jeffrey's comments very interesting for the same reason.

In another part of my career I spent about eight

years as a consulting health physicist and medical physicist, and we had clients in about 26 different states. And what I found was very interesting. Some states did exactly what you just said, they would apply NRC criteria, either regulatory criteria or guidance criteria, to everything whether or not it was an item of compatibility.

In fact, if you look at Part 35 today, very little is an item of compatibility. However, it has transcended the lines and it gets applied.

In some cases I found variances in the ways in which regulatory guides were used. Some states required an exact commitment to a regulatory guide, and some states had variances thereof.

And what I also found was, is that while the NRC sort of puts its rulemaking process out for public comment, due process, etcetera, many times the state regulatory agencies apply things through the licensing process because of a number of encumbrances. Either their legislatures meet only periodically or there are certain procedures that they don't follow, in other words their legislatures don't have capacity to deal with.

So what the regulators do then in order to achieve what they believe to be a reasonable level of safety, is they impose license conditions. And sometimes the things that I would find that were being imposed by license

conditions were much more stringent, if you will, than the NRC's regulations.

So I agree with you totally that, based on my own personal observation as a practicing physicist, that I saw great inconsistency. And it's not clear to me what level of consistency that we have today at all in fact.

CHAIRMAN SIEGEL: Sure.

Bob?

MEMBER QUILLIN: Let me give a perspective from the state's point of view. Just so everybody understands when the NRC promulgates a regulation, they establish what they call a division one, two, three, four, whatever it is, level of compatibility for that regulation.

I don't remember these exactly, but basically division one says it would have to be exactly the same as the NRC regulation. Two says you have to be essentially the same. Three is sort of optional. Then there is a level in there where only NRC can regulate that. And then five is really open to whatever you want to do so to speak.

So the NRC sets this level of compatibility and then the state, agreement state is expected to enact a regulation which matches that NRC regulation exactly or essentially the same, etcetera.

In our particular state, just as an example, our state statute says that our regulations have to be the same as

the suggested state regulations. That's the SS regulation for control of radiation. And unfortunately what we face is that the suggested state regulations take some time to develop and sometimes the NRC regulation time frame, which the NRC gives you to implement this regulation, comes due before the suggested state regulation ever comes around to being, so we have to adopt a version of the federal regulation depending upon the compatibility in a time frame which is such that the suggested state regulation has not been developed yet.

There's been this historic problem of delay and development of the suggested state regulations.

Suggested state regulations go across the board. They apply not only to radiation medicine, but to x-ray, to natural occurring radioactive materials, x-rays in the medical settings, x-rays in industrial settings, etcetera. When the suggested state regulation process development occurs, they try to bring in obviously the state people who have some knowledge in this, but also federal people and in some cases go outside government to participate in this process and add depth to it.

I hate to volunteer anybody, but Dick Gross from the FDA is here and he's been participating in this kind of activity for many years and probably can tell you more about it than I can.

But it's a long involved process. We have, one

of the things that we have at the state level that the federal government doesn't have, for example in Colorado when we have a rulemaking process, we have a public hearing on that which anybody can get up and say whatever they want to say. If it's a significant change from what we proposed, the process starts all over again basically.

And even after this process is done and the rulemaking board is agreed with the rule, it goes before a legislative council. The legislative council has a crack at it to see whether they think the rules is within your legislative purview and intent. And if they disagree with that, then you have a hearing before a legislative committee, which you'd normally lose, but anyway you can try. I've tried it twice and I lost twice so that's why I know.

But anyway, in many states the process is much more open and much more involved than it is at the NRC level rulemaking. And there's much more involvement in trying to resolve issues before it ever gets to the public hearing stage and NRC level. But you know we've got all these other hurdles to jump through beyond what the NRC has to jump through.

So rulemaking at the state level is not an easy process. It's a long involved process. And you're looking at the NRC over your shoulder to see the compatibility issue, you're hoping that the suggested state regulations are in place so that you can use them as a guide, but they may not

be. And sometimes you just have to go ahead and act without all these things behind you.

CHAIRMAN SIEGEL: Let me ask a question, Bob, before we take a break in a minute here, and it will help me develop something later. How did Colorado do it's bit with the Medical Quality Standards Act, what kind of hoops did you all have to jump through to get a program in place and to create any special Colorado provisions of that and how complicated was it?

MEMBER QUILLIN: Well, I can tell you that we are one of the states that is --

CHAIRMAN SIEGEL: I said medical and I meant mammography?

MEMBER QUILLIN: Oh, mammography?

CHAIRMAN SIEGEL: Yes.

MEMBER QUILLIN: I'll just tell you that as far as the quality management program, we have treated that with benign neglect. We never enacted that particular regulation even though it's a compatibility issue.

CHAIRMAN SIEGEL: So shouldn't he be imprisoned right this moment since he's already past due? I actually meant --

DR. COOL: That's the subject of another discussion off the air.

CHAIRMAN SIEGEL: I actually meant, tell me about

Mammography Quality Standards Act. I want to know what Colorado did.

MEMBER WILLIAMSON: Before the Mammography Quality Standards Act, MQSA, went into being, we actually had a movement in Colorado to try to tighten up some of the mammography issues. We had already regulated the equipment issue so that the equipment part of it was taken care of.

But the movement was in Colorado was to try to regulate the radiographer who actually, the mammographers, who actually performed the procedure because of some questions about qualifications there. So we had a statute in place which we were implementing which required that mammographers actually passed the ARRT exam to perform this.

We were not regulating the position part of it at all. The position part of it was not regulated. So when MQSA came in we didn't have that much more to do because the ACR certification process, the regulations we already had in place other than really to negotiate with the FDA to perform the inspections and then to start doing the annual inspections required by the act. So it was a relatively painless project to get into in our particular state.

CHAIRMAN SIEGEL: Was it painless in Texas, Lou?

MEMBER WAGNER: Absolutely not. The state of Texas decided to enact their version of MQSA before MQSA was enacted. And now what we have in the state of Texas is we

have to follow both MQSA and state of Texas rules, sometimes which are in conflict, and it becomes a major issue for us.

I'll give you an example. The state of Texas says that we have to perform monthly phantom tests. The rules within the regulations right now on those monthly phantom tests within the state of Texas follow the old recommendations of the ACR. The new recommendations of the ACR are entirely different. The problem is now we've got two sets of regulations, both of which are in conflict. And I value what the state of Texas tells me to do in that regard, I'm actually outside the practice of medicine, standards of the practice of medicine.

This is where problems start really developing with state's issues versus national issues. And I think there are things that we have to think about. I don't know what the solutions are. I find that when the state has made up regulations and come with the recommendations from apparently the CRCPD, in many cases these regulations have been absolutely ludicrous.

An example, the state proposed a regulation that said you have to check your focal spot on your mammography machine and, if the focal spot gets smaller by ten percent, you have to change the x-ray tube. In other words, if the image gets better, you've got to throw it away.

There are so many things that go on like this

that it really gives me great trepidation to think of the states.

CHAIRMAN SIEGEL: How often does the focal spot get smaller though?

MEMBER WAGNER: I've seen it once.

CHAIRMAN SIEGEL: Okay.

MEMBER WAGNER: I've seen it once. It turned out that the filament burned out and then rewelded.

But things like this occur and it does give me great trepidation to think that the IOM has given, passed over such authority to the states without performing an investigation into how good are the states doing themselves. And therein lies to me a big problem. I'll be anxious to hear what the IOM has to say in regards to what they've done with that.

CHAIRMAN SIEGEL: Dennis?

MEMBER SWANSON: I just wanted to comment on Dr. Cool's concerns regarding a uniform standard of occupational and public exposure limits and uniform standards of patient care.

With regard to uniform standards for occupational and public exposure limits, I think I'm in agreement that there needs to be some kind of a uniform national standard.

With regard to patient care issues, let me present an anecdote. Let me present an anecdote. If I look

what goes on in pharmacy, we have a national association of boards of pharmacy. The NABP develops model rules and regulations so it's sort of synonymous with the role of CRCPD. The state boards of pharmacy can adopt those model rules. They can adopt them completely. They can adopt parts of them. Or they can ignore them. Being somewhat of a transient individual, I've had the opportunity now to work in four different states as a licensed pharmacists. Each state has had its own set of pharmacy rules and regulations that differ in a prescriptive manner from one state to another one. But, I can tell you, in all four states, the qualify of pharmaceutical care does not vary. Even though the prescriptive rules and regulation's different.

So, I'm not sure that that uniform standard of patient care is as much of concern as it relates back to specific regulations as what you might think.

CHAIRMAN SIEGEL: Judy, you have a comment?

DR. STITT: Yes, I'm sort of struggling with it but let me go ahead and just put it on the record.

As a physician and a cancer doctor, I deal primarily with women who have breast cancer and using radioactive isotopes for treating gynecologic cancer. So, I hear our radiologist growl about the mammography rules and then I think you know nothing compared to what we've been living with for all these years with isotopes.

But in looking at, and I understand what the diagnostic radiologist, looking at the medical viewpoint, when they're talking about the mammography regulations. But my view, and this, again, my very own interior view of what the mammographers have to put up with, really talks about the machine qualifications, inspection. And when I try to look at the QM rule brachytherapy, there are some of those issues. But I think that that has really moved into the practice of medicine to a far greater extent than any other aspect of medicine or ionizing radiation.

And that's one of the things that I think maybe has caused some of the comments in this report is that particular aspect of this very small part of ionizing radiation. And then that new extension of here's how you're going to practice medicine. Because I think a lot of that rule comes down to it.

And again, in trying to compare it to the other part of the work I do which has to do with breast cancer and mammograms, I think they're both regulatory sorts of issues but I think they were set up differently and they're carried out differently.

Just some food for thought.

CHAIRMAN SIEGEL: Why don't we take the scheduled 15 minute break.

(Whereupon, at 10:10 a.m. a brief recess until

10:33 a.m.)

CHAIRMAN SIEGEL: We are now back on the record.

The next order of business is for us to decide how we want to proceed. And let me -- two thoughts. One is, first of all, for us to go right into question 1 which was, do we agree that the preferred alternative picked by the National Academy of Sciences before we've heard from the National Academy of Sciences seems a little bit unfair.

So, I'm going to suggest that we defer that question until we've heard from them early this afternoon. And then we can, perhaps, after we've heard their thinking a little bit more clearly, we can attack that question.

The other thing it seems to me as I've listened to the discussion this morning and as I read the report, and I'm sure all of you have this concern, that there are some apparent inconsistencies in the recommendations that, as Trish pointed out, if Congress doesn't do this, then you do this. And please do that. But no mechanism for the transition is provided.

It really does seem to me in a way that the fundamental underpinning of the National Academy of Sciences recommendation, principle recommendation, has to be some action by Congress to change the regulatory schema. And in the absence of that, it seems to me much harder to understand how the NRC, given the law that it currently administers, is

going to make some of the broad sweeping changes that the National Academy of Sciences recommends.

So, I thought what we might want to do now, but I'm open to suggestions, is to try to look at those questions that are least dependent on Congress doing something and most dependent on the NRC taking whatever actions it can take of its own accord.

DR. STITT: Could I ask a question that relates to what you said?

CHAIRMAN SIEGEL: Sure.

DR. STITT: That is that this court has to go to Congress, or that's the primary way to make a change. But how does that happen? Does Congress have to do -- to respond to this?

CHAIRMAN SIEGEL: Of course not.

DR. STITT: That's what I would assume. So tell me -- is there anybody here who can tell me more about that particular gap? I do not understand.

MR. CAMPER: Well, the recommendation to the Congress is that it would enact legislation that would change the authority of the Nuclear Regulatory Commission. Now, that could happen one of several ways. Either a congressman or group of congressmen could read the report, could become interested in and agree with the findings and recommendations, and could pursue initiating legislation. Another avenue would

be that individuals or organizations might attempt to bring to the Commission -- their congressmen the recommendations and try to develop -- stimulate an interest in their congressmen, or group of congressmen, or senators, to initiate legislation.

One of the things that makes it difficult, I think, in terms of the congressional action is that our organization has oversight by several congressional committees which is always complicated, not only for this particular type of legislation but for any legislation when you have multiple oversight committees involved.

But generally, it would be one of those things. Either a congressman, or senator, or group thereof, would take an interest in the report and would decide to pursue the recommendation. Individuals or organizations would capture the attention and interest of their congressmen and would advise, suggesting that they pursue and that would happen. It's hard to say just how that might play itself out.

DR. STITT: What's the likelihood that no one would take any interest in this? Or would prefer to let it sit? Is that at all possible? Is it possible that no one would want to take this to Congress and it could sit there quietly?

MR. CAMPER: Well, it would be -- I would be very hard pressed to comment as to what Congress might or might not

do. I mean, I can --

DR. STITT: But is it possible?

MR. CAMPER: I can venture my own personal observation. That's all that it is. And that is that this is an election year and we are involved in big issues such as budget issues and so forth and so on. I don't see this being high on the scope of attention, frankly, in Congress.

Now, but then again, one never knows.

Marjorie was pointing out to me another thing that could happen in Congress is, and I was -- my comments to you were backwards. What would Congress do? What would it initiate? Another way that Congress could pursue action is that the Commission could go to the Congress and suggest legislative change to the Atomic Energy Act that would remove the agency's authority for byproduct materials as it relates to medical use, medical to be defined getting back to some of the earlier comments about research versus totally medical human use. But that is another way it can happen.

DR. HOLAHAN: The report has been provided to all NRC's congressional oversight committees. So those committees, or the chairman of those committees, are aware of the report.

CHAIRMAN SIEGEL: Jeff?

DR. WILLIAMSON: Yes, I guess along the same lines, I, too, would like to ask a point of information. The

sort of B conclusions or recommendations that the report has made that, for example, you relax immediate enforcement of the quality management program and the misadministration reporting rules, and so on. What's the process for doing that and what level of control do you have for, without legislative action, basically retracting large parts of Part 35?

MR. CAMPER: In answering that, let me try to just pick up one more thought on this other question. You know, the question was, what might Congress do. You know, the Commission, as Don explained in his opening comments, has several pathways open to it. I mean, it could, for example, decide that upon review and listening to the National Academy of Science during its report, that they've heard enough and they want to move to truncate the involvement of the agency, and could do so through the legislative approach, recommendations to Congress.

It also, the Commission, that is, could also decide that it may decide to dramatically modify Part 35. And go through a rulemaking process to effect that change and go through the normal public comment gathering probably facilitated meetings, et cetera.

There's another pathway that Trish covered in her opening comments, too, and it's under your question 3. That the Commission could consider. Now, that calls for a very strong litmus test in that the action would necessitate a

prior finding by NRC that the exemption of such classes, qualities, or users of such material would not constitute an unreasonable risk to the common defense and security to the health and safety of the public. That's another pathway that creates a possibility that could be pursued.

Now, getting back to Part 35, 32, and 33 of the quality management rule. That's a little bit easier to deal with in terms of action the Commission might choose to take. We have been for the last two years now gathering data as we inspect the implementation of the quality management programs by licensees. And we have compiled a database that demonstrates all those findings. It talks about the numbers and types of violations, how the licensees were meeting or failing to meet the requirements of the rule, and so forth and so on.

One of the things that we want to do is, in the very near future, from the staff's standpoint, and again, I call upon this so much because as Don pointed out earlier and I think Trish reiterated, we have presented to the Commission a staff plan for how to deal with this. And we now as a staff await feed back from the Commission as to what it thinks of the staff's plan. Does it want to pursue that. And we could talk about what the staff's recommendation is. But, again, qualifying that with the fact that the Commission has to make the final choice and tell us how to proceed.

But we have been gathering this information on the inspection of the QMTI. We want to go through an analysis of what it has shown us. Currently, the temporary instruction, we call it a TI, associated with that rule is due to expire in August of this year. Amongst the things that we have been pondering is to try to do a prompt analysis of what we have found as we have inspected the rule, see what those conclusions are, and perhaps move to truncate the inspection, the TI, of the quality management rule. But that's something that the staff has a fair amount of leeway in suggesting to the Commission that it do.

Amongst the options that the Commission could consider would be to pursue some prompt rulemaking, if such a thing exists, to eliminate the quality management rule, or components of the quality management rule. Another possible option is, and this again is a bit more manageable and controllable by the staff in terms of how it might proceed to make recommendations to the Commission. We could do things such as exercising enforcement discretion as it relates to the quality management rule.

The truncation of the TI. In other words, ceasing to inspect the implementation of it. Saying we've seen enough. We've inspected enough facilities. We've learned enough. We know what the outcome is. We know how many misadministrations are occurring today as compared to how

many misadministrations occurred pre-QM rule, and we know what the finds are. And we therefore don't think that the continued resources by licensees or by the agency warrants that activity. Those kinds of movements could be made, or recommendations could be made, to the Commission.

So, there's a spectrum of possibilities as it relates to the QM. And it's far easier to deal than the question, of course, at large.

CHAIRMAN SIEGEL: Lou?

MR. WAGNER: Bob Quillin, could you give me some insight as to why the state of Colorado has taken its posture regarding the QM rule? What about the QM rule does the state of Colorado find difficult to enforce or not want to enforce, or whatever?

CHAIRMAN SIEGEL: Before you answer, let me interject. That we are -- No, I'm not going --

MR. QUILLIN: Read me my rights.

CHAIRMAN SIEGEL: You've got the right to remain silent.

The direction the discussion is heading is exactly where I wanted it to go, which is that we should discuss NRC questions 8 and 9 first as things that we can discuss that the NRC can deal with that have nothing to do with what Congress does. And then we probably want to move to question 4 after that, I think.

But let's start with 8 and 9, quality management rule> How it could be changed. What's conceptually wrong with it. And as a start to that, we can begin by finding out why Colorado thinks it's no good.

Gee, is that a loaded question?

MR. QUILLIN: Colorado never said it was no good.

I'll tell you this from my perspective. And that is that I've been in clinical practice myself. I've been an NRC licensee and I'm now a regulator. So I've seen both sides of the fence.

My personal perspective was that the cost of this rule offset the benefits of the rule. The cost to the licensee and the cost to our regulatory program exceeded the benefit of the rule. And the fact that it was not justifiable. We have to do a cost benefit analysis for our rulemaking process. And in all honesty, in the past I have not been impressed by the NRC's cost benefit analyses rulemaking because we looked at it. We couldn't see it was justified.

CHAIRMAN SIEGEL: Lou.

MR. WAGNER: I would also like to state that whenever I talked to the regulators within the state of Texas, they respond with a measured element of disdain for the QM rule. So it is quite clear to me that it is not just the people who are practicing medicine but it is also some of the

regulators in the state who think that the QM rule is inappropriate. And perhaps that is exactly the issue. The cost and difficulty of implementing this rule exceed the benefits to be gained from the rule.

CHAIRMAN SIEGEL: Judith?

DR. STITT: Comment along the same line.

I was asked by the American College of Radiology to write standards for high dose brachytherapy and low dose brachytherapy. The ACR has standards for a variety of things including mammography, external beam radiotherapy, et cetera. And when I -- the QM rule bugs me because it looks like what professional organizations should be doing to set up standards of practice. And I think that's where it lies. It should reside with the clinicians, the professionals, to establish standards. This could be something that's national and then also viewed by the states. Certainly the ACR is a national organization. That's how it influences me and my bias towards it.

CHAIRMAN SIEGEL: Larry.

MR. CAMPER: Let me just share a couple of observation with you about the QM rule, having inherited that 1990 when I became the section leader for the medical and academic section and then being actively involved in a team that brought it to fruition.

I can remember vividly the criticism that was

being levied against the quality management rule. I'll never forget the time when I was asked to give a 20 minute talk at a professional meeting and I was told to limit it 20 minutes because it's a tight schedule and that's all they're going to want to hear. And one hour and 30 minutes into the presentation with 15 people behind the speaker lined up criticizing the rule, I thought, well, this is baptism by fire at best.

But the complaints that I heard a lot are the ones that are being echoed again here today. And that is that you had a low frequency of occurrence of misadministration. Something on the order of 10 to the minus 4. And yet, you're proceeding to put in place arguably what are very prescriptive criteria for what we as medical practitioners believe is the noise level for errors. And why are you doing that because it's not going to improve our performance, anyway, and these are types of things that we as professionals should be involved with ourselves.

Now, the principles of the QM rule, the five objectives, seem to have been fairly well received. I think that there was an underlying feeling by many and a lot of state regulators have expressed to me that you don't need to be doing this. This is not where we should expend resources and so forth. But the Commission felt that it did not want to remain in a watch mode. In other words, just receive reports

of misadministration, some of which were consequential. They wanted to try to do more to improve that standard.

And as a result of that, what was supposed to be created as a performance based rule, and I think the objectives arguably are performance based, was put in place. But I think as often is the case, the devil's in the details. And it deals with implementation. And I watched first-hand this process occurring. I watched it in the inspection arena. I watched it in the enforcement arena. And I'm not criticizing anybody. I'm just saying I watched the process unfold and there was a tendency towards prescriptiveness.

And I will never forget when I was visiting on the West Coast along with Sally Merchant who was a project manager for the QM implementation, and we were instructing a room full of therapists and physicists who were subcontractors of Lawrence Livermore National Lab who had the contract to review the submitted programs. And I watched this room of physicists and therapists become more prescriptive in their thinking, become more prescriptive in the questions that they asked. And the reason was, interestingly enough, and probably of no surprise to anyone, is that someone had to make the judgment call on whether or not a submitted program passed the test and sign off that this program had been reviewed.

And my observation as a regulator is that any time you have a submission of a program and then someone or

someones in the regulatory body, whether they're the actual regulators themselves or the contractors working for the regulators, have to make a judgment call. They want criteria for a pass/fail. They want something to cling to to defend their judgment, if you will. And I think that the major flaw in the quality management rule, and arguably there are a number of them, but I think the major flaw was in its implementation. And I offer that just as an observation of how, to at least some degree, that process happened,.

CHAIRMAN SIEGEL: Lots of people.

Lou?

MR. WAGNER: I think it's an extremely good point because what I see is one of my biggest problems with regulation is the following. You take a standard practice and as long as it's a standard of practice in a generalized rule, you can live by that through your professional functions. But once you take the standard of practice and make it a regulation, there becomes a zero tolerance and no flexibility. Your professionalism goes down the drain and you are now handcuffed and you can't function in various circumstances where you need to make decisions that are unusual.

And therein lies a lot of the difficult I see with the whole regulatory process and the QM rule probably is a fine example of this difficulty. There's a matter of professional function but you cannot be prescriptive about

professional function. It's not something you can write a law about and say, well, if you deviate from this, then that's wrong. It's very difficult to do that and to make that whole with zero tolerance. That's part of the problem with the regulatory process in general.

CHAIRMAN SIEGEL: Jeff?

DR. WILLIAMSON: Yes, I guess I would like to level a few -- direct a few comments to the quality management rule, too. At specific things.

I think no one would argue that there should be clearly defined written prescriptions that the proper patients should be treated. That plans and calculations should be checked. And that has been a standard of practice far longer than the existence and implementation of QM rule and I really would wonder how much it's stimulated people to, practitioners, to adhere to a higher standard of quality treatment delivery.

But I think one of the problems with it is it's sort of narrowness. It sort of pretends to be a comprehensive quality assurance program but it's not. It's focused on such specific safety endpoints. And I think one of the comments that the report, the National Academy of Sciences report, made is that it said basically regulation of safety will always be invasive if divorced from the issues of clinical efficacy and competence of the practitioners. It's also not really a test

of the quality of the program, the inspection and enforcement process. It's basically a test of your compulsiveness in filling out paper work. It is an enormous burden. I don't know where the figure for costs was come up with but I know it consumes probably 200 hours, 300 hours, of staff time in our institution simply to document everything.

And, you know, we're not punished if we violate the rule for a poor quality treatment. We're punished for not documenting it. So, it holds practitioners to a far higher level of documentation than any standard of practice in our field or any other medical field to my knowledge. So, I think that's a problem.

And I think the issue of prescription versus good judgment that Lou brought up is important. I think that physicists and physicians are not quality assurance machines and computers that go on blindly checking everything. There's a great deal of judgment called for in a particular clinical situation. When is more investigation and thorough checking required and when it's not, factors that the rule does not take into account.

So, I honestly think the sort of whole program of trying to prescribe a treatment delivery quality assurance system just isn't going to work. And maybe that's something we could discuss, what are our visions of perhaps how to best encourage this sort of thing in the field which is no doubt

the laudable intent of the rule.

I think also we need to look at, again, uniformity. This, remember, is 10 percent of the practice of radiation medicine. We don't -- aren't required to do this for the other 90 percent and it creates a real dissonance in everyday practice, in my writings and talks on quality assurance now. I used to say there were basically three basic end points for quality assurance in brachytherapy, delivering the right dose, getting the right sources in the right place for the right time, and so on.

Now I have to add a fourth goal. And that is, part of the goal of quality assurance is to minimize the liability of the institution vis à vis regulation and other sorts of legal initiatives. And that means creating sort of a paper work shield to protect the institution. And so we are having to divert a lot of resources from basically clinical care in order to survive the challenges imposed upon us by regulators and other legal forces types of liability, too.

Of course, lawsuits have to be included in this and it kind of -- I don't think it helps to sort of have to portray regulators in this sort of cynical light. That like you're now one of the bad things we have to protect patients from. And our institutions from. You're not helping us.

So, it really sets, I think, into motion a very sort of unfortunate scenario.

MR. CAMPER: You know, a couple of observations in response to your comment. My observations about our findings, if we have inspected programs, quality management programs, has been a mixed bag in the sense that I think that I genuinely believe that some programs are better as a result of the QM rule. They're better in terms of the quality of the written directives that they create. They are better in terms of the observations they make about their program and the attention they focus upon continuing quality improvements.

By the same token, I also think, though, to a large segment of the community it's been a real pain in the neck because the practitioners who are interested in creating the kinds of written documentation that you alluded to, that are interested in insuring that the radiation is administered as requested, for them it's been quite a regulatory burden.

And so, your challenge, then, with the question as a regulator, what has been the net result of the product? Now, interestingly enough in that vein, when the rule was put in place, the Commission charged the staff with coming back to it three years post rule, which would have been 1995, and giving the Commission some assessment of how the QM rule went.

We were -- we had planned to do that as part of our -- and we did give a signal during our last annual briefing of the Commission on the medical use program. But at that time, we told them that we needed to gather more

inspection findings via the TI before we could get back to them and give them more detailed findings.

Now, we would have done that this year but, of course, as we all now know, a number of events have overtaken that in the sense that we're now looking at the program at large rather than focusing upon certain aspects of the program. I think it's certainly no secret. We've discussed it previously with this committee, that there was a feeling within the management of NRC, certainly myself and Don Cool, and Carl Paperiello, and Hugh Thompson. I mean, there is a feeling amongst the management that there is a need to change aspects of Part 35, to recommend changes to the Commission for consideration in changes to Part 35.

But once again, that initiative has been put on hold as we awaited the National Academy's report. So now we find ourselves dealing with this mega issue as opposed to what to do only about the QM rule itself.

CHAIRMAN SIEGEL: Dennis?

MR. SWANSON: I think another consideration here is that the QM rule fails globally as a quality assurance program. I'd like to think that one of the objectives of the NRC getting involved in this is to receive reports of misadministrations so as to provide a database whereby we can go out and look at what causes these misadministrations, or what is associated with them.

By the nature of the reporting requirements, you've limited the number of reports of errors, thereby limiting very much your database. And thereby not providing any useful information in the interest of public safety. And I think that's a fundamental problem --

MR. CAMPER: Because of the narrow definitions of misadministrations?

MR. SWANSON: Exactly. And then if you broaden the definitions of misadministration to include everything, then you're in a huge conflict with the regulated community. That's where this all started out at.

So, it's failed globally as a quality assurance program and I think that's what we really need to get to, is actually reporting all errors and then truly taking a look at what causes these errors if we're doing our job.

CHAIRMAN SIEGEL: Yes, I mean, as a corollary to that, it goes back to something we talked about with the Commission many, many moons ago. Which was the issue of looking for the bad apples as opposed to trying to use a regulatory agency in a predominantly educational mode to really fulfill a public service.

And my biggest concern with the whole quality management rule has been the criminalization of misadministrations is the term that I've used. I mean, as opposed to following Demming's principle that each defect is a

treasure from which we can learn something and perhaps make it better for the world at large, in the case of a misadministration I can tell you that from the viewpoint of a licensee, it is not treasure to realize that you are now going to have the NRC descend upon you, occupy your resources for weeks to come potentially, maybe only a couple of days if it's not too bad. Have a large amount of written response. Have you have institutional legal counsel involved because every -- I mean, my university lawyers say the following. They say, dealing with the Nuclear Regulatory Commission is a fundamentally legal event. And it cannot be left to the medical professionals who understand the issues. When you have a problem with the NRC, it has to be turned over to the general counsel's office because we can't let you do it because you don't have the authorization for the institution to negotiate with these folks.

That's a mistake. That's not where we want to be. Where we want to be is national clearing house, best overall knowledge about problems, best overall knowledge about radiation risks, and try to foster making things better as opposed to going out and punishing the people who are doing a bad job. That's, to me, the fundamental conceptual problem with the rule and certainly it's the fundamental conceptual problem with the way the rule's been implemented.

MR. CAMPER: Yes. For the benefit of the

committee and in particular the new members, let me just shed some light on that.

Basically what's happened here is if you go back over time, you find that misadministration reporting requirements go back to 1980. But along the way they've been changed. Now, with regards to the QM rule which became effective in '92, the threshold for misadministrations was essentially doubled. And of course, the reporting threshold for diagnostic misadministrations was changed dramatically and they essentially went away because of that. And arguably, that's a very positive thing.

But what happened was along the way, as we now look back upon it and know is that, previously misadministrations started out to be a reporting of an event. It's an error in the delivery process. And when that occurs, it ought to be brought to the attention of the agency. Perhaps it has generic implications. Perhaps that information needs to be disseminated. So forth and so on.

Well, when the QM rule came along, what happened was previously most misadministrations did not result in a violation. But with the QM rule, a mechanism then was put in place for violations to occur. Now, violations do not occur in every case with a misadministration today. However, they do occur more frequently as violations than they did prior to the QM rule.

And that's because of two reasons. In the early stages when misadministrations occurred, people were failing to implement a quality management program. Later on, once the QM programs had been implemented, in those instances when a violation did occurred associated with a misadministration, it was often because they didn't follow their own procedures as identified in their submitted QM program.

So, the net result of that is, and I think this is something else that has served to further enflame the community, and it's the enforcement issue again, is that we now see violations for misadministrations as a result of failures, if you will, in the quality management program which result in events that have minimal, if any, consequence. Because, as we all know, most misadministrations are not overexposure. They're exposures that are under that which was required or requested to be administered. So, you have an event of no consequence that results in a violation.

Now, those violations, in and of themselves, don't always get to severity level 3, but some times they do. And of course, that has a very much of an inflaming aspect upon the community.

So, I think one can look at it and say, have misadministrations continued to play out of, and the reporting of them under the quality management rule, as was the original intent of misadministrations, and one goes back to 1980. And

I think that the argument can be made that no, it hasn't, because it's moved now more toward an enforcement scenario as opposed to only a reporting scenario. I mean, I've heard that complaint many times. And I think there's a legitimacy to that complaint.

CHAIRMAN SIEGEL: Dennis?

MR. SWANSON: Getting back to one of these questions, how can we improve data collection. I think it's important to note that there are in existence the FDA, USP, adverse drug reaction reporting program which is a voluntary reporting program. There's also now in existence the USP medication error reporting program. I mean, medication errors happen throughout the pharmaceutical world, not just with administrations of radioactive ionizing radiation.

And that program is in existence. How you force people, if you can do that, to report to that program, I think is a question. If any time you try to force people to do something, you're going to get in this kind of a bind, or regulate it. But, certainly those programs, to answer that question, are in place. And if we can somehow through the professional groups as supported and recognized by the NRC, encourage reporting through those mechanisms, I think we could probably get more data along the lines that we want.

CHAIRMAN SIEGEL: Lou?

MR. WAGNER: I'd like to try to make an analogy

here about criminalizing something versus having other methods of seeking change.

First of all, when you make things regulations, I have no doubt that many people's quality management went up. Any time you raise the consciousness of people for the need to do something right, you will have some kind of a response to that which is positive. So there's nothing wrong with raising the consciousness. How you raise that consciousness is another issue.

Now, there's another issue going on right now that is outside the purview of the NRC in relation to interventional radiology. There are injuries that are occurring from interventional radiology. These injuries have been reported to the FDA and the FDA has responded by taking action of recommending that people, (a) be aware of these issues, and monitor radiation doses that are received when they perceive that radiation might exceed a certain level during a procedure.

That has really raised the consciousness of a lot of people throughout the country, too. I get calls all the time from people all over the nation wanting to know more information about, (a) how do I measure dose, and, (b) could you provide some of the educational materials to me on this. And then I've gotten letters from people telling me how great it is they have this educational material and the effect it's

having on physicians.

So, it's hard to measure how effect you can have through certain actions. But this is an action whether it was the FDA does not go in with inspection people and enforcement people and try to make criminals out of the events that occurred, but rather take a more positive aspect. Make it available to practitioners. Bring it to their attention and call for a need for change, a need to improve.

Two different situations, I think both of which are having consequences. But they're handled in entirely different manners. Now, the one with the interventional work is not meeting with great resistance. It's not meeting with great resistance.

CHAIRMAN SIEGEL: Jeff.

DR. WILLIAMSON: Yes. Maybe our chairman will rule it inappropriate, but I'd like to revisit the issue of uniformity aside from the question of whether the QM rule has any effectiveness in promoting quality. And that is the basic question. Why is radiation oncology and nuclear medicine ionizing radiation treatment any different than any other medical subspecialty that does potentially lethal procedures on patients for a defined benefit? Why should the federal government be making rules relating to misadministration and quality of treatment for radiation medicine when they, say, don't for chemotherapy misadministration? What is wrong with

the current system that this particular sub-sub-area, since you're only addressing 10 percent of radiation medicine, why is it called for for special attention?

I think reporting misadministrations is one thing. I think one of the more punitive aspects of the misadministration enforcement is the requirement that of notification to the patient and/or relatives regardless of the medical implications of the event. That's surely an intrusion in medical practice that's played out in one case in our institution. It just consumed huge amounts of staff time on our part and I'm sure on your Region 3's part, too.

So, why is use of reactor byproducts called out for this special intention? What rational basis is there for this QM rule?

CHAIRMAN SIEGEL: There you go.

MR. CAMPER: Put that spotlight closer.

Well, I understand where you're coming from. Again, let me -- what you have is a situation where the Nuclear Regulatory Commission has developed a posture and a culture for regulatory approach. While the agency has its critics, it also has those who praise how it's gone about conducting its business. And by and large, I think we're often complimented on keeping the genie in the bottle by and large, if you will.

Now, when you get to the medical end of it, you

ask yourself, well, should you be applying the same kinds of vigor and approach as you're using to keep the genie in the bottle at large. Because obviously the levels of risk are quite different.

Now, in the case of the quality management rule, the then sitting commission had before it several options. It could have gone for a prescriptive rule which, if you go back in history of this particular rule, back to 1986 or so, you'll find that we originally were headed down a pathway of a very narrow and prescriptive rule. 1987, the advisory committee on the medical use of isotopes said that if you must do this, then it should be a performance base rule, if you're going to do it at all. And so then we embarked upon an attempt to try to put in place a performance base rule.

Now, performance base rules in and of themselves are an interesting concept. Just what does it mean and to whom does it mean it, and how do you implement once you have it? But, the Commission had before it several options. I mean, it could have, getting back to I think the point that has bene made either by Dennis or Lou. I mean, it could have gone the information route. It could have simply said let us put out an information notice, draw more attention. Or, let us put out some type of generic communication such as a bulletin and request certain things. Or, let us issue a policy statement of some type. Or, let us move toward a wait

and see mode, and wait until we get more data, see how things are really going.

But the Commission opted to pursue rulemaking. And, as we all know, once you go the rulemaking route, you are entered into standardization by regulation. And again, I think it is fair to say that we have always taken a fairly strong approach to regulation and subsequent inspection and enforcement. I mean, what this agency puts on the books, it will inspect and it will enforce. Unlike some other federal agencies who take a bit more of a laisser faire approach to their inspection enforcement program.

So, for whatever reason, it's easy to look back now and criticize, but the decision was made to go toward rulemaking. And as I said earlier, then you get into the devil's in the detail. While I think that we try to put in place a performance base rule with the objectives, the five objectives, I think as we continue to implement that rule and try to insure that we were getting commitments from licensees -- I mean, I'm often asked the question, for example, if it was performance based, why did you have licensees submit the program? And the reason for that was, we thought about it. I mean, we thought about it a lot. And in the final analysis, there was two reasons, really.

One is because we have operated in the posture having licensees bring to us their program and then we work

with them, if you will, or we say bring us another rock until it has the right shade of color and the right lustre, and we feel comfortable the program that is in place is going to be a reasonable and safe program.

We also asked ourselves, look, if you're going to go to all the trouble of having licensees develop these programs, don't you owe the license community the obligation of looking at those programs, of reviewing those programs. Because, if you think it's important enough to impose it upon them, it ought to be important enough to review it. So, then you get into, okay, so we decided to review them. Well, once we started reviewing them, I've already espoused some of the problems that came along as we did that.

So, I offer that as somewhat of an explanation. I hope it tells how we got where we are, at least to some degree.

DR. WILLIAMSON: I guess I wasn't asking for an explanation. I mean, I've been part of some of the history of it, too. But what's wrong with the quality management rule is it's an anomaly. That's what my basic point was.

MR. CAMPER: I understand.

DR. WILLIAMSON: It doesn't seem that there's a fundamental deficiency in medical practice associated with reactor byproduct materials or maybe it's not clear to me there isn't any area of medical practice with such an enormous

error rate that it calls for global federal regulation of how treatment is delivered in the various medical subspecialties to patients.

And one has been singled out, not even a whole one but 10 percent of one. You can -- It's one of the fundamental contradictions in the approach.

CHAIRMAN SIEGEL: Do you have a comment? You looked like you were --

MS. BROWN: I had a thought but I --

CHAIRMAN SIEGEL: Going to let it slide for a moment.

MS. BROWN: I will.

CHAIRMAN SIEGEL: Well, in terms of conceptual problems with the QM rule, I think we've expressed a few thoughts about that.

Theresa?

MS. WALKUP: I want to interject something on somewhat a more simple level. But those of us that work with patients each day know that especially those that are dealing with cancer have faced death at some point in their treatment and what this QM rule and the way that it -- when a problem does occur and with the criminal aspects, and the way the media gets a frenzy over all this, we have to deal with those patients that come in the next day with a bigger problem. And I think we need to realize it how it effects the patients and

the public as a whole on how we handle these issues.

I don't know if I'm getting my point across. But it does affect them and I think sometimes in a negative way. I just wish there was a more kinder, gentle way to handle these problems.

MR. CAMPER: I think one of the things that I find disturbing as I listen to some of the comments that are being made and I've heard the term criminal used a couple of times now. You know, we really don't impose criminal sanctions as a result of the quality management rule. I'm unaware of any criminal sanction that we've imposed.

I think what happens, though, unfortunately, is that licensees, because of the inspection/enforcement process and the fact that some levels are imposed, they feel as if they're being treated as criminals. I mean, as a regulator, we're not treating them as criminals literally by definition. But the certainly feel that way. And that's somewhat disconcerting as a regulator to hear that.

And it certainly wasn't the intent, I'm sure, of that particular rule. And it certainly isn't the intent of the inspection and reporting process. But the fact that people feel that way for what are arguably minor mistakes, just the same, is disconcerting, whether or not that was the intent or the reality, in fact.

CHAIRMAN SIEGEL: Marjorie just reminded me the

same thing that Larry said, which is that an NRC violation, for the most part, is not a felony. And so, the term criminalization is perhaps an incorrect term. However, standing on my First Amendment rights, I would point out that it feels like criminalization much of the time. And that really is the point I was trying to get across. Not that the NRC is treating the people who do this as felons, but rather that it does sometimes feel that way.

So, the conceptual problems with the rule, I think as this committee has said many times, and this committee is in fact on a record at a meeting at the Sheraton Reston, I recall, of saying you ought to trash this baby before you put it out on the street with a couple of abstentions and one not contest or something like that.

The conceptual problem was the rule took very good principles and converted them into a very awkward structure that was much more complicated than it needed to be and then people who tried their best to institute the principles found themselves getting stuck becaUse they had written something in a strange way in their own plan and then they found they were being held to details that they hadn't expected that they were going to be held to. In part, because they didn't understand what they were putting down on paper and they created an awkward scenario.

I've recounted the fact that we initially felt

like really good guys and we extended the rule -- the plan to include those things that it didn't have to include like all diagnostic administrations and non byproduct material. And then we realized that we were committing ourselves in a way, in effect contractually, to something beyond what the NRC required. And so, in a rather silly way, I went back and revised the plan and weakened it to make it a non-NRC inspectable plan even though what I end up doing in my practice is essentially the same thing. I just had to divide it into two documents, the NRC inspectable document and the non-NRC inspectable document. And Jeff does the same thing in radiation oncology. And in a way, that's kind of silly.

If, as I've said in the past, if the NRC had just said certain kinds of activities require the direct involvement of the authorized user, that that in a way would have met the objectives of the quality management program at least for nuclear medicine, and I think largely for radiation oncology, it would have solved the problem of people coming in and getting doses of I_{131} for whole body scans when in fact it was a bone scan was order by simply requiring that if you give 5 millicuries of I_{131}, an authorized user has to be the one who makes that order. That would have been a relatively simply prescriptive thing which I know an ACMUI and a former life argued against, but that relatively simple thing would have addressed an obvious cause of several past problems that the

NRC, based on its national perspective of looking at incoming data said, we've seen 25 events and this is clearly the route cause of those 25 events. Here's a relatively simple solution.

So, one simple approach would be to -- not a simple approach. One approach would be to convert the existing quality management rule to its minimalist prescriptive components, those that were there at the starting gate. And to in a way, perhaps, expand your data collection activities so that you get a broader group of data to allow you to have a national perspective. But then relax what you do with the data until you're convinced that there's a problem that really needs national solutions, again so that we don't have the government by yo yo approach that I alluded to before.

One Indiana, Pennsylvania event doesn't mean that we need a rulemaking. It simply -- and that was a case where a standard of practice wasn't being followed independent of NRC rules that were or were not in place.

MR. SWANSON: And if I can emphasize?

CHAIRMAN SIEGEL: Please.

MR. SWANSON: Critically take a look at if you're going to expand your data collection of doing it through an independent agency such as the USP where the program's already in place, which then takes you directly out of the loop. But

you can certainly still have the outcome of that data as far as taking a look at the types of problems, the causes of problems, et cetera. Which then takes you out of a direct policeman, direct involvement with it. And as I said, the program's already in place.

DR. STITT: And along that same line, the AACM and the American College of Radiology, have standards, professional standards, that are very useful along that line.

CHAIRMAN SIEGEL: Jeff?

DR. WILLIAMSON: Yes, I would also say it would greatly help data collection if it could be dissociated from the concept of harm to the patient and the need to report it to the patient, and so on. If you had sort of a clear definition of on technical grounds what sorts of events device failures, computational failures, that you were interested in, those could be reported and perhaps have some other category for patient, those events that have a potential for patient injury.

CHAIRMAN SIEGEL: Yes. The other -- A conceptual problem with the rule that we've talked about numerous times is the patient notification issue. And this advisory committee repetitively has said that patient notification, as currently constructed, is wrong headed. There's been some minority opinion occasionally on that.

But that I think the National Academy of Sciences

actually made a relatively straight forward recommendation in that regard, that the NRC simply be told whether or not the patient was notified and be told the reasons when the patient was not notified. But not requiring that the only circumstance under which a patient not be notified is where doing so would cause harm and then forcing the case where you have to prove that harm would in fact be caused. Which really becomes a terrible, terrible judgment call. And we've recently visited some events in this committee where that all has come to light. And I'm still very confused by that whole requirement.

So, that certainly would be one approach that would soften the quality of management programs, soften the rule, get it back to its more prescriptive elements that, based on the kinds of errors that were seen in the past. I would argue for, also, a substantial reduction in the audit functions associated with the rule. It's -- You all are in a better position to know what you're learning as a result of inspecting programs and what they're finding in audits. I certainly, in our nuclear medicine program, we look at all administrations, have found no errors.

Except, we've occasionally found some little paper work problems. We've occasionally found one check box on a form that wasn't filled out. And everything went according to Hoyle in terms of the actual administration, but

a form wasn't filled out. Now, we say, now what do we have to do exactly to -- what kind of record do we have to create to make it clear to the NRC inspector that we recognized that this box wasn't checked but there really wasn't a problem and we discussed it at a committee meeting. And in a way, that all seems like a kind of much ado about nothing when you have a program that didn't have any problems.

And having watched the much more complicated audits that Jeff has conducted for brachytherapy and until we trashed our Cobalt 60 machine, for teletherapy, I think the problem is magnified by a factor of 10 with regard to radiation therapy because the number of placed in the medical record where the check mark might not have been made is so much greater in an in process, multi-component brachytherapy. And even though, in the case of radiation oncology, the results may be in the chart but they somehow didn't get transferred to the NRC form -- not the NRC form but the form that was constructed as the inspectable document for the NRC.

So, I think the audit function should be relaxed. I'm not prepared to say exactly to what level of detail it should be relaxed.

Other comments on this general theme?

Lou?

MR. WAGNER: Well, I think we haven't addressed one of the issues, the last sentence of item 8. The NRC were

to follow this recommendation which I think now they've heard pretty much a consensus from what's been spoken. I don't know if there's any dissenters or not. What follow up actions should NRC conduct in the event of a misadministration resulting in serious injury or death? And I'm not sure how-- I'm personally not sure how to start to address that answer because I've not seen what the NRC now does in response to that. I mean, clearly, I think that the events, if it results in a really serious injury or death, there should be some investigation. But to what level, by whom, and to what extent, I'm still fuzzy.

DR. FLYNN: I disagree with that. I'll give you an example with -- since you brought up Indiana, Pennsylvania.

When it was determined that there could be a generic problem with an HDR piece of equipment, one of the responses was that all the users of HDR equipment should have, let's say, an authorized user should be physically present. There should be an independent survey of the patient. There should be an emergency equipment standing by. And there were several incidents that occurred after that, including outside the state of Pennsylvania, including one in Mississippi where if the authorized user wasn't there, there could have been another serious complication or death.

So, I think -- I'm trying to understand what

would happen if there wasn't a, let's say, a national party like the NRC or someone else in existence at the time of Indiana, Pennsylvania? Well, I assume that the state of Pennsylvania would have inspected. They would have kept something within the state of Pennsylvania.

But what would have happened in Mississippi? What would have happened in other places where you only had 300 users but you had a federal authority that could then send out a two or three page information bulletin, not requiring a lot. Just requiring an -- that this could be a problem. A source could break off. And a few simple steps which didn't cost anybody anything to do to monitor that from happening again.

So that was a response to a serious injury. And I think it was effective.

MR. WAGNER: But Dan, I don't know what I said that you disagreed with. You said you disagreed with something. What was it I said that you disagreed with?

DR. FLYNN: Well, I thought you were saying that you couldn't think of any instance where the NRC had followed up on a serious --

MR. WAGNER: Oh no, I'm sorry. If --

DR. FLYNN: -- administration or death whereby they were able to prevent, let's say, the occurrence of --

MR. WAGNER: No, I didn't say that. I didn't

mean to say that if that came across. That was not my intent. My intent was to get us to address the issue and to figure out what should be done and by whom. To what extent should be an investigation into this and what should be the actions. That was just a question. Like I said, I was fuzzy as to what we should do. I really didn't know.

And I think the past history there can teach us a lot as to what those recommendations should be.

MR. CAMPER: Let me try to clarify something from a process standpoint. It's interesting as I read the question which, of course, flows from the recommendation, and it's this idea of discontinuing the inspection and enforcement of 35.32 and 35.33. By enforcement, as written, I assume that means don't require it.

Now, what happens is the following. We have misadministration events defined in 35.2. We have reporting requirements in 35.33 which capture misadministrations. And there's certain time lines for notification to the agency and so forth. Well, when these events occur, we then have a process for dealing with them. We have a management directive, a .10, which deals with medical event analysis.

And in the case of misadministrations, and depending upon the severity of misadministration, we then follow the procedure set forth in the that management directive. And in some cases, depending upon the severity of

the event or events, it can also trigger another process that we have which leads us to the AITs, the augmented inspection teams, or the IITs, the incident investigation teams. So, it's not clear to me, unless you don't have reporting of misadministrations in 35.33, why we wouldn't continue to conduct the same types of reactions to misadministration events, particularly more significant and severe ones, as we currently do.

But, now, obviously if you lost the reporting requirement, we would not have an awareness and therefore could not in turn react to it following the guidelines that I was touching upon.

CHAIRMAN SIEGEL: Jeff?

MR. SWANSON: Well, I guess one way to answer the question is, what should the federal government do if a surgeon operates on the wrong patient, what should the federal government do if five times the dose of prescribed chemotherapy is given a patient? Now we come back to the fundamental issue, I guess, of just what is the role of the federal government, or state government for that matter, I guess, in regulating this particular aspect of medical practice.

CHAIRMAN SIEGEL: So we need to know who are the Jeffersonians and who are the Hamiltonians around this table to try to figure out which direction we wish to go.

No, I mean, your point is well taken, Jeff. And that's the point that we've made repetitively. In a way, even though I don't want it, the most logical thing to do is to have the medical regulatory commission for all of medicine that has a set of rules that say this is the way that surgery has to be practiced and these are the expectations. And this is the way drugs have to be administered. And when there's an event, you go out and investigate it, and you disseminate information when you find generic problems.

But that's not the way the United States has evolved its health care system, rightly or wrongly. Should-- is there anything special about ionizing radiation that warrants this level of regulation. And my answer has been no. But on the other hand, I think the NRC, or whatever agency takes over that function, can serve a very useful purpose as a national clearinghouse of data. I think having an independent group of individuals come in and look at a serious event and try to evaluate what happened can in fact result in important information being generated, lessons that can be learned.

And then the question is, is what you do with the lessons, is do you create a bunch of new rules or do you put out an information notice, or an alert much as the FDA would often do when they see an event like this and don't frequently go to a set of new regulations. It's only when something really gets much more serious that new regulations devolve.

And that, I personally would not argue for you losing your information gathering capability so long as you remain in the middle of this process.

I've argued all along that if we could dissociate the information gathering from all the rest of the horrendous stuff that happens when you report a misadministration, that we would be served much better by the overall quality of the information that comes in. BecaUSe, in a way, the lawyers would be out of the loop. It would just be professional health physicists talking to medical professionals and health physicists about what went wrong without the layer of lawyers in between trying to make sure that people's liability is not being jeopardized by the discussion.

MR. CAMPER: Well, you make a good point in this. I think it goes beyond just the question of whether you're a Hamiltonian or a Jeffersonian, as you're pointing out. It really has to do with ionizing radiation. Because arguably, I mean, I think I can make a convincing argument that the states also, not just the Feds, but the states also apply standard to ionizing radiation in medicine that they don't apply to other aspects of medicine. And that surveys and reporting requirements, and so forth, are in place that you don't see with anesthesiology or chemotherapy, or other modalities that have just as much potential, if not more, for harm.

CHAIRMAN SIEGEL: But to what extent did the NRC

contribute to that? I mean, these two processes were feeding on each other.

MR. CAMPER: Right.

CHAIRMAN SIEGEL: And although the states may have got in first in the early '20s with some minimalist regulations, certainly the existence of the Atomic Energy Commission and then subsequently agreement state programs that required adequacy and compatibility had a lot to do with the shape of the state process.

MR. CAMPER: I agree, that is a factor. Of course, other factors, public perception. Public expectation, be it valid or not, there is a certain expectation which has been generated in the public about the demon ionizing radiation. And as a result of that, there has been a set of expectations which have evolved over time.

DR. WILLIAMSON: Well, I don't want to put myself in the Jeffersonian or Hamiltonian box. I brought it up because I honestly think this is the thought that's -- the premise that's behind the committee that wrote this report. I mean, they're really saying, look at this way. Look at it rationally. Why is this being singled out? That's my read of their basic frame of mind.

I guess the regarding inspection of things incidents, I would have to agree, really, with Barry. I think it would be -- it's useful whenever there's a serious incident

of sort of generic importance that involves lots of different similar devices or practices across the country from sort of a practical point of view. It's a real service to the community to have somebody go there, independently investigate it, and disseminate the information regarding this incident to all users regardless of sort of what bureaucratic jurisdiction they fall under vis à vis radiation protection.

The final comment is my comments are directed to the medical use, medical practice restrictions. I'm not really directing my comments towards basic occupational -- public and occupational health and safety standards, transport of radioactive material, and so on.

CHAIRMAN SIEGEL: A moment's silence. Wow.

Have we covered question 8, more or less?

MR. CAMPER: Well, there is one. What would be the rationale to discontinue without revocation of the rule and what is the urgency? What is the necessity for immediate action as opposed to adjusting the QM rule, if you will, through a normal rulemaking process that might also adjust Part 35 at large? The academy recommends that we do this immediately.

CHAIRMAN SIEGEL: Discontinuing inspection and enforcement so long as the rule is in place seems unlikely to me.

MR. CAMPER: Well, it raises a number of

interesting and difficult questions.

CHAIRMAN SIEGEL: On the other hand, changing what you do with the information is something you can decide to do internally without a lot of major procedural change. I mean, you could continue to inspect as a way of gathering data because inspection is one way you gather a fair amount of your data. But, with the focus of trying to use the information primarily for improving your database and creating better information dissemination about what problems you're finding in the world at large.

MR. CAMPER: Well, certainly we can -- you are correct that we can adjust inspection procedures. We can adjust enforcement activities. In the case of this rule, most likely, we would want to have any such adjustment go by the Commission in receiving -- and receive its approval. Due to the nature of this particular rule, the controversy associated with this rule, a previous override of OMB by the Commission and it relates to this rule, to get the buy in or the endorsement of the Commission as opposed to a staff or management adjustment in inspection procedures.

But again, the specific question of what is the immediacy? What is the rationale for the immediacy in doing that as opposed to -- I mean, clearly the Commission could choose to do it as a show of good faith, if you will, to the community and to the National Academy. And say, we've heard

this specific complaint. We have three or four years of data now and we've analyzed that data. And we believe based upon that analysis and findings, so forth and so on, the number of misadministrations really hasn't changed a lot. There's some events going on now that may change that number. But at least thus far the number of misadministrations haven't changed a lot. Roughly it's about what it was, give or take a few cases as pre-rule.

But that aside, what other rationale could there be for immediately pursuing as opposed to pursuing an adjustment to the rule or a review and critical assessment of the rule through a typical public process associated with rulemaking? Particularly if we were doing facilitated workshops and that type of thing.

So, are there any thoughts as to why the immediacy of it?

CHAIRMAN SIEGEL: It's hard for me to get into the head of the National Academy of Sciences panel, but my guess is that their thinking was that since this has been a focus of so much of the problem, that addressing this problem first is one way to demonstrate that there is in fact some action occurring.

They make the argument, and we also make the argument, that this rule probably hasn't had much real impact. And that it's created a lot of work at a lot cost and probably

hasn't really changed the numerator drastically. And so, that if one subscribes to the fact that this is a rule that really wasn't necessary in the first place, that this was a rule that probably hasn't accomplished anything substantive in terms of its ultimately objective, mainly reducing the number of misadministrations in the second place.

If you further argue that the ACMUI recommended that this rule not be put in place. And if you also argue that the OMB said the rule was not consistent with the paper work production act, then you could make an argument that immediate either withdrawal of this rule or immediate relaxation of its implementation and enforcement would be an appropriate thing to do as a first focus of something that obviously has riled up the medical community. And I know we've been talking about this for six years now, or ten years, or 14 years, or whatever it is. But certainly we've been talking about it at this table or its equivalent for six years. And so, that would be the only argument, I think, for doing it immediately.

Will much change in the country? Will there be instantaneous financial savings? There will be some savings in audits. We've all have done all this work about creating these cockamamie plans. And so that's there. You can't take back the effort we've put into those.

That would be my principal argument for making it

immediate.

Other comments, folks?

DR. STITT: I've got a comment. Just when you read and see over and over again the report comments that make the statement, equal treatment of all ionizing radiation would be a sensible national policy, and then they reiterate that in some different ways. Consequently, unequal treatment of different sources of ionizing radiation in medicine can be construed as illogical if not counterproductive. And it comes down the QM rule in that those particular types of isotopes are being treated unequally and I think some immediacy would be a show of good faith certainly is one of the stumbling blocks in the practice of medicine.

And if you want to look at it from a little different perspective, the point that Judith is here to make sure we don't forget, the individual who thinks that they are being protected or they are being kept safe in some fashion while that's not necessarily the case. As an individual in the community, we have a set of rules that relate to certain types of isotopes and not to others.

And so I think that the policies really relate in a very incomplete fashion and inconsistent fashion. So that the public should not think that things are being relaxed. And in fact, it's a very inconsistent approach to start with. And the way it came from is, as for Jeffrey's question, nothing

that the NRC made up. It was established many, many years ago. It's based in history.

MR. CAMPER: Interestingly enough, your comment, Barry, that we've already developed the programs, and so forth and so on, and therefore the cost of that and the burden of that has past. Interestingly enough, we recently had to do the renewal of the information collection requirements associated with the QM rule for OMB. And the mainstay of the cost of the rule over the next three years has to do with implementation of the rule by the agreement states.

As Bob pointed out, Colorado has -- I forget the exact words he used -- but Colorado hasn't chosen to implement the rule. It turns out about 16 or so of the agreement states have. 12, 13, have not or are in various stages thereof. But when we originally projected the cost for the rule, the assumption was because of the three year implementation by the states because of the compatibly requirement, in other words, they should have implemented it by 1995, turns out a large percentage of them had not. If one looks at the cost of the rule in the next three years, you find that the majority of that cost is imposed upon agreement state licensees and agreement state regulators to review said programs.

And my point is that in terms of the immediacy argument, if one assumes that the points that have been made are valid and so forth, then in addition to that, you could

appreciate a substantial cost savings.

CHAIRMAN SIEGEL: Go ahead, Dennis.

MR. SWANSON: I was just going to say. I think you have a tremendous opportunity here to tie your analysis of the cost with the requirement that the agreement states have to adopt this with your review of the effectiveness of the program to come up with a decision that it's not as cost effective a program. And maybe that's the basis of your decision to stop enforcement of it immediately.

CHAIRMAN SIEGEL: In terms of fairness, one, as an NRC licensee who is at risk of being fined for violations related to a quality management rule, it seems a little unfair that nearly half of the agreement states are no longer compatible and are allowed to continued in that fashion. That would be another argument for -- You're not applying this uniformly despite your intent and it would be another argument for just dropping the baby.

MR. CAMPER: Yes, we wrestle with that very issue here recently. Following a meeting of agreement state managers last year, we wrestled with this issue of what to do given that the compatibility due date was upon up. Ultimately a decision was made by the Commission to extend a deferral of compatibility during the review of agreement state programs if they had implemented the QM rule.

And really, the rationale for that was is that we

knew that the entire -- the NAS report was forthcoming. A review of the program was forthcoming. And therefore, why bring this burden to bear where in a year's time, which is what we deferred that for, you may know more than you know now.

But, while that's the good side, the down side of it is, you're right. There is an unfairness there that exists today for NRC licensees who have in fact had to deal with the program.

DR. FLYNN: Have you ever taken an agreement state and withdrawn that agreement? I --

MR. CAMPER: Not that I'm aware of that we've ever withdrawn. We've had an agreement returned to us but I'm unaware of us ever withdrawing an agreement. Maybe some of the others -- Any attorneys --

Marjorie, do you have an awareness that we've ever withdrawn an agreement? I don't think we ever have.

DR. FLYNN: Because that's another example of non-uniformity, as Barry was saying. How many more years would you go on in states, let's say like Massachusetts, whereby we're required to do all these things while you allow other states to go on year, after year, after year, where the authorized users don't have to comply with the requirements?

MR. CAMPER: Well, we have two standards that we impose upon the states. One is adequacy of programs and the

other is compatibility of programs. We have a much more aggressive approach to inadequate programs. And an intolerance thereof. Regards to compatibility, it's variable. I mean, some states remain in the status of not being compatible for a number of years, for legitimate reason. Because, as Bob pointed out, the mechanisms they use to put in place their regulations are often lengthy and cumbersome.

But with regards to this particular issue, we extended the deferral of the compatibility finding upon the implementation or the lack thereof for only one year. And that was because, again, we were looking at this issue in a much larger perspective.

But once that one year passes, we have to revisit what we're going to do about that. And a lot of that will depend upon what the Commission has decided to do about the medical program in toto by that point in time.

CHAIRMAN SIEGEL: Right. Should we move on to question 9 in the little bit of time before lunch? How can we achieve improved data collection on actual incidents and rates of adverse incidents and misadministrations. I think we've, in a way, largely addressed that, or partially addressed that, by suggesting that your legitimate need to gather information, or the legitimate need to gather information about events relating to ionizing radiation uniformly, which would be the ideal, still stands because a national clearinghouse for the

data to look for national trends that might -- that any individual practitioner will never be able to figure out, and that even individual states may not be able to figure out, is a laudable activity for a federal agency.

Now, the trick, though, of course, is the dissociation of the gathering of the data from turning it into a very unpleasant experience from the people who are willing to give you the data. And in a way, you could argue that you might want to go back to something like lowering the reporting thresholds, having the reports come in quarterly instead of within 24 hour telephone notification to the operation center. It's not good enough to call the region. And then working with the data.

I mean, certainly earlier reporting of events that cause serious injury or death would be logical. But for the events that cause no harm, what you should be interested in is did those events occur because the machine X isn't working properly and there was one last week and now, oops, there's now nine others. And something's obviously changed and you're in touched with the company that makes machine X and you find indeed there's a software problem and the next thing you now, there's an information notice out to the world at large.

Gathering this data in a less judgmental way, I think, would serve you well. Whether quarterly reporting of

diagnostic administrations in the past was useful is arguable because maybe the threshold was set too low and maybe the kind of events you really needed to gather was not properly captured by the rule. But I think you and we helped you think about what is it you really want to know about, what will help you detect generic problems, then making the reporting requirement be broader but less judgmental would be a good way to get where you ought to be, I think.

Comments?

MR. SWANSON: Can you make the reporting -- consideration, can you make the reporting so it's anonymous? Or, they don't have to provide their name or they can provide their name? I mean, that's kind of the way that the adverse drug reaction reporting and the medication error reporting programs work, so that people don't feel that they're going to come back and be haunted on these issues. That's how they've gotten around some of that. And it's just a thought to throw out there.

MR. CAMPER: Is that voluntary reporting?

MR. SWANSON: It's a voluntary reporting program Confidentiality is maintained if they do give their name. Or they don't have to give their name.

MR. CAMPER: One of the things that's always troubled me about the data on misadministrations and so forth, and we see it now, we have a -- under our office of AEOD, we

now have a database which is in place. And we have volunteer reporting of misadministrations by the agreement states. And I've watched that, as you always have with any new process, sort of a growth curve where the reporting of misadministrations improves over time, even though it's voluntary, because people understand what the requirements are and the value associated with the reporting, and so forth and so on.

But having said all those positive things, I still look at the total numbers of misadministrations reporting and it appears to have voids in information. And then the result, then, is that you never really know through a voluntary program how many events are actually occurring. And of course, another part which we've talked about in great length from time to time, is we don't know what the denominator is, either. We have some pretty good idea, I think, because we know the trends and practice studies and so forth. But voluntary reporting, it's not clear to me that that's an improvement in data collection.

You believe that the collection of the data has merit?

MR. SWANSON: Yes, I think that there's going to be problems with any reporting system that you try to establish. I would encourage that you think about a voluntary reporting program. And in that light, that you work very

closely with the various professional organizations because I think the professional groups, through their standards, can help to make sure that that voluntary reporting does occur or does occur with a higher frequency than perhaps it does now, or perhaps you expect it does now. Let's put it that way.

But that would be an approach I would recommend.

CHAIRMAN SIEGEL: Dan?

DR. BERMAN: With respect to misadministrations, it's -- I wasn't around at the time when it was determined that the level of misadministrations should only be at the higher level of diagnostic mistakes or therapeutic mistakes. But when you look over the report of the Institute of Medicine, and they say that the rate of these misadministrations is infinitesimal, they're ignoring a type of misadministration that isn't reported. And it leads to a little confusion that ultimately could reach the public.

In other words, I think it's much more frequent than only 10 to the minus 4 that a patient who was an unintended patients gets an amount of diagnostic radionuclide.

CHAIRMAN SIEGEL: I don't think the past database bears that out. When mandatory reporting of diagnostic misadministrations was required before the QM related rule changes, those things had to come in quarterly and the 10 to the minus fourth frequency for diagnostic for misadministrations was where the number was living. It was

not wildly different from that, correct?

MR. CAMPER: That's generally correct, yes.

We also have more specific data. I can't remember the numbers now but we were saying patients who were not intended to receive materials but who inadvertently did receive, there was something -- there was an estimate of what, a couple hundred of those a year, I think. Between 100 to 200 of those were estimated per year.

And of course, what has happened is the Commission has made some changes now making it clear that even in those cases, the criteria associated with diagnostic misadministrations is the determining factor, or otherwise you would have some patients, so-called blue patients, at 100 millirem and you would have pink patients at 5,000 millirem. And that didn't seem to be a terribly orderly way to proceed. So now they all are subject to the threshold for diagnostic misadministrations of 5,000 millirem.

DR. BERMAN: Just in my own experience, I've seen that the human error rate, I believe, in misadministrations with diagnostic agents is closer to -- is underestimated by what is reported here. And I'm not stating that this is a major public health hazard but just I think in terms of the record, that the frequency with which we have errors in misuse of diagnostic amounts of radioactivity is somewhat higher than what has been alluded to in this report.

CHAIRMAN SIEGEL: I'm not sure -- Well, I think the numbers in this report are based on therapeutic data and the extreme kinds of diagnostic. And those do occur at a lower frequency than the diagnostics. And I agree with you. I mean, there certainly are some mechanisms by which diagnostic misadministrations in the past might not have been reported. And intended patient can become an intended patient simply by requesting that the referring physician create an order for that study fairly quickly and then all of a sudden it's not reported any more.

But, that's all the past and nonetheless, I think it is reasonably safe to say that the event rate in diagnostic nuclear medicine has been a very low even rate. Nonetheless, there's some legitimate need to gather information about trends in this area, and in fact, there's legitimate need in all of medicine. It seems not likely that we're going to get a better mechanism any time soon for the rest of mechanism.

It would be nice to know about anaesthesia as it would be nice to know how often the wrong foot is amputated or the wrong lung is resected and those kinds of things. We don't have an easy way of getting at that. That really is where the fundamental fix ought to occur if the country believes that that's the kind of data we ought to have.

If the NRC continues to want to do its bit, then, under the Atomic Energy Act, then relaxing the reporting

thresholds, getting the reports less frequently, and gathering, as I've suggested, before some denominator data with each quarterly report. How many diagnostic misadministrations did you have in the last quarter? Three. Describe them briefly. And how many diagnostic doses did you administer during the quarter? You even got some instantaneous denominator data as well there, assuming the OMB will allow you to collect those data. And I understand that problem.

That seems to me a better way to fulfill a legitimate national need without linking it to the odious portions of the QM rule as it's currently conceived or conceptualized by many of us.

Jeff?

DR. WILLIAMSON: Again, I don't know if it's appropriate but I think it would be probably worth knowing what these event rates are in the other 90 percent of ionizing radiation medicine, too. So it might be appropriate for us to endorse the concept being applied generally to LINAC based radiation therapy as well teletherapy, for example.

CHAIRMAN SIEGEL: Well, i think that's part of a general endorsement that I suspect that we will all endorse, that uniform -- a uniform approach to ionizing radiation makes sense so that we can understand these overall even rates.

I mean, the NAS report is -- one could criticize

it because they say, well, we really don't know whether things are better in NRC regulated states than in agreement states because we don't have all the data about the agreement states. And we really don't know whether byproduct material is better or worse than non-byproduct material because we don't have the data. And I would only submit that that's the tiger argument that I alluded to earlier.

I think there is reason that the -- and Judith, you're going to view this as a trust me, I'm a doctor statement, and it is -- but there is reason that the NRC can draw upon its advisory committee when we tell you that it is our belief that things that occur with non-byproduct material and things that occur with diagnostic radiology are not at wildly higher or wildly lower rates than things that occur with byproduct material.

MR. SWANSON: I think it has a lot to do with the spirit of the issue, too. If somehow the NRC can convey to the community that the purpose of this is to collect information to help the community and the public, and it's truly done that way, and that information is shared is back again to the community, then I think you're going to get the community's buy in.

MR. CAMPER: Well, the place in medicine where radiation, I think, were more events occur, if you will, is repeat X-rays. That occurs a lot.

Now, the consequence is not there. It's nothing. But there are an awful lot of repeat X-rays that don't get reported. Now, it's gotten better as techniques have been standardized, as we've gone more towards automated systems, and so forth. But there's still al to of repeats. But we have no idea what they are.

CHAIRMAN SIEGEL: But the collective dose from that --

MR. CAMPER: Oh, I understand.

CHAIRMAN SIEGEL: -- is substantially higher than from all the byproduct material misadministrations put together.

MR. CAMPER: I understand.

MR. WAGNER: There's also other regulatory means by which those things get controlled and that is they're expensive. They cost a lot and then people, the administrators, work very hard to get those repeat rates down. We have little charts we post in the areas to try to get competition amongst the technologists to get their repeat rates down to show how they're doing against another group. And it builds a little bit of internal competition to try to keep those repeat rates down because they get expensive.

CHAIRMAN SIEGEL: It's a big push for digital radiography systems, too, so that rarely, if ever, have to retake.

The second part of question 9 was if NRC lacks statutory or regulatory authority governing the medical and biomedical research of byproduct material, why should NRC continue to gather data on user errors, drugs, and biological products to share with FDA under its memorandum of understanding with FDA unless reimbursed by another federal agency? I think that's sort of a self answering question.

If you weren't involved, you wouldn't be the ones gathering the data, right? Isn't that really the answer?

On the other hand, as long as you're involved, then there's reason for you to participate in the data gather for the part that you're responsible for. And, again, this is an issue of where Congress gets into this loop. This unless reimbursed by another federal agency is a good questions. I mean, if Congress thinks some of this stuff is important because it's good for the country to know about these things, then Congress ought to figure out a good mechanism to get it paid for as well. So we'll put the challenge to them.

And at that point, are we ready for lunch, folks?

MR. CAMPER: So moved.

CHAIRMAN SIEGEL: See you back at, let's say, 1:10.

(Whereupon, the Advisory Committee was recessed at 12:06 p.m. to reconvene at 1:10 p.m. this same day.)

A-F-T-E-R-N-O-O-N P-R-O-C-E-E-D-I-N-G-S

(1:15 p.m.)

CHAIRMAN SIEGEL: Can we go back on the record? We're missing Bob and Judith, but they'll be here in a moment. Oh, Bob's here. Great. There are a couple of folks who made requests to make some big comments to the committee regarding some things we've already talked about and some things we're about to talk about.

And I have decided that -- they both promised they would be brief, so I'm going to give them about three minutes each and let them do it. Three minutes is effusive on my part. Just so we stay on schedule. So either Mark Selikson or Shawn Googins, whichever of you wants to go first, you may.

Why don't you come up to the front podium and please introduce yourself for the record. Indicate your affiliation so that we capture that all on the transcript.

MR. GOOGINS: Thank you. I'll use quite a bit less than three minutes. My name is Shawn Googins. I'm a certified health physicist. I work at the National Institutes of Health right here in Bethesda. I've also had the opportunity as working as a regulator for the Environmental Protection Agency, so I've seen things from both sides.

I just want to preface this with the fact that these are my personal opinions and do not necessarily

represent those of my employer, the National Institutes of Health. So far this morning, the committee has concentrated on the QM rules, at least the point I hear, and the effect on medicine.

But biomedical research also affects medicine quite profoundly in the development of new diagnostic and treatment modalities. And the Institute of Medicine report makes the same recommendation that the NRC should withdraw from the regulation of biomedical research. The observations made by the IOM and this committee this morning are the same.

And I'd like to share some of my personal observations. The NRC all too frequently focuses on process and punishment. And after being a licensee, I can tell you we do as well feel like we're treated like criminals, as many medical people do. And also to reflect that there is also a practice of health physics.

And overly prescriptive regulations in the form of 10 CFR 10 and in Part 35, which carry with them many necessary health physics procedures also divert money and resources away from the important things that we're trying to do, that is treating cancer, diagnosing illness, and treating other illnesses.

And in this standard of practice reflecting about before, going to a regulation into a zero tolerance such that a licensee is penalized and in position of violations with

regard to regulations, but not necessarily the net effect on safety or overall risk.

The response is disproportional to the actual risk. And I have some examples of things like that. First of all, recommendations that say should often become shall in the eyes of an inspector and tend to focus on the actual limits and exceeding limits rather than the actual -- and the process of guilt rather than helping or assisting a licensee.

And it is -- in my opinion, it's been a very unpleasant experience. Some of the issues and things to reflect upon here is survey methods such as in Part 35, conducting a survey and requiring that a dedicated check source be sent with the instrument and always with the instrument and sent with the time of calibration.

This is a practice issue here. There are other ways to assure the proper response of instrumentation. And the fact that this is in a regulation, as a matter of fact, discourages use of perhaps the most appropriate instrument, that being an ionization chamber.

Secondly, requiring contiguous surveys of areas surrounding therapies of patients with either implants or administered radiopharmaceuticals when practice and previous monitoring can demonstrate for a given level of administration that the regulatory limits are not exceeded, but requiring a licensee to do it every single time causes an additional

expense and something with no net benefit.

One other issue is the item of press releases for the -- whenever a licensee has a violation. The NRC appears to have a propensity to issue press releases on items which are not of particular significance just for the fact that this is their procedure and they issue a press release. And I'll have some comments about that later on relating to AIT that was present at NIH.

But overall, to sum up, that I think the parallels that you have drawn today, this morning, with the effect on medicine has the net effect on biomedical research. And the two are integrally connected and meshed together, such that if you impact biomedical research, you are also impacting medicine and the level of patient care and treatment that will -- the medical community will ultimately be able to provide.

CHAIRMAN SIEGEL: Thank you. Any questions for Shawn? Mark?

MR. SELIKSON: Yes, my name is Mark Selikson.

CHAIRMAN SIEGEL: Wait until you get to the microphone, please.

MR. SELIKSON: My name is Mark Selikson. I'm Director of Radiation Safety at the University of Pennsylvania, and I'll say the same disclaimer. I'm not here representing them. Just as a professional who's been close to this issue for over 20 years now, I guess, something like

that.

I wanted to echo some of the things Shawn said and just make a few comments that might add to your discussion. I notice it was heated this morning. But a couple of comments. One, I think this anomalous argument -- and I know you made it over here a couple of times -- I think that's an issue that says oh, well that bears investigation, but I'm not sure that's a criticism in and of itself, just the fact that something is anomalous.

Another thing is that we always talk about how much time and effort that is associated with regulation. I think that's inherent in the regulatory process. We like to make things as efficient as we possibly can. But you will not regulate something cost free -- free in terms of labor and in terms of time.

And I think when it comes to this quality management, I think it's kind of a general consensus that maybe this wasn't the best idea. It is really getting back to when the decision was made to regulate it. Larry pointed out before that back in '92 the evidence was there or the numbers were there, that you were down in the noise region, 10^{-4}.

And that the Staff knew this at that time. So I think the question should really be -- and you as a group -- or Barry, you were here, and many of you here -- had been saying that at that time and maybe for a couple of years

previously. So to me, the fundamental question is why did it go forward? If the Staff knew that it was inappropriate and this committee knew it was inappropriate, then why did this whole very rigorous program -- I mean, everybody knows how much time and effort's gone in here.

And by the way, that's just one example of rules and regs that are out there that may be less than effective. And there should be some review of that process, almost like an incident report. Maybe the NRC should ask -- be asked to answer the question why did this mistake happen, what changes are you going to make to make sure that it doesn't reoccur?

You know, the kinds of things they make us go through sometimes when we make a mistake. Maybe that's something you should think about here as well. Anyway, I just wanted to get those comments -- good luck to you on a complex question.

CHAIRMAN SIEGEL: Good, thank you. All right, while we're waiting for the folks from IOM to come, shall we tackle --

MR. CAMPER: Tackle 11?

CHAIRMAN SIEGEL: What's 11?

MR. CAMPER: I think it's the last one.

CHAIRMAN SIEGEL: I know it's the last one. Well, the only trouble with tackling 11 is that 11 still depends on whether we think the recommended approach is really

the right approach. And I'd sort of rather hold it, but I don't feel strongly. I mean, I can be swayed. Looking at three or four.

MR. CAMPER: Four.

CHAIRMAN SIEGEL: In a way, four is the next logical one in the -- not much really changes what at least could the NRC do that would be more logical, at least in our eyes, about Part 35. Great, we're hearing a lot of comment here. I guess we love it!

Does anyone want to take a stab at that one? General issues related to Part 35. I mean, what do we not like about Part 35?

MEMBER WILLIAMSON: Well, I'm never at a loss for words, so if no one else will speak -- as I -- this is specifically -- this question focuses on protection of occupational workers and members of the public. Part 35 has numerous small procedures, very explicit procedures, that are required.

For example, there's a highly detailed description of how -- if you're using brachytherapy sources, how all the sources are to be counted in the safe before you remove any and how they're all supposed to be counted at the end when you return them and so on. And just as a sort of general comment, I think it might be better if the regulation were less prescriptive and merely announced, you know, the

goals are you should be able to account for the sources at all times -- not lose them, not lose control.

The regulation says develop a process for doing that. Instead of perhaps having very detailed requirements that -- for example, when we receive I-131 oral solution in our hot lab, we of course have to assay the activity. We do not open the vial or have really any chance of contamination at that time, but nonetheless, we're required, as I believe, to do surveys of the work area before and after.

It would seem that perhaps the level of detail in Part 35 is very highly prescriptive and it could be -- given that the basic end points are listed as regulatory end points you're supposed to achieve, you know, could be left to the professional discretion of the, you know, health care workers to make decisions at that level exactly what sort of process is needed to inventory sources.

You know, if they're not lost, you know, why should there be a concern? And if there arises an incident, well then, you know, it would be -- could even -- might be incumbent then upon the user to develop an improved program. I guess that's my general comment about Part 35.

CHAIRMAN SIEGEL: We might want to try to -- before you go, Lou, you might want to try to approach this in terms of big picture items. And if you look in your copy of the NAS report, you've got Part 20 and Part 35 there. So

after Lou makes his general comment, then I -- maybe try to walk us through some big picture items and see what elements of Part 35 we think are archaic and what elements would exist no matter what went forward in the future.

Lou?

MEMBER WAGNER: I think it's important for the NRC to understand that there is a tremendous disproportion in regards to the need for certain regulations at various institutions, especially in their enforcement program. I mean, part of the problem is the following. If you're a large program and you're running a real good program, you still have this enforcement policy that goes through in a very scrutinizing way what's going on.

And if you find small violations, you still issue citations and violations for these things, which cause a lot of concern amongst people to answer and to appropriately address. But you don't get any evaluation of the overall program. Good program, bad program, diminished efficiencies.

That is where I think a lot of the prescriptive problem comes in. It's not that the philosophy is wrong. It's simply that we've made these regulations and we require zero tolerance. And that zero tolerance level for a large program versus a small program is disproportionate. Just the example, I have a facility where we do 500 wipe tests a year because we always get these packages of radionuclides in, and

we have to do wipe tests on every one of them when they come in.

They don't contain any large amounts of activity. And I don't see where they really represent a real harm to people, and there's no issue about they're leaking or broken or damaged or anything; but we've got to do wipe tests every time. We've never found any contamination on any of these shipments.

The inspectors come in and find that twice we didn't document what we did, so we get written up for that. Yet 498 times, we had complete documentation of everything we did for this whole system, and we're running a good program. But the focus is on these two times where you didn't document it.

It's this kind of a problem with regard to looking at the overall quality of a program and how -- what are the people doing good? What are they doing well? What's the important things they should keep and keep functioning and keep nurturing? Instead of looking at the positive things, we're always looking and focusing on those negative aspects.

And that's causing the -- a lot of the difficulty from the user's point of view is to what's wrong with this program.

MR. CAMPER: Let me stimulate the conversation a little bit, the discussion, by sharing with you some

observations that the management and Staff had made about Part 35. I mentioned earlier this morning that if -- I think there's a high probability that if the Academy stay had not been put in place by the Commission, that we would probably be well on our way at this point in the process of revising Part 35.

Every since 1987 when Part 35 was last revised, the Staff has been collecting observations about Part 35. These have been presented to us by professional societies, licensees, inspectors, our own observations, and the headquarters staff in dealing with technical assistance requests for the regions.

A practical problem that we see is being an impediment and so forth. And there are really three or four major categories of things that we could observe -- and I could go on and on and on in the details, but I won't. But I'll give you three or four key observations just to stimulate the discussion.

One is that we know that there are parts of Part 35 that simply do not track the current state of technology. An example of that is high dose rate remote afterloading. I mean, arguably HDR's are of such a nature that they warrant a separate and distinct section within Part 35 similar to what we do for teletherapy units.

Now today, we have in place a policy and guidance

directive dealing with HDR. We have updated that in the recent past following the event in Indiana, Pennsylvania. But one of the things that concerns me is as a manager is that we've never subjected all the kinds of things that we've put into the policy and guidance directive, FC86-4.

And in fact, the subcommittee of the ACMUI worked with us last September on that particular guidance document and others. But it would be worthwhile and appropriate to subject all that guidance to the public process, putting in place those aspects of that guidance which warrant being elevated to the level of a regulation than having to undergo a public scrutiny comment and so forth.

And there are other technologies. The gamma knife, for example, is another one that comes to mind. Another broad category is that to the extent possible, Part 35 could be made more performance oriented. The classic example that comes to mind whenever I get on this particular issue is the criteria that we have in Part 35 with regards to evaluating dose calibrators.

I think it's arguably very prescriptive. As you probably know, there is an ANSI standard that deals with evaluation of dose calibrators. An approach could be embodied whereby licensees would follow the ANSI standard or some equivalent as opposed to having to do this prescriptive requirements.

And sometimes those prescriptive requirements result in some of the violations that have been alluded to in that someone doesn't do a constancy evaluation of the dose calibrator 365 days of the year. They do it 360 days of the year, and that results in a violation; albeit a minor violation, but a violation just the same.

So this question of movement toward performance versus being so prescriptive. Another issue that we have observed is this issue of using industry standards wherever possible. You know, from a regulatory standpoint, if you could have industry develop those standards which they deem to be appropriate and safe and that ensure protection of the patients and public health and safety and so forth, and then embody those in the regulations so that everyone will participate, not just voluntarily participate because they're an industry standard, then that seems like a worthwhile thing to do.

The idea of putting into Part 35 only those things which are essential as a requirement. Arguably there's some things in there today that can be viewed as being somewhat superfluous and not essential in the context of a regulatory requirement. And then finally, the idea of trying to line up more carefully the guidance that exists and provide alternatives in the guidance.

If one looks today in Regulatory Guide 10.8, one

finds an example as a guidance. Well, sometimes that guidance becomes a regulatory reality. And maybe what you should have is a general requirement of a performance nature and then several options for achieving that or several organizations identified that have developed programs that would lend to a licensee being able to use that to achieve compliance of the regulation, and therefore substantial modification to Reg. Guide 10.8 for that reason.

And there are many others. But that just gives you some idea of some of the observations that we have made about Part 35 and some of the things that I think that we would have probably already moved toward modifying through a rule making process if we weren't, you know, where we are currently in terms of looking at the program at large.

The other one that comes to mind very quickly is we currently have very prescriptive authorizations in 35.400. We say that particular radionuclides as sources can be used for certain purposes. That really ought to be modified to say that they can be used for any reason or approach for which they have been reviewed and approved.

So those are some examples of the kinds of things that we have seen, and hopefully that will help you think in terms of broad consequences.

CHAIRMAN SIEGEL: So is it -- is this question really premature to answer? I mean, in the event that

something drastic does not happen as a result of the NAS report that involves change and enabling legislation or -- then isn't it a given that Part 35 is going to be revised along with your long range plans anyway?

MR. CAMPER: Well, certainly if we were to -- if the agency were to stay in the business of the medical program, then certainly I think there's a high probably that Part 35 would be revised. I think the value though of your comments and dissertation at this point in time is the Commission has before it a significant decision to make in terms of how it wants to proceed with the NAS report.

I think there is value to the Commission in terms of getting a perspective from this committee as to -- if we look at Part 35 today and if, in the final analysis commission, you decide to remain in the business or Congress doesn't take you out of the business, what do we think is warranted for change in Part 35.

I think that could be of value to them in their decision making process.

CHAIRMAN SIEGEL: Got it.

MR. CAMPER: At this point in time.

CHAIRMAN SIEGEL: All right, then let's just go through it. Redo all of Part 35 in the next 20 minutes. Is that enough time?

(Laughter.)

We wouldn't want to overdo it.

DR. HOLAHAN: If I can just make a point before, is the way -- and it would be helpful too is first of all, all of Part 35, if we're keeping patient safety in there and also if a finding can be made that there is adequate protection for patient safety, how do you protect public health and safety.

CHAIRMAN SIEGEL: Got it.

DR. HOLAHAN: Of occupational workers.

CHAIRMAN SIEGEL: In terms of things we said this morning, I think if we look at definitions currently in Part 35, we would -- this committee would probably say that the definition of a misadministration needs to be changed to first of all something altogether different than -- a different word, and that it be linked to some new reporting requirement that allows the NRC to capture information about untoward events as part of a function whereby it serves as a clearinghouse for that data and tries to look for systematic or generic trends.

And I think we've pretty much said this morning that the whole misadministration concept is something we just as soon see thrown out with Part 35, that you should still gather data. I'm just kind of flipping through this, and then -- big general administrative requirements.

So do all think that the concept of an ALARA program, requirement for radiation safety officer, and the

requirement for a radiation safety committee are necessary in order to use byproduct material or non-byproduct material in a medical institution for either research purposes or medical purposes?

Or are those concepts that are needed any longer? Bob?

MEMBER QUILLIN: Personally, I never saw the usefulness of a radiation safety committee for a purely clinical facility. I can understand the need for it for a research facility where you're talking about research activities where you might have an institutional research review committee, that sort of thing.

But I never saw the purpose of a radiation safety committee per se for just a straight clinical program.

CHAIRMAN SIEGEL: What do others feel about that?

MEMBER STITT: I don't know which came first, the chicken or the egg; but this would -- a radiation safety program committee and an officer -- well, at least a committee are required for hospital accreditation purposes. You can find any number of different agencies, certainly JCAHO, that's one of the things they're looking at.

CHAIRMAN SIEGEL: Jeff, you were going to comment, or Lou, either one.

MEMBER WAGNER: Well, as far as hospitals are concerned, my experience with radiation safety committees in

hospitals are that most of the people on the committee don't know what you're talking about and have a large difficulty in trying to understand what you're trying to get across.

And the person who really runs the show is the radiation safety officer of the hospital. He's the guy who really knows what's going on and he organizes it and plans it, and basically it's a reporting mechanism. Now, it might be a way of disseminating information, but I don't know how effective that really is.

There probably is some usefulness to a radiation safety committee in a hospital in terms of trying to communicate information. And I'll just give you an example with ours -- radiation safety officer is aware of difficulties with radiation incidents across the nation. He goes to the committee, he says here's what's happening across the nation, now what should we recommend to the hospital to do in order to make sure this doesn't happen at our institution.

That's an example of how our committee worked in order to try to bring things to people's attention. And then the committee makes recommendations to the staff, the medical staff, as to things that ought to be done. So I think it is a forum for making communication. There is that benefit.

At the university level, I would like to stimulate some discussion from other people because from my own personal experience is that many members on the radiation

safety committee do not have a thorough understanding of all the duties of the radiation safety office. Many members on the committee don't know where all the laboratories are that are being regulated and things that are going on.

And I think that the NRC's idea is admirable, but I don't think that it is -- that the radiation safety committees always meet the full function and anticipation of the NRC in terms of its operation simply because it's very difficult to run by committee.

And I think the important things that I always depend on is I've always stated to my committee the most important thing is how confident is the radiation safety officer and his staff to bring to the attention of the committee those features that need to -- need our input and our facilitation.

And if the radiation safety committee -- you know, the radiation safety officer rather and his staff aren't good, the radiation safety committee's not going to be terribly functional either except to recognize that and perhaps try to recommend a change.

CHAIRMAN SIEGEL: Jeff?

MEMBER WILLIAMSON: Well, I guess I tend to agree with Bob on one part. I think it's a useful vehicle in a large medical institution where there are many users and, you know, very complex array of competing programs using

radionuclides and lots of safety concerns and labs being run by scientists and individuals that otherwise, you know, might not have much oversight.

So I think it's kind of useful for getting an overview of the scope of the operations, providing a level of review for the radiation safety office. Are they doing a good job and can plugging in some component of management into the operation of the program.

You know, the way I'd like to think about it is if we didn't have NRC requiring us to have it, what kind of radiation safety committees and programs would we have in our institutions? That's sort of the conceptual -- since we're sort of questioning the foundations of the regulations, that might be sort of a useful way to think about it. As professionals for different types of institutions, what would we need?

I suspect in a very small facility with just a few focused activities, you know, Bob might well be right. And the very detailed requirements of meeting at least quarterly with a quorum and so on might in effect just be sort of for show effectively and of no real importance to an institution of that size.

So again, it might be better to -- I suppose outline in regulation form the objectives of a successful administrative structure, what it's supposed to do and kind of

leave it to the institution to figure out how to structure one instead of prescribing that it meet in a certain way.

CHAIRMAN SIEGEL: The only problem with leaving it to an institution is that it means that you're also leaving it to an inspector. And that's where we get into difficulty. I agree with you. I mean, a community hospital that only has a nuclear medicine service, doesn't do radiation oncology -- I mean, it's kind of silly for them to have a radiation safety committee.

The one guy who does the nuclear medicine is the radiation safety officer. He regulates what he does, and presumably hospital management -- presumably hospital management is paying attention to the fact that environmental regulations are being dealt with and that exposures are being dealt with, and you don't really need a committee to do that.

In a complex place like Washington University where we've got 500 laboratories, a committee structure is something that probably would exist even absent the NRC because a committee is a way for management to draw lots of different forms of expertise and to provide it with the muscle that it needs to wrestle with recalcitrant scientists in laboratories, people who are being trouble makers, and things that occur in large institutions.

So a committee structure probably would have existed. I'm attracted to the concept of RSO responsibilities

and radiation safety committee objectives as being objectives of the program if one can figure out a way for the NRC, assuming they stay in the business, to administer these programs without it being left to the discretion of individual inspectors, because that's where we'll run into a serious problem.

Larry?

MR. CAMPER: Just as a bit of history, some of the logic that went into the creation of the RSC goes something like this. First of all, it grew out of the old isotopes review committee.

CHAIRMAN SIEGEL: Right.

MR. CAMPER: Back in the days when institutions were more actively involved in actually approving radiopharmaceuticals and their use, if one goes back in the 60's and 70's and that type of thing. When the regulations were changed, the emphasis was placed upon that committee, or what was that committee, as a radiation safety function.

And some of the logic went like the following. If you have a committee, then you're getting institutional participation and buy in and active responsibilities in all of those places where materials are being used. It also serves as an additional audit function on your radiation safety program. And you have management participation because the success of a radiation safety program ultimately dwells with

the highest level of institutional management buy in and participation.

And then finally, the idea that the radiation safety officer in some cases felt that they were functioning as a lone wolf with little or no support from institutional management or with no entity to turn to for a collegial interaction to resolve radiation safety problems. So those were some of the kinds of logic that went into the creation of the requirement for the radiation safety committee.

CHAIRMAN SIEGEL: Right, and I think, you know, your document -- your NUREG on management of radiation safety programs in medical institutions talks about the tripod. And I think conceptually those are good. The notion that some of the very prescriptive parts of this could be lightened up I think would be attractive.

Small committees -- do small committees really need to meet once a quarter in a place where everything is working like a charm? Does that really have to be a requirement?

Yes, Lou?

MEMBER WAGNER: I'd like to proffer the concept or idea for discussion that the ALARA as a regulation ought to be eliminated, and that ALARA as a principle should be promoted. And I'd like to respell ALARA. I'd like to respell it with a lower case a, lower case l, a lower case a, capital

R, lower case a (alaRa). Because I believe the sense of reasonable has gotten out of control.

Too much of the regulation that I see coming out from my state is as low as absolutely achievable rather than is reasonably achievable. So I think that as a regulation, it ought to be abandoned; but as a principle and a concept, it ought to be promoted.

MEMBER SWANSON: I would agree with that. I think it's basically the same thing we talked about today with quality management rules. The principle here that's a standard that has now become a regulation, okay. So I would agree 100%.

CHAIRMAN SIEGEL: Jeff?

MEMBER QUILLIN: A question. Where did the industry standard get developed that ALARA means that in medical institutions, you know, the allowable limits are 1/10 of those in Part 20 for occupationally exposed individuals?

MR. CAMPER: That's an interesting question. My recollection is that for years and years and years, you know, it was a qualitative concept rather than a quantitative concept. But sort of a working rule of thumb under the qualitative approach was trying to achieve a factor of 10%. And I think along the line, that became memorialized as a quantitative value.

MEMBER WILLIAMSON: Then, you know, my comment

would be that that sort of seems that's what ALARA means. It just means the real limits by de facto limits are 1/10 of those published. It's -- we ought to just republish Part 20 and say the limits are 500 MR per year, if that's what you want.

No, well don't do that. I mean it facetiously. I take that back. But it seems -- it's a contradiction that it's expressed the way it is. And for that reason, I think it should sort of -- I would agree, it should be dropped because that's not what it means anymore.

MR. CAMPER: I think what happened along the way is in an attempt to move from the qualitative -- to have some standard that everyone would strive for, because to want ALARA might mean 70% of the release value; to someone else, it might mean 10%; to someone else, it might mean 1%; to someone else, it might mean 90%.

I think it became a working number. I don't think there's really much more a basis to it than that.

CHAIRMAN SIEGEL: All right, do we want to -- I guess Kate Gottfried is here. We're waiting for a slide projector, so we won't proceed. Let's keep going then. All right, we've sort of dealt with RSO's and ALARA and RSC's, and I guess we're arguing for reducing their prescriptiveness without having specific language in mind on short notice.

What about 35.25, my favorite regulation? The

one that allows you to be cited no matter what goes wrong! Someone probably wasn't following the instructions of an authorized user at some point in their life history. How often do you all use 35.25 as a basis for --

MR. CAMPER: I don't know how many times that citation occurs per year, but I -- it's certainly one of the more frequently cited violations.

CHAIRMAN SIEGEL: I mean, it's hard to argue with the principle that in this particular activity, you want the individuals in whom you've given the major responsibility -- to whom you given the major responsibility, namely the authorized users -- it's hard to argue with the fact that you want them to be in control and that you want the supervised individuals to follow their instructions.

On the other hand, it is in a way demeaning to the supervised individuals because it implies that they are not capable of making any judgements. And it ends up being a very, very stringent rule. And so that any time anything happens where it turns out that a supervised person was making a judgement call, then you have an opportunity for a violation under 35.25.

And it's not really the way people work.

MR. CAMPER: The supervision issue is an interesting one. If you go back and look at the statements of consideration for the 1987 rule making, there's some

interesting words in there that something along the lines of -- you know, individual physicians are in the best position -- the authorized users are in the best position to determine what constitutes an adequate level of supervision because of the differences in the practice of medicine and the differences in state law and so forth.

And therefore, we have exercised I think a fair amount of discretion with regards to the supervision violations. Most of the supervision violations for 35.25 are when there is a clear indication that there was not instruction. It's a 35.25(a)(1) violation that occurs more time than not.

And that's a situation where the inspector determines, based upon discussions, typically with the technologists, that instruction wasn't provided on a particular aspect of the program. You know, 35.25(2) does require the supervised individual to follow -- that is cited occasionally, because they do not follow a program -- they were instructed. A program does exist, but they do not follow it.

That is a citation occasionally. But more of them are against (a)(1).

CHAIRMAN SIEGEL: What about -- how often does (a)(3) become a problem? Because I have been personally moderately concerned about what constitutes an adequate audit

of the supervised individual's use of byproduct material.

MR. CAMPER: I would say that (a)(3) violations are the most infrequent of the ones against 35.25, and for a couple of reasons. You have the word periodically in there, which of course has a band of flexibility associated with it. And again, I would say that's occurring when it becomes clear to the inspector that there is no ongoing review of the individual's work.

You know, we've had a couple incidents recently where they were double dosing, for example, you know, patients. And it became clear in that case that there was absolutely no review. There was little or no supervision occurring, and there was no review of the activity of these individuals.

Because reasonably, in the case that I have in mind, the authorized user should be able to detect via the dose log. Because actual dose entries were entered that were much higher than called for in the clinical procedures manual. So the point is, 35.25(a)(3) occurs occasionally. I don't know again the exact number, but it's probably the least of the three.

CHAIRMAN SIEGEL: Bob, do the standards state regulations include a 35.25 equivalent?

MEMBER QUILLIN: I honestly don't know.

CHAIRMAN SIEGEL: Okay, I don't know either. Is

it likely they would based on your perspective?

MEMBER QUILLIN: I just don't remember.

CHAIRMAN SIEGEL: Okay. You know, if you were writing them from scratch, is that something you would include? How about that? Let me put it to you that way.

(Laughter.)

MEMBER QUILLIN: No, that's a different question.

CHAIRMAN SIEGEL: I know it is! I asked it intentionally that way.

MEMBER QUILLIN: I understand that.

MEMBER STITT: I'll answer for Bob.

(Laughter.)

MEMBER QUILLIN: Thank you.

MEMBER STITT: No, my comment is I just had to have my privileges reviewed to sign on again for the University of Wisconsin. This would be a very typical thing that my medical -- my chairman and the chief of staff at my hospital want to review my performance. So there's a whole variety of things that can be reviewed. Infections, deaths, performance in a variety of ways.

These are medical standards that I don't know that I would write into this sort of a document. But as a physician, you are reviewed -- is easily one of the ways a department would look at a radiation oncologist or a nuclear medicine doctor.

CHAIRMAN SIEGEL: Yeah, except in this case, these are the -- these are not the authorized users who are being reviewed. These are the technologists whom you supervise who are being reviewed and -- no, that's okay. And the fact -- how you determine whether or not they routinely follow your instructions.

Jeff?

MEMBER WILLIAMSON: Well, I think they -- the intent of this regulation, as so many, is good. What it says it that in an institution that has a treatment delivery system or process for some type of modality, there should be sort of good interpersonal communication among the team members in delivering that therapy.

There should be good records kept, there should be, you know, various levels of oversight where, you know, the records are reviewed and the physician correctly conveys to the treatment deliverers what is desired. It also says the intent is that there should be well trained and qualified professionals carrying out the appropriate tasks.

I think this sort of -- I find this section for myself, being sort of a supervised individual, sort of a little insulting like I'm sort of some monkey that needs to be periodically retrained in some very mechanical, rote way. And you know, maybe there are a certain level of employees whose involvement is so peripheral in the treatment, that might be

so, that there's, you know, few things, you know, that have to be explained over and over again.

But I think sort of the prescriptiveness is sort of missing the main intent. And I would again suggest that some sort of a intent or goal based specification of what the goal of this be put in there, and I really think that to cite an institution, as has happened, because an employee didn't realize that the various procedures they were carrying out were required by the quality management program and instead answered, it's because good treatment practices require it -- that's not right to use it for that kind of reason.

MR. CAMPER: See again, one of the fundamental historical logics, if you will, was -- if you look at the wording under 35.25(a), it says that a licensee that permits the receipt possession user transfer byproduct material by an individual under the supervision of an authorized user, ie. a physician, shall be instructed -- so forth and so on.

In other words, (a) says you shall instruct; (b) says you shall follow; (c) says you shall periodically review; and (b) is Barry's fatal flaw where you're responsible regardless. Well, one of the underlying logics there was is that if you look in Part 35, the only individuals that are called out from a regulatory standpoint of having some minimum level of training experience are authorized physician users, authorized nuclear pharmacists, and teletherapy physicists.

These supervised individuals that are alluded to in 35.25 can be anywhere from certified technologists, dosimetrists, to on the job trained individuals with little formal training. So what it was doing was placing a great deal of responsibility and importance upon supervision by the authorized user.

And that was part of the underlying logic in the approach.

MEMBER WILLIAMSON: But it's not really true that any of them are complex radiation oncology procedures.

CHAIRMAN SIEGEL: Right, and we've actually recognized in recent meetings that there were additional professionals that needed to be incorporated in any revision of Part 35 that would have essentially authorized user equivalent status like brachytherapy physicists. And we actually -- I think the term we suggested was just medical physicist, right, last time around?

Dennis?

MEMBER SWANSON: Larry, am I correct that in your previous discussion about where you want to go with these that you want to get more of a standard and less prescriptive? So could I view that a standard here might be that individuals should have appropriate training and experience commensurate with their duties?

Would that be a standard, for example?

MR. CAMPER: Possibly, possibly. I also think, frankly, if we ever get into reviewing Part 35, if we do that, I mean, I think we ought to go back at some point and ask ourselves what is the role of the authorized physician user today. Because I think the regulations as they currently exist had in mind an authorized user that played an active role in the development and administration of materials and so forth.

I don't think that the authorized user necessarily means the same thing in 1996 as it did 25 years ago. And so I think if we -- again, if we ever go that way and revise Part 35, I think that we ought to explore that underlying issue as well.

CHAIRMAN SIEGEL: Yeah, we're less important now than we used to be. Technologists make all the decisions now.

(Laughter.)

And I wish I were kidding you! Are you ready to answer my question?

MEMBER QUILLIN: Yeah, I'm ready to answer your question. Actually, I think under our medical practice act in Colorado, the physician is responsible, and it's under B in the -- or C -- regulations here. The person under them is not a licensed practitioner of some sort. They are responsible for the acts and omissions of the supervised individual.

So basically that's covered under a medical

practice act. The other things I think are rather straightforward. But I think the problem is, as Larry pointed out, the concept of the authorized user has changed over time. And the authorized user, as I think -- or was originally envisioned here, really doesn't exist in many cases anymore as far as one sole person who has knowledge over all things and does all things and everybody else is just sort of a -- working under their direct supervision.

There are many specialists now in this field who -- with expertise that maybe the authorized user is aware of what the expertise is but doesn't know actual mechanics of what they're doing.

CHAIRMAN SIEGEL: Are you referring to nuclear medicine specifically or to radiation oncology?

MEMBER QUILLIN: Brachytherapy, for example. What I said was that you don't know all the mechanics of what they're doing. Actual steps. You know what the outcomes are and procedures are, but you --

MEMBER STITT: Well, when I'm listening to the conversation, I was curious because you said that there's less -- well, Larry, that the definition has changed and the practice had changed. And I actually wasn't sure what direction you meant and whether it referred to nuclear medicine or radiation oncology.

You're right in the high dose rate arena. I

think that frustration as a clinician is that so much of what goes on with the remote afterloading could be lower -- it could be high dose rate -- is that if the physician lost some of that control where you were placing sources in certain specific body parts and certain orders, because it's all computer generated.

And so there can be whole parts of the computerized process that are lost to the clinician. We depend even more so on the physicists, and they have to try to make qualitative assessments and really speak down to us about this is or this is not going well. And several things that we've all seen recently relate to software for computers -- brachytherapy computers, and problems in software.

And we really are no longer as knowledgeable because of that different layer of technology that's evolved. So in that sense, I think particularly with the high dose rate technology -- actually remote afterloading technology has put the therapeutic oncology -- in that position.

MR. CAMPER: Yeah, the point that I was making was that if one goes back and looks at the history of the authorized user concept, you'll find that those were typically physicians that were actively involved in developing and applying the application of radiopharmaceuticals or sealed sources in therapy.

What's happened over time though is that many

authorized users today simply want to use radioactive materials in the course of practice of medicine and have little or no interest in supervising as authorized users did historically. Now, authorized users that are radiation safety officers have a different set of functions, of course.

And all I was saying -- and I think this is what Bob's getting at too, is in addition to that, you also have an emergence now of more highly trained individuals who play a more active role in the delivery of the radiopharmaceuticals, be it diagnostic or therapeutic, than you used to 25 or 30 years ago when the AU was playing a much more aggressive role -- the authorized user was playing a much more aggressive role.

And all I'm really saying is that if we look at the concept of supervision, we should also look at the concept of who supervises and why.

CHAIRMAN SIEGEL: Good. We'll come back to this. Now we're going to proceed with our regular schedule and let Kate -- are you ready, Kate? Okay, and let Kate Louise Gottfried from the National Academy of Sciences Institute of Medicine tell us more about the report.

Kate, we have been discussing the report for much of the morning. What we have carefully avoided doing was discussion of whether we agree with -- a discussion of whether we agree with the alternative you selected and with the

principal implementation strategies that you chose. What we've been focusing on instead are those things that NRC could do assuming not much changed.

And there were some specific questions we had from the NRC, and we focused on those. So I think we'd like from you -- I know you've prepared to give us an overview of the report. We've all read it. But we'd very much like to know as much as possible about the rationale that led you to your preferred alternative.

MS. GOTTFRIED: Great. Do I need to talk into this mike? I guess so.

CHAIRMAN SIEGEL: It will move a little bit if you want to move it.

MS. GOTTFRIED: Well, first I'd just like to thank you for the opportunity to be here today. Unfortunately, John Villforth, which is why we scheduled this for this afternoon, was supposed to accompany me. I know you all know what's in the report, that you've seen it, you've read it.

And actually these slides, I'm going to run through them really quickly and then just focus on the preferred alternative and the recommendations. I understand that Patricia already went over the recommendations with you this morning. This is what I use when I go to present the report elsewhere, not to an as informed audience.

John is at a hearing this morning, and so we were hoping he would be able to make it by this afternoon. And originally, that was not scheduled at the time that we appointed today for the presentation. And I definitely apologize for that, because I think, you know, you need the benefit of committee members and their expertise.

The other unfortunate consequence of this whole timing and scheduling of this presentation is that we're going to be briefing the commissioners next week on the 27th, which is an open public meeting. There will be several committee members, probably six committee members attending that meeting.

And we had thought they would be back to back so that you would have the benefit of that information as well. And that's something that was beyond our control. Having said that, let me just start off.

Everybody knows that the committee was called. Reminder of who the committee members were. The methodology that we used to carry out the study. I'm just looking to see if there's anything that I should note in addition to what's on here. I think you're all aware that we have commission papers, committee meetings, public hearing, QM panel and site visits.

I'm not going to belabor this. This was a statement of task that the NRC provided the IOM with. This is

just an expansion of that. This was a table we used to present the scope of the study. Those items in gold are subject to NRC regulation. The ones in white not subject to NRC regulation.

The committee looked at the entire scope, both yellow and white. It's basically broken down into radioactive materials and machine produced radiation. These were the subcommittees. Everyone knows we had a public meeting. Okay, the committee derived a variety of goals. These were the three goals that the committee pursued.

To promote greater uniformity of regulation of all ionizing radiation in medicine. To shift federal oversight to an agency experienced in matters of public health, and to further ensure adequate protection of the public's health and safety. And to consolidate regulation of all ionizing radiation in medicine by delegating regulatory authority for reactor generated byproduct materials to the states, which presently regulate NOARM, approximately 98% of radiation medicine.

Before I get into this, I will take some time now to talk about our approach to the preferred alternative. Chapter five of the report, which as an aside should be out in final sometime in March, is really the heart of the report. It focuses on what were the proposed recommendation -- well, the proposed alternatives that would result in the eventual

recommendations that the committee made.

The focus of those alternatives really should be on alternative C through F. The other alternatives, the status quo, the laisser faire approach, and then sort of all encompassing, were in fact because the committee wanted to consider the entire spectrum of options. The reality is that the heart of the discussion by the committee focused on alternative C through F; and in particular, alternatives C, D and E. F was discarded because it calls for a centralization of all ionizing radiation subject to federal regulation, which is currently not the system.

And again, felt to be too all encompassing and not too -- and something that would not achieve the committee's end, which was to ensure adequate public health and safety, but in an efficient, expeditious manner. Alternative C, D, and E are all sort of a variation on the theme. C, state control; D, the preferred alternative; and E, again a variation of alternative D, but with some authority for federal regulatory authority.

I'd say that the committee spent meetings three, four, five and six debating these issues and continuously. And they revisited them, and they deliberated, and they came up with proposals, and they revised those proposals and spent an extensive amount of time really debating the virtue of federal regulation of ionizing radiation as opposed to federal

guidance.

And I'm terribly sorry that John Villforth isn't here today, because John of course is a strong proponent for federal -- some federal influence. Because in fact, the committee really did struggle between state control, alternative C, and some federal influence. And I would say that John Villforth's expertise, among a number of other committee members who deal with the area on a day to day basis wielded a lot of influence with respect to having some federal involvement in the area.

So what was the issue with respect to federal regulation and the alternative? Alternative D -- well, the first recommendation refers to the elimination of NRC's medical use program. And elimination of the NRC's medical use program from the committee's perspective would not alter the basic structure of federal regulation.

That the federal government would still retain responsibility for the entire area with respect to the generation, transport, non-medical use, disposal of radionuclides, and for the approval of radiopharmaceuticals and certification or approval of equipment that generates ionizing radiation.

The committee's perspective was that we're looking at a very small area that needs to be examined, and in fact, revised. But that overall, federal regulation of this

area would not in fact be changed. As a consequence, the NRC and its agreement states would continue to license the production of byproduct material for radiation producing devices and radiopharmaceuticals in the medical context.

The NRC and its agreement states would, as relates to the non-medical use of byproduct material, continue to license the production and use of byproduct material. The DOT would continue to regulate the transport of radioactive materials.

EPA would continue to develop guidelines that set occupational and public exposure limits to be implemented by the respective federal agencies. The FDA would continue to regulate the manufacturer and labeling of radiopharmaceuticals and medical devices. It would also continue to regulate the MQSA.

DOD, VA, PHS, would all continue to be responsible under the regulations of the appropriate agencies for the safe use of radioactive materials and radiation producing machines in their hospitals an laboratories. And HCFA, with respect to Medicare and Medicaid, would continue to develop reimbursement guidelines.

Based on -- and I can only say that it's a matter of deliberation and confidential discussion amongst the committee over a protracted period of time, the committee derived the preferred alternative. The committee felt that a

regulatory structure that transferred authority to the states and identified a federal agency other than the NRC to work in conjunction with the CRCPD and other professional organizations to develop recommended state laws and regulations for all ionizing radiation in medicine.

And the committee spent a great deal of time also determining or considering what type of guidance this entity should in fact provide. The following is a list. Again -- Mr. Villforth. John Villforth's just walked in. The identified federal agency would assist states in establishing regulatory programs and trained radiation control personnel, address problematic incidence of national concern, educate the public of the benefits and risks of radiation medicine, conduct research so the science of radiation medicine continues to advance, collect risk data, and monitor the effects of deregulation.

Recommendations then were made before both Congress, the NRC, the CRCPD, and to the states. And then the rest is just -- which I know you've reviewed this morning -- a repetition of the recommendations made by the committee.

The point that Senator Glenn made in an article that appeared after the report was released was that he would like to recommend adoption of the committee's recommendations, but he would add that in fact he would like to see it monitored over a -- and he didn't describe in any detail in

how he would want it monitored or over what time frame.

But that in fact he thought that was essential. And of course, the committee doesn't agree with that at all. John, the -- one of the questions really revolved -- or the main question that the ACMUI has put to us is what the process was for deliberation and deriving the preferred alternative.

And I have described the process as the committee met and over the course of several months, really focused on our alternatives and proposing what the preferred alternative would be. That that was the result of extension deliberation, and that the main emphasis was state control versus some sort of federal influence.

I would love to open it up and have you ask some specific questions or to -- to myself or to John. I don't really think it's worth going over the -- do you want to do that?

CHAIRMAN SIEGEL: No, I think I agree with you.

MS. GOTTFRIED: Okay.

CHAIRMAN SIEGEL: I think that's fine. We probably saw them this morning, and we all have a pretty good feel for them. Dennis, you had a question? You were ready to jump in?

MEMBER SWANSON: Just one comment. You kind of took me back by your statement that the committee didn't recommend monitoring of the program. I actually thought that

that was one of the tasks of the federal agency --

MS. GOTTFRIED: No, no, they did; I'm just saying they don't have any disagreement with Senator Glenn's comment that he would in fact push for a monitoring of a -- if there were deregulation.

MEMBER SWANSON: Okay, and then I do have a specific question. If one of the goals was to promote greater uniformity of regulation of all ionizing radiation in medicine, what deliberations -- why did the committee stop at simply the medical use? Why did they not also look at uniformity and regulating the production and distribution of byproduct material?

And in particular, related to my area of practice, which is pharmacy -- nuclear pharmacy, we're right -- certainly what we do in nuclear pharmacy is directly related to the medical use of radioactivity. We're regulated, in fact, by the NRC under -- not under Part 35, but under Part 32.72.

So I'm real curious as to how all of these recommendations are going to affect the practice of nuclear pharmacy, and are we going to have to continue to exist under a dual set of regulations?

MS. GOTTFRIED: Well, and that's a great question. I don't have the answer for you. In terms of what the committee restricted itself to, we really had to adhere to

the statement of task provided by the NRC. And I think in the area that you're outlining, it became an area that was beyond the expertise of the committee at that point.

I don't know if you want to add anything to that, John. I think that the issue of uniformity is certainly the issue that the committee was grappling with. And the fact that that should be what the committee strove towards -- there's so many details and nuances that the committee just could not address.

CHAIRMAN SIEGEL: Lou?

MEMBER WAGNER: I'll ask the question I asked this morning. There's reference within the document that the IOM's recommendations pertain to medical uses, as well as biomedical research. Could you elaborate a little bit on the scope of what the IOM meant by incorporating also biomedical research?

MS. GOTTFRIED: That was an issue that came up because of all the various people who deal with research and radionuclides in research and the fact that you wouldn't want to have a dual system with respect to -- if in fact the NRC was removed from the regulation of radionuclides in the hospital setting, and then how that would apply to people conducting research in laboratories within a hospital.

So they were able to make that expansion.

MEMBER WAGNER: But would this, for example,

include biomedical research in a medical school? Would your recommendations apply to a radiation program of research within a medical school that's disjointed from any hospital affiliation?

MS. GOTTFRIED: That was the intention, yes.

MEMBER WAGNER: Okay. What about biomedical research that might occur at reactor facility sites such as up in the state of Washington and other places? If they're not affiliated with a medical school, would they still come under this type of regulation?

MS. GOTTFRIED: My sense is that they would.

CHAIRMAN SIEGEL: John, at least for the record, could you just introduce yourself and --

MR. VILLFORTH: Excuse me, I'm John Villforth. I'm with -- a member of the committee. And I was with the Food and Drug Administration. I'm now with the Food and Drug Law Institute, which is a non-profit organization downtown. It's my understanding that the intention was that all biomedical research -- we're talking sort of the animals in vitro types of stuff that will eventually lead to human use should be covered under this provision.

CHAIRMAN SIEGEL: So restated, it really means that the materials program currently administrated by the NRC as it applies to medical institutions would transfer to this new responsibility? Because really, you'd have to deal with

the whole materials program with a medical institution focus.

MR. VILLFORTH: I think it's the medical -- ultimately the medical research, whether it's in the medical institution or if it's in a -- if it's at Brookhaven in the reactor side as opposed to the hospital side that technically would be -- as a part of the intention of this.

CHAIRMAN SIEGEL: Okay. Jeff?

MEMBER WILLIAMSON: Yeah, where would basic standard setting reside such as occupational exposure limitations and so on? Also maximum MPD's for the general public. Would it be possible that New Jersey and Texas, for example, could have different whole body exposure regulations?

MR. VILLFORTH: It's possible. You know how those state folks are.

(Laughter.)

The intention, I think, was that the type of oversight that's been provided in the past by the conference of radiation control program directors through the suggested state regulations was a way to provide the uniformity and consistency. Now, there's no requirement that those things -- up until now, there's no requirement that those things be mandated to the state.

The intention, I think, was that those are the good -- that's a good basis in that that process would continue. The suggested state regulations would continue.

And as the need for -- in new areas or new modalities or what have you, that those would be incorporated. And that would include the occupational side of things as well as the whole schmier, the whole nine yards.

MEMBER WILLIAMSON: Okay, so the occupational and public safety standards, all of that would revert to the states, so most of Part 20 would be -- as well as 35? I'm confused, I'm sorry.

MR. VILLFORTH: I don't think the idea was to change the 10 CFR 20 types of requirements and take that away from the NRC. Because it involves all the industrial and all the other research applications -- non-medical research applications. That would reside with the NRC. That material -- however, the concepts that are contained in the suggested state regulation.

So there's an element of consistency as to how they would be adopted. But I don't think the intention was to pull away the occupational side of this away from the NRC.

MEMBER WILLIAMSON: Okay, so basic standard setting that's independent of medical practice and common to all ionizing radiation uses would stay in Part 20 and presumably all the state regulations would be compatible with it?

CHAIRMAN SIEGEL: At the moment, in a way, isn't it a little bit by default that that's with Part 20 and not

coming out of the EPA? Isn't it kind of by agreement between the NRC and the EPA that the NRC is setting those standards rather than the EPA setting those standards? Don't they have the ultimate federal authority to do so if they chose to

MR. VILLFORTH: You're talking about the old Federal Radiation Council responsibility, and I suppose technically the EPA would have the ability to set those standards under its old Federal Radiation Council guidelines much in a similar way that they did in 1975 and said x-ray performance standards --

CHAIRMAN SIEGEL: Did you want to address that question?

MR. COOL: Just for the record once again, I'm Donald Cool. I'm Director of the Division of Industrial Medical Nuclear Safety. NRC issues its requirements in Part 20, implementing the agencies requirement to implement the EPA's federal guidance authority. Kate Louise Gottfried noted that in their proposal, federal agencies would continue to be in the implementing role of the federal guidance, which is under the mandate of the Environmental Protection Agency.

EPA now implementing -- as John Villforth had indicated -- the old Federal Radiation Council, if you go back now 30 years or so, for occupational and public exposure. The latest occupational exposure, federal guidance having been written in 1987; the latest public exposure guidelines, which

have been subjected to some comment, but the official ones go back to around 1960.

And it's those guidelines which NRC implements through Part 20.

CHAIRMAN SIEGEL: Just to elaborate though on the question about state non-uniformity, is there anything in the current structure that would prevent Colorado, say, from deciding that the public health limit -- member of the general public limit should be 10 millirems per year?

MR. COOL: Most of those basic limits -- most of the Part 20 definitions and fundamental limits are fundamental matters of compatibility adequacy. They're what Bob Quillin called earlier today division one where they're supposed to match.

CHAIRMAN SIEGEL: Okay. So that -- so in the final analysis at the moment, the NRC is setting the standards, but the EPA has some role in the process, and then the states have to follow?

MR. COOL: That's basically correct. In fact, most of the time NRC and EPA are sort of running their processes in parallel. In the occupational case, the revised federal guidance for occupation exposure and revised Part 20 were being developed simultaneously. We in fact went ahead and moved forward also with the public exposure arena thinking back at that time that the federal guidance for public

exposure would be shortly behind the occupational guidance.

We are now eight years later, and that might not have been such a good assumption.

CHAIRMAN SIEGEL: Larry?

MR. CAMPER: I had a couple of minor questions, and then maybe what might be a more major question in terms of the alternatives. In looking through the slide on federal authority maintained, you say that DOD, the VA and the public health service would continue to be responsible under the regulations of the appropriate agencies for the safe use of materials.

And it wasn't clear to me exactly what the committee meant by that. I looked at a couple of pages in your text last night and tried to get an understanding, but what I'm focusing upon is the safe use. For example, we currently issue licensees to DOD facilities. We currently issue licenses to the VA and the public health service hospitals for the use of materials.

And I was curious exactly what you meant by continue to be responsible under the regulations of the appropriate agencies. What appropriate agencies were you referring to there? Were you referring to DOD, DVA, PHS themselves, and does that imply self regulation? What were you getting at there?

MR. VILLFORTH: I think the intent was that this

would not apply to the federal agencies, that the federal agencies would continue to work out their relationships with the NRC in whatever fashion, whether that would -- you might issue a broad license to the particular element of the military or the public health service to accommodate that or not.

But that would not be something that was going to be under this consideration.

MR. CAMPER: So you envision then that NRC would continue to license those entities referred to there?

MR. VILLFORTH: Yes.

MR. CAMPER: The next question I had was under the federal guidance, the identified federal agency would assist states in establishing regulatory programs and trained radiation control personnel. I'm just curious, what mechanisms did you consider as a committee when you looked at that, that that federal agency, in this case DHHS, would assist the states in establishing regulatory programs.

What mechanism were you thinking about with that suggestion? I mean, how would that -- what would be the mechanics of that? How would it play itself out?

MS. GOTTFRIED: Well, in part, that referred to the prior experience that the FDA had with respect to the MQSA and using that as a model. That the FDA was a convener and worked with the various professional organizations to derive

the regulations that were then put in place.

MR. CAMPER: I see.

CHAIRMAN SIEGEL: And actually we haven't gotten to that part of our discussion yet, but I mean, that was the model that I was going to throw out on the table is the one that had to work. Because one of the things I'm concerned about is that it seems like alternative D really is absolutely contingent on congressional action to put alternative D in place.

And that there almost is no way the NRC can move towards alternative D on its own. Is that the committee's consensus on that thought or not?

MR. VILLFORTH: I get my numbers mixed up. Which one --

CHAIRMAN SIEGEL: You need something like the MQSA for medical use of ionizing radiation to put in place a set of federally mandated standards that the states would then administer, and presumably there would have to be some teeth attached to it. And teeth could be HCFA reimbursement or the fact that if you don't do it, then the federal government comes in and takes over your state or something like that.

(Laughter.)

Manifest destiny, or whatever it is.

MS. GOTTFRIED: Well, there was actually some sentiment that the NRC could initiate, for example,

elimination of Part 35 on its own given proper legal counsel. So that recommendation (b)(2) talks about NRC initiating formal steps under the APA to revoke Part 35. And then if Congress fails to act within two years in response to the two recommendations to Congress stated above -- in other words, I'd like to see Congress step in and take some action.

In the event that it can't or won't, what are the options for the NRC?

MR. CAMPER: And under that model, who filled in then? Who took over those responsibilities? If the NRC were to remove itself, let's say in the course of a year's time, for example, what was the committee's thoughts as to who would fill in that regulatory void, if you will, at that point?

MR. VILLFORTH: The states.

MR. CAMPER: The states?

CHAIRMAN SIEGEL: But absent some congressional mandate like the MQSA that they have to administer this new process, what would be their incentive for doing so?

MR. VILLFORTH: You're asking what the stick is to do that?

CHAIRMAN SIEGEL: Right.

MR. VILLFORTH: I don't think there is a stick.

CHAIRMAN SIEGEL: I mean, the only stick that you really hold out in the report is the fact that people in that state wouldn't be able to get the materials that NRC controls.

It turns out that, you know, you can make technetium in a linear accelerator if you're clever and choose to.

It's expensive. So there potentially would be work arounds. What? It might be less expensive than license fees. How much -- and this may be a tough question, but how much were you bothered by the how hard the states had to be pushed to get where you wanted the states to be, and especially in terms of ensuring that the states would achieve the level of uniformity that I think we agree and that you all thought was appropriate so that -- I mean, we wouldn't want there to be five standard deviations of difference behind the way things are done in Idaho and the way things are done in Massachusetts.

MR. VILLFORTH: I think it's a difficult question to determine how much we're going to -- how much of an incentive is going to move us in that direction, particularly when you have the non-medical side -- the whole industrial side there that's unadjusted. So you've got this kind of schizophrenic way of dealing with these sorts of byproduct materials.

On the one hand, you want to encourage the states to pick them up in the medical area. On the other hand, there's nothing to give an incentive to the industrial or other kinds of applications of byproduct materials other than being handled in the traditional fashion. I think if this

thing gets looked at, one has to ask the question if you go this far for this -- you know, the Congress may want to look at this and say this -- you know, maybe this doesn't make sense.

This was not the charge of the committee to go beyond the medical arena. But it begs, I think, the question does one need consistency in all the use of byproduct materials.

MR. CAMPER: So I assume then for that reason that that's why the idea of expanding the existing agreement state program -- in other words, the states that currently do not regulate byproduct material that are currently regulated by the NRC have a great deal of responsibility and work to do under the model as proposed.

Similarly, that could be accomplished through the agreement state program. And so what I think I'm hearing is that that wasn't an alternative because it went beyond the scope of medicine.

MR. VILLFORTH: That's correct.

CHAIRMAN SIEGEL: Yes, Dan?

MEMBER BERMAN: A lot of the import, I think, of the report is based on the idea that only about 10% or less than 10% of radiation medicine is covered by what the NRC regulates. But isn't it -- did the committee give any thought to the possibility that the fact that the NRC has been so

involved in that 10% may have had a spill over effect on how the states treat the rest of the 90%?

And if that 10% -- that if you turn around and remove the regulation of the 10%, that it might lead to increased variability of how the whole of ionizing radiation is handled.

CHAIRMAN SIEGEL: That's why they still have federal guidance --

MS. GOTTFRIED: In part, that's true.

CHAIRMAN SIEGEL: -- in alternative D.

MS. GOTTFRIED: I mean, I think that's a fair question. And I think the committee felt that in fact -- if you talk to some people around the country, they will say that the NRC's influence with respect to byproduct may in fact influence their overall programs. The notion is to sort of take that and authorize the states to expand and include it so that in fact their programs will be maintained and strengthened.

You know, whether that will occur -- and I guess going back to the previous question, and I just feel compelled to add some of the committee's sentiments with respect to the degree of variation from state to state. This is a very minuscule area of radiation medicine. And it's very minuscule in terms of what states regulate in general.

And there's great variation in aspects within the

health care field and within environmental issues, etc., etc. And so in fact, it becomes a philosophical issue in terms of state regulation versus government intervention. And I think that's important to recognize. And the committee felt, with respect to a cost benefit and with respect to the incidence of "misadministrations or adverse events," that in fact the "risk" was worth assuming and testing.

CHAIRMAN SIEGEL: Jeff?

MEMBER WILLIAMSON: I was going to, you know, ask about this issue. Did you assess or make any attempt to assess the variability of regulatory practices and their effectiveness in the federally unregulated 90%? That is, assess the consistency of state practice.

MS. GOTTFRIED: We did. We actually wrote to all the states. We tried to get the regulations from all of the states with respect to NOARM and byproduct material. We talked with the CRCPD. Their database was less than up to date with respect to those issues. It was very, very difficult to obtain accurate information with respect to regulation of NOARM.

CHAIRMAN SIEGEL: Judith?

MEMBER STITT: A question. The preferred alternative identifies a federal agency other than the NRC to work as the federal agency that would provide guidance. Could you just comment on the choice of the Department of Health and

Human Services?

MS. GOTTFRIED: I'll be glad to start off, and I'm sure John will have some additional comments. The committee felt that the DHHS, and in particular -- well, DHHS as the Department of Health and Human Services, and then in particular the Food and Drug Administration, has an extensive background history in dealing with issues of radiation.

And in fact, the training there is also more attuned to issues of public health and safety with respect to medical issues. And so, in fact, DHHS might in fact -- might be a better locus for this area since there is that history. Although the committee stepped short of actually saying it should be FDA or CDRH within FDA, it suggests as a possibility. But the committee did not want to assume as sort of a presumptuous attitude and prevent the secretary from designating where it should fall within HHS.

MR. VILLFORTH: I think that's right. I think you were pulling on the history that the FDA was involved. And as Kate said, they didn't want to be presumptuous. I think that what's happening downtown, at least this morning with Senator Kassebaum with her new senate bill where I was at the -- or preparing her proposal is to move the -- all the radiopharmaceutical programs from the Center for Drugs into the Center for Devices and Radiological Health.

Now, what -- there were -- hearings are going on

through this afternoon and through tomorrow. I have no idea whether -- to what extent that will be commented on, but that's in the bill. And whether that will end up in the -- that will go anywhere or not, but it's interesting that that particular proposal had been made to -- I guess recognizing that perhaps radiopharmaceuticals aren't really drugs in the same sense that some other things might be defined as drugs.

It's a little loose translation. But it's an interesting observation. So I think some things are happening down there too. Down there being in Congress.

CHAIRMAN SIEGEL: Lou, you had a comment?

MEMBER WAGNER: Yeah, on the recommendation (a)(1), page 16, there is a sentence here that specifies some of your goals of removing authority from the federal level. And you say first it eliminate prescriptive and costly regulations that yield marginal risk reduction. Did the IOM investigate whether or not state regulations that are not NRC driven are perhaps also prescriptive -- too prescriptive and costly, and that indeed the states will end up perhaps falling to the same folly that the NRC has fallen to?

MR. VILLFORTH: I don't know that that was considered that the states would be overly prescriptive. I think the feeling was -- and it's just a feeling that I had -- that the states were not particularly enthusiastic about the specifics of some of 10 CFR 35 in terms of quality, the

quality assurance, or the aspects that have to do with the patient reporting. And my impression was that that was not something that was greeted with a lot of enthusiasm within the states. And I may be wrong.

MEMBER WAGNER: Well, I think that that's probably true. I'm not sure what all the motivation for it would be, but I think that that is true in part. But I'd like you to read some of the state regulations and see how prescriptive they are and how costly they become for users because they're equally as burdensome in many cases.

The other issue is in regard to the IOM's investigation into the causes of why the regulations perhaps got out of hand and were overly prescriptive and too costly, did the IOM really investigate the actual cause?

I know there was a lot on the history and there was a description of the history of what occurred, but could the IOM possibly give us any insight into why this occurred, what was the mechanism, the driving force? Was it a matter of knee-jerk reaction to events, single events, or was it a matter of something intrinsic within the regulatory way that they develop regulations that could have led to the state we're in today?

MS. GOTTFRIED: I don't think the committee really understood that or knew. The history, in fact, gives some suggestion of the way in which regulations are developed,

but there is no documentation that we could uncover or that we really focused upon in order to understand that.

It's an interesting question. My own sort of guess is that that's part of the way in which things unfold when you're developing regulations.

MEMBER WAGNER: The thing that I worry about is now if we turn it completely over to the states, we're going to have 50 different regulatory bodies falling to the same folly, committing the same errors that were done before without any recognition of why they got themselves into that fix in the first place.

MS. GOTTFRIED: I think that's a fair question, although, I mean, the hope and expectation is that the CRCPD in its divine wisdom and its expertise will, in fact, be an important leader and, in fact, provide models for the states to adopt.

CHAIRMAN SIEGEL: I think Dan's been chomping at the bit.

MEMBER FLYNN: Yes. It's a follow-up. I'm somewhat concerned about your statement that you tried to get all the state regulations. That means you didn't get all the state regulations. Is that correct?

MS. GOTTFRIED: Correct.

MEMBER FLYNN: Well, then --

MS. GOTTFRIED: We've got a hodgepodge from the

various states in terms of what exists. And we've got millions of pages of things from some states and fewer pages and comments that said, "Well, we have four volumes. We don't know how we'd get them to you." It was really not something that was a clean, "Give us Statute X, Y, and Z for us to review so that we can understand the way in which you regulate."

MEMBER FLYNN: Well, that concerns me because it seems very premature for you then to put the whole program onto the states. I mean, it sounds to me then you have no way to evaluate whether the CRCPD's suggested state regulations are being implemented by the states or being adopted by the states. And I'd be very concerned about states that didn't respond.

For example, I don't see what would be the problem with Alternative E. And I'm surprised, then, you didn't adopt Alternative E, which goes one step further than Alternative D by giving regulatory authority to a federal agency in a situation of last resort, namely no state program.

You don't have the evidence to present to us that the states are doing it. You haven't collected, you haven't even gotten, responses from all the states. The responses you've got have been nonuniform. You have no way to see whether the state programs even comply with the CRCPD. So I really don't understand your recommendation at all.

MR. VILLFORTH: I'm under the impression that the conference does do some evaluations and has done some evaluations on certain states. So that there is an attempt through the conference to get a sense of uniformity.

In terms of the extent of that, I don't know how extensive it is, but there is some element of quality control in that process. I think that the experience that FDA had with, say, the X-ray or the industrial side, the industrial machine side, of this with the states' programs would indicate some elements of consistency.

Quantitatively I can't give you an answer to that. And I don't know what the numbers were when you -- whether you have the actual numbers, Kate, from the response to the regs. I think they're so close to the suggested state regs I didn't note whether those are different.

I'm not sure that having all of those regs would necessarily be an indication of the quality of the state program. I think you have to go independently and see how well they are being maintained.

MEMBER FLYNN: But wouldn't you want to know, at least on a voluntary basis, how well the states have recognized the CRCPD in terms of: Have they seriously considered some important suggested state regulations that, let's say, the CRCPD felt were extremely important and very core recommendations that perhaps a number of states haven't

adopted?

Perhaps those are the states with very weak programs. These are the states you're going to turn the entire program over to. They're probably the states you haven't gotten responses from.

So Alternative D doesn't give a backup, a fallback position, where this federal agency, whatever that federal agency might be, can step in and provide the protection to the citizens of that state in that event.

MR. VILLFORTH: I have seen some data -- I don't have access to them, and I don't know how far back they go -- showing the comparison of some of the state programs with those who have adopted the regulations and how extensive they are.

The conference did put some of that out in the past. There are probably some other people here who can comment on that much better than I can who have been involved with the conference.

I'm not sure that my being unable to answer that necessarily means that it doesn't exist.

MS. GOTTFRIED: And I would like to just add again, as we were discussing earlier, it's an important point, but the 90 percent that's already subject to state regulation, what's going on with that in terms of people being concerned or not concerned, we don't have this outcry that there's

inadequate regulation of NOARM. And there are hundreds of death as a consequence or even misadministrations.

I think you really have to take into consideration the expense and the time consumption and all of those issues that people who were dealing with medicine on a day to day basis consider and the safety of the public and whether or not there is, in fact, a disconnect.

MEMBER FLYNN: Well, many of these states, quite frankly, may not have the expertise. And they simply adopt the NRC regulations and apply them to linear accelerators and radiation oncology.

MS. GOTTFRIED: Why would they change, then?

MEMBER FLYNN: Some may not.

MS. GOTTFRIED: I guess I don't know what would make us presume that, in fact, they would suddenly rescind their existing regulations for NOARM.

MEMBER FLYNN: I'm just not confident that the states are administering the regulations in a relatively uniform fashion. I haven't seen that. That's why I thought perhaps all 50 states had responded to your request for information, but I guess they haven't.

MR. VILLFORTH: I would say with my experience in the machine area, X-rays specifically, that if one goes back and looks at the extent with which the states have conducted surveys, conducted enforcement programs, have worked with the

federal government or the FDA in this area, I would guess that there's a tremendous degree of effectiveness and efficiency there.

I don't know the data for the byproduct material. I think a large extent is also applied to the NOARM. And, again, you've got people here in the audience who could probably speak more competently on that.

CHAIRMAN SIEGEL: Larry?

MR. CAMPER: My question is sort of a follow-on to Lou's question and deals with cost. As I read the report, the conclusion is reached that the NRC program is expensive. And in Chapter 4 you provide a fair amount of data in terms of numbers of the cost of our programs, fees collected, licensure costs, et cetera, et cetera.

But I didn't see a comparable body of information for the states. And, therefore, I could reach no conclusion as to what the delta is between the two approaches. Did you decide that that wasn't necessary or that the data wasn't available or you didn't think it was necessary to reach a conclusion? Why no comparative information?

MR. VILLFORTH: I don't remember that we went out and tried to get that information. It's a good question.

I think that certainly one of the presumptions is that the state people working in the area if one is doing a hospital inspection, one has all the sources available, both

machine NOARM and byproduct material. There certainly is an efficiency in that process, as opposed to going into a hospital for just X-ray and then having somebody from the regional office go in there for byproduct material. It has to be a cheaper process than having somebody come out of the state capital and go into a facility and review all of the radiation sources that are there.

MR. CAMPER: But, as a practical matter, though, many of the states are using inspectors strictly for X-ray, for example, and strictly for materials uses.

MR. VILLFORTH: I'm sorry? Say it again. The --

MR. CAMPER: Some states --

MR. VILLFORTH: Yes.

MR. CAMPER: -- are, in fact, using inspectors strictly for materials uses and strictly for X-ray uses. The inspectors are not one and the same.

MR. VILLFORTH: I don't know that. Again, you're probably right for some of the programs. And some of them are split.

MR. CAMPER: Right, exactly.

CHAIRMAN SIEGEL: Jeff?

MEMBER WILLIAMSON: Yes. When I read the report, I agreed with many of the sort of basic philosophical premises, but I was concerned a little bit at the lack of specificity, not so much in the criticisms of the existing NRC

regulatory framework, but I really didn't see articulated a sort of positive vision of what a successful regulatory framework for ionizing radiation medicine would be.

And without sort of echoing what Lou said, putting your thumb on what is the cause why we have this sort of awful problem now and what is to prevent one big Attila the Hun from becoming 50 little Attilas? Attila the Hun? I got the number right here. That that concerns --

MEMBER SWANSON: Attilas the Huns.

MEMBER WILLIAMSON: Attilas the Huns? Okay.

So that concerned me. And I'll put it in the form of a question. What's your positive vision for what an appropriate regulatory framework, regardless of who administers it, would be for medicine?

MR. VILLFORTH: Well, first of all, I would say it wouldn't be regulatory. It would be public health. And under public health, I would say that there are two elements. One is a regulatory element, and one is an educational element.

And I think the states tend to be focused in on public health, and I think the states use regulations as a tool. The states also use education as a tool to try to accomplish their mission.

And it would seem to me the vision would be that if one can get this out of a federal regulatory program, NRC,

which is attuned to the regulatory process, and put it into a state which has the sensitivity to use education as well as regulation, that you're going to achieve public health much better than you would under the present system.

MEMBER WILLIAMSON: I guess I was more concerned -- I think many of my concerns as a practicing physicist have to do a little less with NRC and agreement state involvement in protection of personnel and public health and so on and more on what seems to me to be a well-intended but still somewhat misguided intrusion into the practice of medicine as it's applied to specific patients, that there are specific criticisms; for example, the quality management program, the misadministration reporting rule.

So back to more specifically the issue of quality in medical practice, what would be your answer, as opposed to public health, if I'm understanding?

MR. VILLFORTH: I'd like to think that public health is quality, but I'm not quite sure I understand your --

MEMBER WILLIAMSON: Quality of medical treatment delivered to the patient, I guess, if --

MR. VILLFORTH: And that is to make sure it's available, on the one hand, and to make sure that it's safe and effective, on the other hand. So you're talking about the spectrum of it. And that's to me what it's all about or I think that's what the committee reflects that it's all about.

And I think the way to do it is as identified here.

The collegial environment that I think that many of the states have been involved in, many of the states have started in these programs years back without a regulatory mandate and had to use a collegial environment to get things done.

And then as the regulations develop, I think they still, many of the states, continue or most of the states still continue with that cooperative effort. And it doesn't mean when they have problems they don't use the enforcement as a tool, but I think that that has been perceived as missing under the NRC program, that it's been very -- I've heard words "punishing" in its enforcement.

MS. GOTTFRIED: In addition, in terms of quality issues, I think it's really important to recognize that quality is not something that you regulate necessarily at the federal government level and that, in fact, there's a tremendous amount of in the marketplace drive for controlling quality and that as we enter into the era of managed care, we're going to see that more and more.

And the reality is that there are so many organizations, the JCHO, all the different professional organizations, that relate to issues of quality.

CHAIRMAN SIEGEL: Lou?

MEMBER WAGNER: How do I put this in perspective

here? First of all, I'd like just to make the comment that the fact that you got voluminous regulations from some states should have been a clue that perhaps in some states they're over-prescriptive. And this is simply going to be repeated on a massive scale unless there's some guidance as to how to prevent over-prescriptive regulation. And I was disappointed in the lack of that within the report.

So what I would like you to focus on now is the answer to this question. When you made the decision regarding going to states or having a federal body, what is it within that decision led you to believe that the mechanism to prevent the very things that we have now from occurring would now occur in the way you would want it to occur? Why the state decision versus a federal oversight body? What made you draw that line between those two?

MR. VILLFORTH: Well, again, as I said, the states are there. They've done this. They've worked in that collegial environment in the beginning of those programs that's evolved. They're closer to the users.

And I think that there's a greater sensitivity and a commitment on their part with their advisory committees to be responsive. I think there's a perception that Washington's a long way from most of the states, and it's hard to influence the decisions that go on with the regulatory process in Washington. It's easier to have a sensitivity in

that process at the state level.

What will prevent them from being more prescriptive if we have, which we have, the suggested state regulations, which provide some consistency? It's going to take a breaking with their state colleagues for somebody to go off and be unreasonably prescriptive with some aspect of a regulation. I think the whole purpose of the conference and the purpose of the various committees that meet constantly on these areas is to try to provide a consensus among the states to be in line.

Now, anybody can pop up. Any state can pop up and do something ridiculous. What's to prevent that? I don't know that there's anything to prevent that other than the possibility that their colleagues or the federal agency that's supposed to overlook this will have an influence.

CHAIRMAN SIEGEL: Dennis, then Dan.

MEMBER SWANSON: One question I have --

CHAIRMAN SIEGEL: I'm sorry.

MEMBER SWANSON: And maybe you can enlighten me.

CHAIRMAN SIEGEL: Up next.

MEMBER SWANSON: Who constitutes the conference on radiation control program directors? How are people appointed to this? What mechanisms do they have to ensure involvement of the regulated community in the development of their model regulations and evaluation of their model

regulations? Do they publish these in Federal Register notices, like the NRC does? Is there a mechanism for ensuring that the regulated community is actively involved in model regulation?

MR. VILLFORTH: You almost have to again go back to the audience and find out whether notices of availability of these are published. Do you guys know?

MEMBER QUILLIN: They're not published in the Federal Register.

MEMBER SWANSON: Notices of availability are available?

MEMBER QUILLIN: I don't think so, no.

MEMBER SWANSON: Okay. So the answer is there is no way to assure other than the -- go ahead. Dick Gross?

CHAIRMAN SIEGEL: Please come to a microphone and identify yourself.

MR. GROSS: I've been successful at avoiding this microphone up until this point. I'm sorry to raise my hand. I'm Dick Gross. I'm with Food and Drug Administration, the Center for Devices and Radiological Health. And the reason I'm standing up now is that I've worked with the conference now for about 10 years, I guess, as the FDA project officer for the federal funds that fund this program.

With respect to the operation of how the suggested state regulations work, for one thing, they're in

the process of changing those methods. And so what I say right now may not be true in about six months.

But right now the regulations as they are developed, the regulations themselves come from a lot of different places. They come from: one, federal regulations, where federal regulations must be adopted by a state and NRC regulations or EPA regulations or OSHA regulations or -- I don't know. You guys can list them off a lot better than I can.

Where those regulations demand that they be identical, that's a pretty simple process. They don't get into the suggested state regulations document until they're federal regulations. So they come directly from there.

The next source of ideas for regulations comes from things like the NCRPM, National Council on Radiation Protection Measures. Acronyms get embedded too deeply, I'm afraid.

The concepts that are outlined in those kinds of documents get then translated by a working group within the conference to take these concepts and put them into regulation. That process involves people on the committee, which include members of state radiation control programs. There are some federal people involved in that typically and a range of what are known as advisers, who are people from the medical profession or industry or wherever who are interested

in that topic. And they participate in the development of that.

And so from that point, then they go through the development of a final draft. The draft gets circulated for review. Now, who does it get circulated to? Well, obviously the people who have been working on the document are expected to take care of their constituents. And, therefore, the professional groups, the industry groups and so on are involved in that review. And then it also comes eventually to the federal agencies for concurrence or not. And then it is published as a final document available from the conference.

The process from that point, though, I think is important to this group. I think it's very important to understand that once a regulation shows up in the suggested state rules does not necessarily mean that it's going to wind up in state rules because the states also have their administrative procedures acts which require them to go through an open process of adopting these rules. And so, as a matter of fact, everybody gets now a third crack depending upon where you're coming from, at least a second crack at how these rules are going to be finally implemented.

And so I think it's important to recognize that the suggested state regs are simply suggestions, that before they can become enforceable by anybody they have to go through the individual state administrative procedures that are

required to implement these regulations.

Thank you.

CHAIRMAN SIEGEL: I think Bob was next, actually. Yes.

MEMBER QUILLIN: I just want to add one thing to what Dick said, and that is that the conference publishes a newsletter which basically updates the membership and those who take that newsletter as to what rulemakings or suggested state rulemakings are in the process. So that it also invites participation to for people who want to participate in that process.

CHAIRMAN SIEGEL: Dan, go ahead.

MEMBER FLYNN: What you brought up about managed care I think is very important in terms of assuring quality. Some insurance companies are requiring, for example, radiation oncology facilities to be accredited by some body. And I know because I was a site visitor. I'm on a committee for the American College of Radiology.

But the American College of Radiology standards, as other professional societies, are developed at a national basis with feedback and input from everyone in all the states and a certain number of core standards, let's say, in radiation oncology are developed. And when these facilities are surveyed, they're surveyed on the basis of whether they meet these core standards.

Now, the American College of Radiology has almost 50 state chapters. They could have delegated these standards to be developed in each of the 50 states, which I think would be a nightmare personally to have 50 sets of standards by which the facilities in those states would be judged. And then I can see these insurance companies dealing with Montana and Nebraska and Idaho, all with different standards and not quite sure where to put things.

The same with the JCHO. They don't have 50 state JCHO chapters with 50 sets of regulations.

So when I read your report, I think putting the power in the states is important. And uniformity is important. But I guess I still don't understand why Choice E isn't superior to Choice D because if you had some very loose or distant federal oversight they could look at, let's say, in the 50 states, they may find two or three states which are too prescriptive and maybe two or three states which aren't prescriptive enough and aren't meeting these core standards, which are developed on a national basis. And so I think that's where I personally feel the weakness is of the report.

But I think Choice E is much better than Choice D for that reason.

CHAIRMAN SIEGEL: Lou?

MEMBER WAGNER: I'd just like to comment that the prescription I just heard about how the CRCPD goes about doing

things and offer to the states and the states offer to their constituents for comments is exactly the same as what the NRC is doing on a national scale. I don't see any difference.

It is completely, it is very much dominated by people within the bureaucracy who have domination over what it's going to be in decision-making powers. And it ultimately comes down that you end up with rules that, even though the advice is against the rules and even though this Committee recommended against a QM rule and did other things, it still comes out. And they come out in these overly prescriptive forms. And it still gets generated the same way. And I don't think this is going to stop the process unless there's some good guidance as to how to stop the mistakes of the past.

CHAIRMAN SIEGEL: To use this morning's analogy, 50 yo-yos, instead of one.

MEMBER WAGNER: Yes, 50 yo-yos, instead of one.

CHAIRMAN SIEGEL: We were talking about government by yo-yo and reacting to the last bad experience as the way we govern in the United States much of the time.

You're attracted to Option E. Summarize for us just for a moment why F, what the principal arguments against F were. Were they primarily because you thought F would be too expensive? Because clearly ensuring uniformity would be best achieved if there was one federal agency, ideally a medical agency, not a radiation agency per se, that had

overall responsibility, at least so it seems to me.

MS. GOTTFRIED: F I think: a) was the cost, but also b) was the issue of now you're federalizing all regulation of radiation medicine. And the committee felt that that was more extreme than they wanted to propose, that, in fact, you know, 90 percent isn't being regulated at the federal level, it's not necessary, and you're going to create an additional monolith.

CHAIRMAN SIEGEL: So that the committee was dominated by Jeffersonians, rather than Hamiltonians.

MS. GOTTFRIED: Absolutely.

CHAIRMAN SIEGEL: Absolutely. Jeff?

MEMBER WILLIAMSON: No. You've said essentially what I was going to say, that, remember, they were driven by the view that it's not rational to make radiation medicine an anomaly when it appears that none of the rest of medicine has this kind of oversight nor appears to need it.

CHAIRMAN SIEGEL: Judy, you've been very quiet today.

MEMBER BROWN: I have. I was interested in the composition of the committee and specifically the separate statement by Robert Adler. Can you tell me how his remarks that must have gone through the deliberations were received? Was it a total one against the world or --

MS. GOTTFRIED: There was unanimity amongst all

the committee members with the exception of Robert Adler. And the committee and the IOM, the National Academy of Sciences, recognizes an individual committee member's right to, in fact, register a formal disagreement or supporting statement for their perspective and that, in fact, that goes through the review process, as does the entire report. And it was felt that there are instances where those statements might not be incorporated into a final report, although they're rare. And in this instance, there was no question that this should be included in the report.

MEMBER BROWN: Thank you.

CHAIRMAN SIEGEL: Jeff?

MEMBER WILLIAMSON: Well, to restate my concern in a different way, the argument against federalization of regulation in radiation medicine is essentially the Jeffersonian one. But, yet, what concerns me is that nothing in your proposed mechanism turning everything over to the state and the Council of Radiation Program Directors assures us that they're going to follow sort of the Jeffersonian dictates of you philosophy. There's nothing at all, it seems to me, to make them do anything except sort of slavishly follow NRC -- well, I shouldn't. Let me rephrase that.

It sounded like from the description a lot of the content of these suggested state regulations was basically simply sort of imitating or adopting in more general form what

NRC ruled should be the case with the 10 percent of federally regulated medicine.

And so what is there in your -- I don't understand what mechanism there is to sort of prevent this mechanism from simply following the path, well-established pathway, of the past of over-regulating, maybe not just the 10 percent, but now 100 percent, of radiation medicine in a way that is a complete contradiction with the rest of the practice of medicine?

MR. VILLFORTH: Well, I think the answer is that it hasn't been done that way as far as the rest of ionizing and non-ionizing radiation as far as the states are concerned. I don't think that I'm aware that they're out aggressively pursuing something that's detrimental or overly prescriptive or what have you.

I think the states are saddled with an incredibly complex problem of dealing with the EPA and the OSHA and the FDA and the NRC and so forth. And I think they're trying to do the best they can with those kinds of resources. So I don't think they were out there looking for new areas to become overly restrictive. And it hasn't been that way that I'm aware of in the machine-produced areas.

You're shaking your head. You disagree.

MEMBER WILLIAMSON: I'm no expert, but my understanding, there are some states that have extremely

active and vigorous enforcement agencies and kind of have pretty much taken the NRC perspective and generalized it to NOARM, if I've got the acronym right. Among the states by reputation, not through any thorough investigation I've done, would include New York, Texas, extremely vigorous and aggressive by reputation.

MR. VILLFORTH: I was talking about machine-produced radiation.

MEMBER WILLIAMSON: I'm talking about machine-produced radiation, too.

MR. VILLFORTH: You said NOARM. I'm confused.

MEMBER WILLIAMSON: NOARM I thought was your acronym for stuff that was produced by other sources, other than byproducts.

MR. VILLFORTH: No. It stands for Naturally Occurring and Accelerator-Produced Radioactive Material.

MEMBER WILLIAMSON: Yes.

MR. VILLFORTH: So it's radioactive material. It's not machine, not X-rays and --

MEMBER WILLIAMSON: Okay. I'm talking about external. I'm from radiation oncology. So I --

MR. VILLFORTH: Right.

MEMBER WILLIAMSON: -- naturally think of linear accelerator when I think of the 90 percent.

MR. VILLFORTH: Well, that wouldn't be NOARM.

Well, the materials would be NOARM, but the accelerator would be machine-produced.

CHAIRMAN SIEGEL: Dan?

MEMBER BERMAN: I think the opposite side of the coin might also occur. And that's what I was getting at before. I think there are certain states that probably don't consider that they have the expertise or want to put much time into regulation development as others. And they follow NRC guidelines, probably extrapolating from the 10 percent potentially to the 100 percent.

It's possible that if there is no longer the 10 percent being regulated, that a laisser-faire kind of approach could develop in certain states with respect to overall regulation in radiation medicine and that you get into the problems that were the kinds expressed about the laisser-faire approach if there aren't any teeth put into making states comply with a certain level of regulation. Was that considered by the committee?

MR. VILLFORTH: I don't recall that there was any discussion of any punitive action or financial action that would be taken against a state. I don't think that was a part of any of the options if they did not comply or became so lax in their enforcing of it.

MEMBER BERMAN: No. Was the potential that there could be a laisser-faire development in certain states if

there's no longer an NRC control of the 10 percent?

MR. VILLFORTH: Yes.

MEMBER BERMAN: Was that discussed? And what was the outcome?

MR. VILLFORTH: No. I think the point might be that in some states where, for whatever reason, whether it's the medical community or the user community, that the consumers might feel that even what is recommended by the suggested state regulations is too restrictive and that one should go to a laisser-faire approach. That could happen, yes. So there was a potential for that to occur.

CHAIRMAN SIEGEL: And that would make Thomas Jefferson happy.

Judith?

MEMBER STITT: Question: If the states then took over this business, that would I assume increase their cost of doing business? Is that absorbed by the state or monies come from any other directions to take on this business?

MR. VILLFORTH: It's going to cost the states more, whether that goes through, whether they adopt user fees to pick that up or whether they transfer from other programs. And that's a concern, and that's possibly the kind of question, concern that was expressed here, that it may be more an economic reason for laisser-faire than it would be for a philosophical reason. It's a potential.

CHAIRMAN SIEGEL: Any other? Bob?

MEMBER QUILLIN: One of the statements in here is that if there was not a state program to license a facility, then they could not receive material. Was there any discussion of what would result from that alternative? Was it just assumed that they, therefore, would get a licensing program or what would happen where a state such as Wyoming, which has no program and has no intention of getting a program, stays the same?

MS. GOTTFRIED: You're referring to they wouldn't get byproduct material?

MEMBER QUILLIN: That's right.

MS. GOTTFRIED: The committee considered that, and they felt that that was, in fact, a very important aspect of the report and that, in fact, it would be an incentive for the states to expand their existing programs to incorporate byproduct materials.

CHAIRMAN SIEGEL: I heard that Wyoming wants to buy its services from Colorado.

(Laughter.)

CHAIRMAN SIEGEL: Larry?

MR. CAMPER: Under the federal guidance the DHHS would play in the model, there's one of the things that they were going to do: monitor the effects of deregulation. The deregulation that's being referred to there is what, the

effect of NRC withdrawal?

MS. GOTTFRIED: Yes.

MR. CAMPER: Over time?

MS. GOTTFRIED: Yes. Barry?

CHAIRMAN SIEGEL: Theresa?

MEMBER WALKUP: My question is under A2. It's the one following his. "Enhancing training and standards for health care personnel." Could you explain what you meant by that and who exactly would pay for that?

And the reason I'm asking is radiation therapists and people on that level right now by the ART responsible a lot of times with downsizing in hospital and the costs are responsible for their own continuing education. Is this going to be another financial burden on those people or is this going to be supplied by the Health and Human Services?

MS. GOTTFRIED: I think the thought in this instance was that one of the guidance areas that the HHS should be involved in is educational and so that there would be an emphasis from the federal level to help and assist in the training of personnel.

MEMBER WALKUP: So you're talking about at the college level or at the working level or --

MS. GOTTFRIED: We'd not get into that kind of detail, but my assumption is more along the lines of in the workplace, as opposed to within the educational system itself.

But I suppose if it was determined that it should start at an earlier phase, then that was something that they could look at.

CHAIRMAN SIEGEL: Lou?

MEMBER WAGNER: Did the committee recognize that there is a preponderance or a pervasive difficulty in the education and qualifications of people who are performing procedures with ionizing radiation?

MR. CAMPER: May I ask a trailer as you think about your answer? More specifically, in 1980 there was the Omnibus Reconciliation Act. You're familiar with that. And through that process DHHS brought to bear the concept of licensure of technologists, for example, in the states.

It is now 16 years later. I think it's had a mixed pathway of success or failure depending on how you look at it. Did the committee look at the track record of how that training implementation and licensure has gone? And would that be some benchmark of success perhaps in the future for DHHS in the area of training of personnel?

MR. VILLFORTH: I don't know that the committee looked at the effectiveness of that program. The template is there through that program if it's needed as described here. There is regulatory authority for that training, which would apply to nuclear medicine as well as X-ray and any of the other applications. So that the tool is there. And that's

administered by one of the other elements in the Public Health Service.

So no, I don't know that I know the effectiveness of that.

CHAIRMAN SIEGEL: Lou?

MR. VILLFORTH: I could give you a guess, but --

MEMBER WAGNER: But you didn't answer my question. And my question was: Did the committee address any issue or have any findings that there was a deficiency in the education or the training of some individuals who are responsible for the delivery of radiation in medicine?

MR. VILLFORTH: No. I don't think the committee went out and searched that information that nuclear medicine physicians or radiologists or technologists needed additional training, I think. But the question of quality assurance and the aspects of radiation protection in these specialties, there's always the importance of continuing education. And these are the kinds of things that have some value.

I think, again, the mammography quality assurance is not a bad example where there is some supplemental training and awareness that needs to be done in that area.

CHAIRMAN SIEGEL: All right. Looks like we're questioned out for the moment. We still have a lot of work to do as an Advisory Committee here. I think it's time for us to take a break, 15-minute break. And then when we resume, we

will start to tackle some of the remaining questions. We hope you will be able to stick around as we tear down your report. Remember, we're a friendly audience.

(Whereupon, the foregoing matter went off the record at 3:28 p.m.)

CHAIRMAN SIEGEL: Professor Wagner, seat thyself. Professor Williamson, sit down.

We're about to provide you with wisdom now. Are we ready? All right. We are back on the record. All right. We have had a chance to ask some key questions of the folks from the NAS and IOM. Now I think we need to get back to the questions, at least as a framework for continuing the discussion. I actually think we can just charge right in now and attack question one, since that's actually the one we've talked the most about for the last hour and a half. So let's do it.

I am not quite sure of the right way to do this, but I suppose we could begin by asking how many of us support alternative D as it's currently expostulated by the NAS IOM. I only use real words.

The other way to do it would be to just go around the table one at a time and say which alternative would each of us have picked and why. Which would you find more helpful?

MR. CAMPER: Well, I think it would be interesting, be valuable to the staff and particularly to the

Commission to know as a question is whether or not the committee agrees with the recommendation of the academy, given that you have been in the position of advising us on policy matters for some time now.

Then in addition to that, specifically where each committee member stands may be of value as well. Actually I guess I'm saying I think both are important. I think both are important.

CHAIRMAN SIEGEL: Okay. Let me suggest that we also consider the following. One is that D as currently configured, we are troubled by the fact that D doesn't seem to have very much teeth. So another way that we could consider D is D with more teeth. Namely, D modeled after something like the Mammography Quality Standards Act, where there was a Federal mandate with a set of regulations put in place by a Federal agency to be defined and administration by the states, but in accordance with the Federal mandate.

So that is a little bit stronger than Federal guidance.

MR. CAMPER: That's E. You just explained what E was.

CHAIRMAN SIEGEL: Well, it's not quite E. It's D and F. It's E-ish. D-ish E, I suppose.

MR. CAMPER: I think it's a little bit different. E seems to imply that the Federal Government steps in in those

cases where the states have not, for whatever reason, chosen to implement a program or an acceptable program.

As opposed to having the hook, if you will, that currently exists in the MQSA, in that the MQSA must be conducted in facilities, because if your facility doesn't undergo the certification process, thou shall not be reimbursed.

MEMBER FLYNN: I guess I didn't know what teeth meant. You mean you're going to step in with gums with no teeth?

CHAIRMAN SIEGEL: Teeth would be no reimbursement. That's I mean currently one way the Federal Government makes things work for medicine, is to say if you don't do this, you don't get Medicare reimbursement. Since Medicare is arguably anywhere between 40 and 50 percent or 40 percent in most hospitals, and increasing as the boomers get older -- yes, Medicare is going to go to managed care, so that will be even worse. That will be a double whammy.

At any rate, where was I? I lost my thought. So that would be the teeth on D and a half, if you will. Would be a federally mandated program administered by the states, and necessitated by that's how you get reimbursement. It still allows the states to have some latitude, but still a little bit Jeffersonian. That's one thing.

Now the other thing, concept that Larry threw out

on the table and mentioned briefly, and I want to make sure all of you understood that, was this issue of simply figuring out a mechanism, Congress figuring out a mechanism, that would essentially force all states to become agreement states, which means that essentially all the materials programs lock, stock, and barrel transfer to the states.

At that point, the NRC is left with essentially no licensees except for Federal facilities.

MR. CAMPER: That would appear to be the case, right.

CHAIRMAN SIEGEL: Then they have to get all their license fees from Federal facilities, which is a good thing. No, but the NRC then is left in a position of creating policy but not directly administering licenses. It transfers a lot to the states. In some ways, it seems cleaner than kind of saying that what is going on in the hospital is this is regulated this way, but what's going on in another part of society is regulated differently. So that's another option that I think we ought to consider.

I don't really know how to structure this. But why don't we just start off with the simplest way to do it. How many of us feel that we would endorse alternative D as laid out by the NAS IOM outright, and just go with their choice? Let me just do that as a show of hands.

I guess ideally -- or we can go around the table.

Theoretically the non-voting members would not participate in this statement. Lou.

MEMBER WAGNER: I would not endorse D. My opinion is that I don't feel that the report is thorough enough to have identified the source of the problems that we currently have today.

They have identified the problems, but they have not identified why we have the problems. I feel that unless we identify why we have the problems, we are doomed to repeat the failures of the past. I think D is a prescription for doom by having the states take over.

CHAIRMAN SIEGEL: Well, as long as we're doing that, why don't you say which of the alternatives --

MEMBER WAGNER: I think in all the alternatives there's aspects that I like and aspects that I don't like. If I were to devise my own alternative, it would be to first come up with a prescription as to how a regulatory organization should be structured in order to have checks and balances to make sure that over regulation and interference into the practice of medicine is avoided to the extent possible.

I do not see any recommendations on checks and balances in the form of adopting a specific program. Without that, I can not make any further recommendation.

I would venture to say it would be okay to turn it over to the states if we could adopt measures by which

these checks and balances could be implemented at states levels. But there is nothing there to prevent states from just repeating what the NRC has done. So I can't endorse that.

As far as the Federal Government is concerned, I do not think that the -- I guess if there were one that was preferred, I would adopt for alternative E, which would be the least of all the other problems. I'd take alternative E and then hope that a system could be developed by Federal authority to have enough checks and balances in it to ensure that we don't repeat the problems of the past.

CHAIRMAN SIEGEL: So you are in effect saying that you think the administrative procedures act works better in the Federal Government than it does at the state level, in terms of ensuring that appropriate public input into rule making occurs at all stages of the process?

MEMBER WAGNER: Yes, but I feel uncomfortable to some extent with that, because I also know that other aspects of medicine are not regulated as much as radiation. Now we are doing what the NAS didn't want to do, which would be to expand Federal authority over all, 100 percent of medicine.

So right now, it's difficult for me to devise an answer, not having had the wisdom of many months of inquiry, et cetera, and deliberation in looking at alternatives in the systems. I can only specify that of the things that are done

here, there doesn't seem to me to be enough homework to know what the real good alternative would be at this time. I think more homework has to be done.

But alternative E at this time would probably be my preferred naive preference at this time. But I must preface it with in fact I think it's naive.

CHAIRMAN SIEGEL: I think that part of what we are doing here is we're drawing on our own long experience to give an impression, recognizing that we didn't spend anything like as much time on this as the National Academy of Sciences did. But nonetheless, we've read their report carefully and listened to their arguments, read their arguments, and can express our impression as part of the next part of the process, which is to help guide the NRC to figure out how they are going to react to this thing.

Dennis.

MEMBER SWANSON: Yes. I support proposal D from the standpoint of, you know, the states are currently regulating 90 percent of the use of ionizing radiation. It doesn't make any sense to not give them the other 10 percent.

Also, the states are currently regulating the professional practices associated with providing medical care in general. It doesn't make any sense to separate this out into another agency. So for that reason, I think it makes sense to give the states the power to regulate this.

I think I share some of the concerns where I see proposal D coming up a little short, is I'm very concerned that there needs to be some type of mechanism to ensure active involvement of the regulated community in the development of the model regulations, the evaluation of the regulations, et cetera. I don't see where that comes into this currently. Okay?

I have a concern about that. I don't think the answer is E, necessarily. I have the same downside to creating a national Federal regulatory authority over medical uses. Okay?

CHAIRMAN SIEGEL: That's actually F, isn't it?

MEMBER WAGNER: Well, F is the one that is completely centralized. E is one that has some reserve Federal authority.

CHAIRMAN SIEGEL: So you meant E?

MEMBER WAGNER: I meant E.

MEMBER SWANSON: And I think the other concern is as has already been expressed, there has to be some stick in making sure that the states do actually assume the regulation of the by-product material.

CHAIRMAN SIEGEL: So do I hear you saying D and a half?

MEMBER SWANSON: D and a half, yes. I think we need to go a little further with D, okay?

CHAIRMAN SIEGEL: So it's D with a stick, basically.

MEMBER SWANSON: D with a stick, and to ensure involvement of the regulated community, somehow.

MEMBER STITT: Well, you're not going to hear much different from me. The thing that I just don't understand, and I thought that Dan brought the question up well, is what do the states do, how do they do it differently between the states, and when asked about the leaders didn't support their case by saying well some responded, some didn't. We've got thousands of paper here, and we've got some toilet tissue with some regulations written from that state. And I'm not going to adopt your attitude, I'm a doctor, trust me. Because Judith, she rightly calls us on that. I'm a state, trust me, but I do wonder are they slogging around in the dark? Are they more competent than we here seem to be giving them credit?

It would seem that a 10 percent ought to be able to be added to the 90 percent that they already manage, but I think that there are complex issues that because they are a small part, each state wouldn't might have some reluctance to come up with adequate overall guidelines.

So I also support some form of a Federal involvement of work being carried out at the state level. I guess I'm saying a D plus.

I think D as it is written, there's not much connection between the federal and the state. I think there would be a lot of wondering around looking for sources, so to speak, figuratively as well as literally.

CHAIRMAN SIEGEL: Okay. Bob.

MEMBER QUILLIN: I think I would probably go with D and a half. I put it down. When I looked at D, I looked at it through several different lenses. One lens was if I were at a state or federal person, how would I operate in this environment. Although under D they do go into some discussion on the funding issue, they don't really flush that out so that you have feeling for what this would cost, who would be paying for it.

Right now, both at the federal level and at the state level, money is a major issue. If there's no funding to do this, no new funding to do this, the source of funding, government stream, whatever you want to call it, it's just not going to happen either at the state level or at the federal level.

That was one of my concerns about D, is how this new Federal agency activity within HHS was going to be able to do what they were supposed to do.

I was also concerned about the issue of the stick wasn't there. So the term was D with a stick.

I wasn't quite willing to go all the way to E,

but it does have some positive aspects. So I am somewhere between D and E.

CHAIRMAN SIEGEL: Okay. We'll start at that other end. Dan.

MEMBER BERMAN: Not much to add. I actually don't see much of the drawbacks of E. I think I am concerned that D as stated is too much like C. That it's kind of optional. I see kind of a federal advisory role with D, but there's no necessity that the state follow what the federal agency would be stating.

So it is either D, I think in order to avoid too much of drifting into the laissez-faire and being kind of very contrary to the goals that were set out to improve uniformity of use of ionizing radiation, the missile goal that we were trying to look at, that I think we would go too far with D of creating greater disparities, and that we need either D with kind of stick or E, in order to handle that problem.

CHAIRMAN SIEGEL: Yes. I think implicit in all of this is our thinking would seem to imply that the stick that they held out, which is that you wouldn't be able to get by-product material if you didn't have a program in place in your state, wasn't enough of a stick.

MEMBER STITT: Is that what they kept referring to as the bully pulpit? We put that on our list for the glossary here, but where does that phrase come from and what

in the world is the origin?

CHAIRMAN SIEGEL: I don't know. You'll have to ask Teddy Roosevelt about that.

MEMBER STITT: But they used it over and over and over and over again. So it must have been --

MEMBER WAGNER: But he did want to carry a big stick.

MEMBER BERMAN: Just related to what you brought up, I think there would be the states that wanted to just adopt their own system and wanted to be iconoclastic, save money, they were anti-regulation, and I think there will be some states along those lines, would find a mechanism of avoiding this problem of being able to obtain by-product material. That's a suspicion I have.

CHAIRMAN SIEGEL: Okay. Judy.

MEMBER BROWN: My background and experience doesn't really qualify me to make judgements between these choices. But I can tell you a few things that I would like to see.

One is -- and I guess it puts me in a position of the D with teeth or E-ish, if there has to be a choice between these.

Personally, I like Robert Adler's statement, the dissenting opinion. I'm not sure how much of that is my knee-jerk consumer advocacy or just made a lot of sense to me, just

as someone reading it.

I do know that I don't trust the states, many of them.

CHAIRMAN SIEGEL: Because you think they won't go far enough or they'll go too far?

MEMBER BROWN: Because I wouldn't want to be in them if I was sick.

CHAIRMAN SIEGEL: Do you want to name some states?

MEMBER BROWN: Massachusetts is not one.

I would scared about giving authority to them, the ones I have in mind. I guess I want the most over-arching guidance and authority from a Federal uniform source that could be provided to the states, and you know, taking over I guess the E part where they aren't competent or need help, that there would be some place they could go to.

I think that's all.

CHAIRMAN SIEGEL: Okay. Dan.

MEMBER FLYNN: I would favor D. I think maybe I read it different -- E. Maybe I read a different E than you all read, because I'm going to quote this.

It says, "The most critical --

CHAIRMAN SIEGEL: What do you favor? You say E?

MEMBER FLYNN: E. "The most critical feature distinguishing alternatives D and E" -- this is the committee

talking -- "pertains to a situation in which the state does not elect to devise a program for regulation or rescinds the existing program because of economic or other considerations."

It says here, "Alternative E has all the advantages of alterative D, except it goes one step further than D by giving regulatory authority to a Federal agency in a situation of last resort, namely, no state program."

Then on the disadvantages, the committee said, "Incorporating a legislative provision that authorized the Federal agency to regulate states that have no program raises the following issues. First, what is the minimum level of regulation that would be required by the states to prevent Federal regulation."

I do not think that is such a difficult issue. I think this Federal agency, one of the mandates would be to make sure that the states are not too prescriptive. This is the Federal agency. To make sure the states don't interfere with the practice of medicine, and look for the out-lyers.

You have 50 states out there. There may be two that are too prescriptive getting involved in medical issues. You may have two or three that have for economic reasons have just abandoned the whole program.

Alternative D allows the CRCPD, which is not a Federal agency, but it would be sort of acting like an advisory role in a federal way. I don't think -- that has no

teeth behind it.

I think that this alternative E, a Federal agency with very loose controls, extremely loose controls, working with CRCPD could do a much better job.

I think the reason, you know, to turn this over to the states, you know some of the states are very strong. Texas, Illinois have very strong programs, very strong opinions how the program should be run.

But some of the states, from contacts I have had, are very weak. The reason why they regulate 90 percent is because they follow one in a copycat-like fashion after the NRC.

When the NRC is not there any more and changes in medicine develop, who are they going to copycat after at that point? Then as you see all this non-uniformity developing in states with different economic priorities, I think things will get worse. I think it will be more expensive to regulate 50 separate programs that have this non-binding CRCPD kind of floating around there with some suggested regulations.

I think alternative E does not give strong authority to the Federal agency, but it is a reserve Federal authority, just like it's described. I think that is a much better alternative.

I'm surprised -- I was quite surprised that they chose D. I thought that the way they wrote it, including the

disadvantages, they were going to be pointing towards E. So I would adopt E.

CHAIRMAN SIEGEL: Okay. Eric, realizing you're speaking for yourself.

MEMBER JONES: I'm not a voter, am I?

CHAIRMAN SIEGEL: Yes. I think you actually are a voting member.

MEMBER JONES: Well, I'm serving with the FDA. So I have quite a bit of bias in this.

One of the things I see that's a big problem is that our agency does not regulate the practice of medicine. That's where we're -- we don't have any uniformity.

The problem I am getting at is that this agency is doing that, is regulating it. NRC through its quality management program is regulating it. The problem is is that between the agencies, we really haven't got any -- we did not come to some sort of uniform agreement if we could have done that.

The NRC has had a definite clear role in managing all this in the past, and probably still should continue to do that. I do like the idea of keeping the management of medicine, however, with the state licensing authorities. That is the practice of medicine.

But actually the use of ionizing radiation going into the states, it's true they vary a great deal. We were

looking at pharmacy, the practice of pharmacy with regard to PET. We found that we were unable to get a uniform feeling as to how pharmacy was regulated.

I am hearing the same thing here with the Institute of Medicine report. There's some variation about how the states would regulate things. So it would need some strong Federal oversight. If this were put into one agency, again resources would have to be a concern, as to where those resources would come from, and the states' resources as well.

So there's a sort of a pie in the sky approach here, as to what we think we'd like to see and what actually may come about. I'm not sure that any particular suggestions are likely to happen. But I --

CHAIRMAN SIEGEL: How sanguine of you.

MEMBER JONES: Exactly. I do think that the FDA would I think from the community's point of view be a very good sight for situating all this radiation control and regulation. Again, it's resources.

Somehow we would have to try to apportion out the regulation of medicine into the states. I'm not sure how that would be implemented. So I'm sort of caught up with situation E. I do think we need a very strong central overview, because there's such a variety of quality out there between the states. I agree with everybody that's made a comment along that line. You just don't know what you're going to get

between states with regard to practice of medicine. I'm not sure that they are all equivalent.

Again, if I were a patient, I don't know which state I'd choose to land in, but you don't often get that choice. It happens wherever you happen to be. But some uniformity would be what I'd be in for.

CHAIRMAN SIEGEL: In a way though it sounds to me like you are arguing for G, which is an over-arching Federal agency that contains the practice of medicine.

MEMBER JONES: Well that would suit my kind of bureaucratic approach, wouldn't it?

CHAIRMAN SIEGEL: In a way, that would be the fairest to ionizing radiation use in medicine, because it means every physician would be in the same boat. We'd all have to put up with the Federal presence in our face every day of the week. We'd learn to live with it.

MEMBER JONES: I'm not sure that would be less expensive. Thinking of safety and effectiveness, the public health situation, it may not be the least expensive, but it may be the safest thing for people.

MEMBER WAGNER: I'd like to make the comment and a statement that I think the major deficiency of this IOM report is the fact that it simply did not look at the mechanisms of regulation development and enforcement that led to the state of affairs we are in right now. It did not look

at that mechanism.

It gave us the history of what occurred, but it did not set down any concepts or ideas, as these are the problems. For example, is the fact that the regulations are passed and finally approved by an organization that has very little and almost zero medical background the problem? That's an issue. They didn't address that. There's no where in here that that's addressed.

CHAIRMAN SIEGEL: No. Actually, they do address it. If you look at --

MEMBER WAGNER: They make the statement that that's true. In one place they do make a statement that that is the background and that that's a problem. But they are not delineating in my opinion. They are not delineating it anywhere else. I mean it's sort of hidden in there. But it really to me is a very vital point.

It's a vital point -- and I don't mean that that particular issue is a vital point. I mean that the whole process by which these regulations come about has flaws. That's why we've gotten to the state of affairs we're in. Unless we identify those flaws and find ways to correct those flaws, we're going to end up doing the same thing again. That's why I had such a difficult time looking at these options, because none of these options look good to me. They are all options of how to change things, but I didn't see

there the really good solid options as to how to correct things. That is the difficulty I have with this whole thing.

I would like to see a document that would be investigating to try to find out how do you change the regulatory process to get regulation and enforcement to be effective for the protection of the public and the protection of patients, without being over-prescriptive and burdensome to the good practitioners out there who are trying to get the job done.

CHAIRMAN SIEGEL: Well a fundamental problem, and perhaps the fundamental problem, is government by yo-yo. Virtually everything that's in part 35 was originally something that had been imposed by license condition in response to a perceived problem that often was based on a few events.

Not everything, but almost everything came about, many of the very prescriptive things. Here was a problem, we had to fix it. Okay, how are we going to fix it. Well, we'll make it license conditions across the board.

Then when part 35 was consolidated, a lot of those things were put into part 35. They were there. They were subject to public commentary, but there wasn't a great deal of incentive for the NRC to tear it all down and start from scratch and say what are the objectives.

The part 35 re-write was really an attempt to

codify the culture that had already been established, as opposed to leaving it up to individual regions and license writers and inspectors to get it all set down in concrete.

A fix, and that's part of what we talked about earlier today, is to literally look at part 35 and say what are the goals of this regulatory process, what do we want to achieve, and what does it take to achieve that.

MEMBER WAGNER: I think if that wisdom would have been in this report, this report would have been improved by a major amount. It is that kind of wisdom that I think is important for people to look into in order not to repeat the problems of the past.

CHAIRMAN SIEGEL: Well the report is saying it obliquely. What it's saying obliquely, tear down part 35 and let the to-be-generated newest version of the SSRCP or RCR be the thing that guides what the states are going to do.

MEMBER WAGNER: Yes. That is absolutely right, but I think that that is really a cop out. Because what really would have been nice is for them to say whatever regulatory agency is set up, here's how it should be set up to protect against repeating problems of the past. This is what it should do. This is how it should have its checks and balances in the rule making and enforcement process. There's nothing like that in here.

CHAIRMAN SIEGEL: I haven't told you what I think

yet, although you'd probably know at this point.

I am actually torn between F, which is complete centralized Federal authority because of the fact that I think it has the potential, said naively, to be the most efficient, but I know better.

It has the potential to be the one where the Administrative Procedures Act process would work the most effectively, because all the people in the country focusing on something that all the members of the regulated community in the country focusing on a proposed rule that they don't like is possibly better than people in 50 individual states trying to do the same sort of thing.

So F is one direction I'm torn, but in the final analysis, I end up with D and a half as being Jeffersonian, which I'm a little bit of. Providing flexibility that fits best local needs while yet still leaving a strong standard setting role for the Federal Government.

I would couple D and a half with the notion that the enabling legislation and the enabling regulations would basically tear down part 35 and start from scratch in terms of what those regulations that the states are going to administer would look like, and would be very clearly based objectives based on what is really essential for public health and safety.

We have not really addressed this issue. We will

come to it. I would get as far removed from patient-related issues as possible, and would be as much focused on public and occupational worker issues in the process of doing that, because I think patient-related issues as I've said a million times, there's nothing unique about ionizing radiation that needs a higher level of protection than all the rest of medicine. Ionizing radiation is just one more tool used by doctors. It's dangerous.

We use devices. We use drugs. We use surgical procedures that have never been evaluated by any Federal agency and likely never will be. There are mechanisms at the physician censure level and at the tort law level for dealing with the way medicine is practiced. So that's where I vote.

So the way I am reading the consensus of the committee is that we are concerned that option D as it is laid out hasn't really completely thought through how this collegial almost voluntary system is going to work effectively, even though we're attracted to the process that the Federal agency would be this leader and guider and educator, we're not sure that states left to their own devices will follow through with it, and that we're either more in line with D with teeth or E, and maybe there really is no difference between D with teeth.

MEMBER STITT: Tell me what -- as I hear people talking, there's various euphemisms, D with teeth, with a

stick or whatever, reads to me like E. How are they different?

CHAIRMAN SIEGEL: Well, it's more than the Federal Government rushing in to fill a void. It's having a front end thing that says basically you had better comply or here is what's going to happen. What's going to happen is, there won't be reimbursement.

To me, a simple form of teeth is tying it to HCFA reimbursement for that particular aspect of medical care in that state or in that facility.

That approach also -- and D and D with teeth also leave the option for professional organizations to get in with various types of deemed status, an ACR or SNM accreditation program of a nuclear medicine practice can work under a state approach, may work, just like it works now for mammography.

Jeff.

MEMBER WILLIAMSON: Is it possible to ask a question about your opinion? I know I can't give my own opinion.

CHAIRMAN SIEGEL: We're not really voting, so I was being unfair. Why don't you and Theresa both tell us how you would come down on this issue. We're really not voting, we're generating --

MR. CAMPER: Jeffrey, you are at liberty to espouse your opinion and take an active role in discussion.

It's only when the votes are actually taken that you have a limitation at this point, okay?

CHAIRMAN SIEGEL: Well I apologize then, because I actually perceived we were sort of voting on this. But we'll call this opinion generation.

MEMBER WILLIAMSON: Well alright. Well I wasn't sure how to distinguish your view from option B, laissez-faire, because it seemed to me that the part you said -- whatever the new regulatory system is, it should stay as far away from the regulation of the actual medical treatments as possible. That's what all this is about.

As I understand the report, it's not suggesting the abandonment of occupational or public safety standards vis a vis exposures of employees.

CHAIRMAN SIEGEL: I'm not suggesting that either.

MEMBER WILLIAMSON: So it's just those things that the report takes aim at, those specific regulatory activities that involve the delivery of the treatment to patients and surrounding research.

I'll give my opinion I guess. I guess when I read the report and think over my own experience, I am less concerned about the consequences of under-regulation in the various states, should it be turned over to the states.

I do think there are certainly very profound disparities in the standards of practice across the United

States, but my belief is that the current part 35 style regulatory system has contributed very little really to the sort of improvement of quality, at least in my chosen field. There has always been a very big commitment to quality in the 20 years I have been in the field. There certainly are some practitioners that are on the other end of the tail, and I'm sure the regulations have helped bring a few people, a few institutions into the fold.

But my overall belief, is that it has not been the major dynamic by which quality is preserved in radiation oncology. So in a sense, I'm a sort of option B, laissez-faire. I really don't think that things like the quality management program really help.

On the other hand, I do perceive there sort of is a problem with non-uniform standards of technical practice in my field. I would like to see a sort of non-punitive regulatory system erected that could really make some good contribution to improving the quality of care. I do not think the current one makes much, in my opinion.

Again, I want to make it clear I'm not attacking basic safety standards for members of the public and workers in radiation. It's simply that I think the report is right. There is no more reason to find radiation medicine treatments more suspect and bad than orthopedic surgery treatments or cancer surgery or chemotherapy in my mind.

So I guess I would be in the end, sort of an option D if there were some mechanism to ensure that an appropriately interactive and collegial system could be put in place of the current part 35 that could make some substantive contribution to the improvement of the uniformity of radiation medicine delivery.

I think this is not a very simple problem to address. If it were simple to give a solution, we'd have solutions on the table that we could -- specific solutions we could discuss, but there aren't.

It seems to me something like the Mammography Standards Act comes closest, which is it's basically an enunciation of some basic practice standards, a lot of flexibility, what are the mechanisms that you use to implement those standards, including an array of protocols developed by the professional societies, and kind of an inspection that certifies you and looks at sort of the basic -- what are the basic infrastructure of quality treatment delivery is there, and doesn't hammer you because you didn't check off the box that says did I identify the patient in two ways, or something like that. It's not focused on that.

So I think that sort of provision, I could sort of buy a level of Federal involvement under that condition. If it's going to be the same as what we have now, I'd almost rather have option B to be honest. So I guess a D plus with

these two qualifications, being one to try to maintain some sort of a uniformity in this standard of practice, and that it be a truly useful vehicle for improving quality of radiation medicine as I've attempted to characterize it.

CHAIRMAN SIEGEL: As we talked about this morning, quality by education and real quality improvement as opposed to quality by inspection.

MEMBER WILLIAMSON: Yes.

CHAIRMAN SIEGEL: Lou, you had a comment before we --

MEMBER WAGNER: I'm getting very concerned about the idea that we're holding up the MQSA law, something that we should revere.

I think the MQSA rule is in many ways way too prescriptive from the legislative point of view. From the legislative point of view what's in the law as to what has got to be done is to me in many situations bad. It's not good. It doesn't have the flexibility that it needs in many respects. I think we have run into this in a few instances.

So I don't want to hold that rule up as being something we should model after. I think it did a great job in bringing to the attention of the medical community the need to codify your quality of imaging in mammography in order to provide good medical care. It did a wonderful job in that. It also did a wonderful job in bringing people up to higher

standards of practice.

But there are things in it that are overly prescriptive, overly costly and unnecessary. Those unfortunately are in the law and can't be changed by the FDA.

CHAIRMAN SIEGEL: I only suggested that it was a model. I didn't suggest that we should copy it exactly.

Okay, Theresa.

MEMBER WALKUP: Being new at this, I feel like I should abstain. But I wonder if perhaps we shouldn't work at fixing what we have more so than throwing it out and starting over.

In order to be consistent, we're going to have to have some sort of Federal leader, which we already have with the NRC. Just letting it go in the states' hands concerns me a little bit. I lived in the state of Texas for a while. I do realize what can happen. That does concern me.

Right now I'm in Oklahoma. I think we're in the process of heading that direction. So it's just a concern of mine.

I really would rather abstain from saying which one I feel --

CHAIRMAN SIEGEL: Okay. That's fine.

MEMBER SWANSON: Thank you for those comments.

CHAIRMAN SIEGEL: Texas is certainly taking it in the ear today. Dan.

MEMBER BERMAN: We went around and we seemed to have picked one of the alternatives that was proposed. Just related to Theresa's comment, I guess by not speaking, we are I think all of us seem to be accepting the concept that the NRC should not be the vehicle, shouldn't be the agency involved in this kind of regulation.

I think there is some of let's just start over on this whole process and do it in some other agency that's more directly related to health. We spent a lot of time looking at the differences between E and B. I think we ought to at least give some thought to whether we are endorsing the concept of just starting over with a more health related agency.

CHAIRMAN SIEGEL: I think that was actually one of the precepts that I laid out this morning, that we had regular -- had consensus on. Was that -- uniform regulation was a goal ideally within an agency with responsibility for assessing the risks and benefits of all of medicine rather than one that was just focused on radiation alone.

The NAS is appropriate they say in their discussion of alterative F, that appropriate regulation of ionizing radiation of medicine demands knowledge and experience with the medical issues, that those should be emphasized over knowledge and experience with byproduct materials.

I guess I really do believe that. Being able to

put this in its overall medical perspective is a key component of the equation. So implicit in what we were saying I think, unless anyone wants to go backwards, is that we were endorsing the NAS concept that housing this somewhere more closely linked to health made more sense to us. Does anyone disagree that we were saying that?

MR. CAMPER: May I interrupt you for a minute?

CHAIRMAN SIEGEL: You may.

MR. CAMPER: I hate to interrupt this important deliberation at this moment in time, but we do have --

CHAIRMAN SIEGEL: Like anybody is going to pay attention to it.

MR. CAMPER: Seriously, we do have an important guest who is here for a very important purpose. We have Mr. Hugh Thompson, who is our Executive Director of Operations, who has dropped by to visit. He has a special mission in mind, Dr. Siegel.

MR. THOMPSON: Maybe I should come up here. Barry, you may have to come up and join me in a moment.

CHAIRMAN SIEGEL: I'll stay.

MR. THOMPSON: Many years ago, gosh, it must have been about six, we elected to make a real shift in the way this committee was operating. It was a shift that the agency hadn't really been able to come to grips with for some time. they said it would never work, that you could not allow one of

the committee members to chair the committee. I said there's no other way that it really will work. We looked around to find the individual that we thought would be like the first astronaut, will be the first person fired off into this never-never land of being the chairman of the Advisory Committee for the Medical Use of Isotopes.

Barry only had one request when we approached him, could we change the title from ACMUI to Advisory Committee on Medical something else. But we never quite got around to changing the title. It has been a time of real vision. I think you have brought that vision along with the members that you've worked with over the years. You have worked with a wide variety of memberships. Your skills at reaching consensus or allowing differing views to be presented in a very professional way is certainly appreciated by all of us at the commission, particularly those of us who deal with the activities that all of you have to deal with.

We are not sure whether right now you are dealing with the transformation from a caterpillar to a cocoon to a butterfly or visa versa. I mean we are talking about really some enormously important activities that this committee has been involved with. You have been involved with and directly and personally involved in many of these, I wouldn't necessarily call them troubling times, but challenging times. They have obviously been a bit of trouble.

We all have had the fundamental objective at our heart, is protecting public health and safety and protecting the patients obviously in trying not to interfere with medicine. The judgements being made in those areas are ones as you debate today. But I think that with all good faith and all good effort, you have done a yeoman's job in your leadership for this advisory committee.

On behalf of the chairman, I'd like to read a plaque. This was the time we knew we had you for sure. Apparently you will be coming back for a few other things, but this is a certificate of appreciation presented to Barry Siegel in recognition of your service as Chairman of the Advisory Committee on the Medical Use of Isotopes, which resulted in a significant improvement in the Nuclear Regulatory Commission's understanding of the use of byproduct materials in medicine.

So if I could present this plaque to you today.

(Applause.)

MR. THOMPSON: Thank you very much. It's been a privilege on my part to know you professionally and to also know you as an individual. I will cherish those thoughts. I hate to see you depart. But maybe if we're out of the nuclear medicine area, will be one of the areas that we'll part on, we'll meet on other fields at other days.

CHAIRMAN SIEGEL: Very good.

MR. THOMPSON: Thank you very much.

CHAIRMAN SIEGEL: Thank you.

I said something at my last meeting of the FDA Advisory Committee to the effect that old gadflies never die. It is true here too. Thank you very much.

MR. THOMPSON: I look forward to the results of today's deliberations.

CHAIRMAN SIEGEL: We'll keep truckin.

MR. THOMPSON: Keep going.

CHAIRMAN SIEGEL: Okay. We have at least 15 more minutes here.

MEMBER BERMAN: I'd like to correct him. Actually, you've done a yo-yoman's job.

(Laughter.)

CHAIRMAN SIEGEL: Yes. It's not entirely clear how many more meetings we're going to have before my term is officially up, which I guess is the end of the Federal fiscal year.

MR. CAMPER: It's in the summer of this.

CHAIRMAN SIEGEL: September 30, or there abouts.

MEMBER BROWN: So you will be chairing the May meeting?

CHAIRMAN SIEGEL: Well, we actually have already picked a date in April, not in May because of the fact that I am going to be in Korea and/or China for a good fraction of

May. But it's not clear that we're having an April meeting yet. That is to be determined. But I would emphasize that we probably do need to decide quickly if we're going to.

There is a possibility that we're going to have a commission briefing either in May or June or something like that. If we do that, then we will need a day's meeting at a minimum to prepare for it as we have done in the past.

MR. CAMPER: Let me take this opportunity to make a couple of comments to sort of clear up a couple things so that members of the public will know, and for that matter, all the members of the committee.

We did take this opportunity today for Mr. Thompson to provide Barry with this plaque, thanking him for six years of very valuable service. We did that as Barry is alluding to, because we weren't certain if there was going to be a meeting in April.

We certainly have plenty of issues that the committee can deal with, but it's a function of how does this meeting go, what does the Commission decide to do about the NAS Report. There's a number of questions that have to be answered in the short-term for us to reach a decision upon that point.

So we took this opportunity, knowing that we had him today to provide him with the plaque, not knowing that there would be or would not be an April meeting.

The second point is is that we as you know in the past, there have been at least one occasion that I can recall, if not two, when the committee has actually briefed the Commission directly twice. The rule on that has become one of either party can ask for the briefing. Either the Commission can request it or the ACMUI can request it if they feel that there are issues worthy of such an interface.

Well we learned yesterday afternoon that the Chairman is interested in a briefing in May. Now I emphasize Chairman because we are, all the agencies are also going through transition, where we now for the first time in some time have a Commission functioning as a quorum, but I think it's safe to assume that there is an interest by the Commission in a briefing by the ACMUI in May, given the view expressed by the Chairman yesterday.

So I think there is a high probability that the Commission briefing will take place in May. So one of the things you're --

CHAIRMAN SIEGEL: Ideally when I'm out of the country.

MR. CAMPER: One of the things you are going to need to decide is in reaching some of your answers today in preparation for that briefing, and whether or not you feel an additional meeting is in order, or subcommittee meeting or what have you as you prepare for that briefing.

One of the things we've been asked to do today is to pulse the committee on possible available dates for participation in that briefing. So if by the close of business tomorrow you can have some idea of possible dates, that will be helpful to us as we proceed with the planning for such a briefing.

Then the final point is Dr. Siegel departs the committee, a couple of other administrative issues are worthy of mention. One is that we have published a Federal Register notice and sought nominations for the nuclear medicine physician to replace Dr. Siegel. That process is ongoing, just as with every solicitation of nominations for the committee. Ultimately that position will be filled.

Obviously Dr. Siegel's departure leaves a tremendous void to be filled as far as a chair of the committee. The staff has recommended, and the Commission has approved the appointment of Dr. Stitt to serve as the chairman of the committee once Barry departs. So that is what Hugh was alluding to as he was leaving. Obviously Dr. Stitt has some big shoes to fill, but we have great confidence in her. We look forward to working with her, just as we have Dr. Siegel.

So those are the administrative points I wanted to cover.

CHAIRMAN SIEGEL: All right. All that said. I can't tell you how thrilled I am about a May Commission

briefing. I can't imagine how we're going to fit it into the schedule.

What is our pleasure for the remaining time today? We can keep trucking for a while. We can --

MEMBER BROWN: Adjourn until tomorrow.

MEMBER WAGNER: Yes.

MEMBER BROWN: Adjourn until tomorrow.

MEMBER WAGNER: We could do that.

MEMBER BROWN: We're only talking 15 minutes here, right?

CHAIRMAN SIEGEL: Well, unless we just kept going because we were so energetic we wanted to keep going.

MEMBER WAGNER: Let's look and see what we've got.

CHAIRMAN SIEGEL: That's not really what I think.

Trish, which of the remaining questions, based on the things we've talked about up to this point would you identify as the most important to you in terms of being sure that we provide you with our input.

MEMBER STITT: Barry, while she's thinking, let me ask you a question. You raised a question to us, and we haven't answered it. Are you going to go back to it tomorrow?

CHAIRMAN SIEGEL: Which?

MEMBER STITT: We looked at options. You kind of polled the group, but none of us really got into Federal

agency as being the guiding agency.

CHAIRMAN SIEGEL: I think we just discussed that.

MEMBER STITT: You brought it up as a question. I didn't think we --

CHAIRMAN SIEGEL: I actually thought that based on the morning discussion that it was implicit that we were in favor of DHHS in some form as being responsible for that.

MEMBER STITT: I guess the only reason I wanted to see if everybody agrees with that, and does that become another salient point of our discussions here.

CHAIRMAN SIEGEL: Does anyone have any concern that that's the right recommendation? Would anyone prefer EPA? Just checking.

MEMBER WAGNER: How about OSHA.

CHAIRMAN SIEGEL: OSHA or the IRS or you name it.

MEMBER WAGNER: Or NRC. That's an option.

CHAIRMAN SIEGEL: I think the medical focus, given what we've talked about, is really key. I am still wrestling with the fact that this is primarily medical versus materials. I'm still not totally reconciled how we're going to have this kind of dual process. I'm not sure whether they need to be separated.

I am very attracted to Larry's approach of having 50 agreement states plus territories, somehow figuring out how to deal with Federal facilities and having the NRC, at least

with respect to issues of occupational exposures and public exposures, setting the standards, and letting the states run essentially agreement state programs.

I find that concept attractive. It gets the NRC itself intrinsically out of the inspection and enforcement business and gets it into the policy setting business.

MEMBER WAGNER: I guess one other issue though which maybe we haven't addressed yet today that perhaps is important. I forgot to ask the question when the IOM was here.

You know part 20 is never addressed, or never was addressed. Everything here centralizes around part 35. But indeed, when you talk about occupational exposure in the medical environment, you are talking about situations that indeed have differences as opposed to occupational exposure in the industrial environment. I wonder if you set up a system where you try to take 35 out but 20 stays in place with the NRC, now the NRC is still only concerned with occupational exposure as it relates to that for byproduct materials. It does not address --

CHAIRMAN SIEGEL: I think a state-administered system would essentially put part 20 as the responsibility of the states.

MEMBER WAGNER: I know. Therein I'll point out your problem.

MR. CAMPER: Well, the model as proposed calls for the NRC to eliminate its involvement in the medical program, that being part 35, and those regulatory activities under part 20.

Now what that translates into is if there is no part 35 and there are no medical licensees, there is no part 20 NRC regulations in place for occupational workers in the medical setting.

MEMBER WAGNER: Okay. That then clears it up. Thank you.

DR. HOLAHAN: I was just going to follow up on what Larry had said, is part 20 only applies to NRC licensees. However, if your license under other parts of NRC regulations and therefore are still an NRC licensee aspects of part 20 could apply. But if you are a medical licensee only a part 35 licensee, that goes away.

MEMBER WAGNER: Okay, thank you.

DR. HOLAHAN: Part 20 --

CHAIRMAN SIEGEL: But that's why it's important for any of us to work toward, either for this entire materials program to transfer to the states or for materials associated with medical institutions to transfer to this new system. Because otherwise, if you're working one day in the nuclear medicine lab and you get an exposure, and then the next day you walk over to your research lab, how do you know whether

you report an over exposure to the NRC or to the state? It's the same thing that happens now in byproduct versus non-byproduct material. That inconsistency needs to be eliminated, however it's done.

MR. CAMPER: I have two questions, Barry. So with regards to the question of DHHS as being the agency, are you in a position now where you feel that you have consensus, the committee has consensus?

CHAIRMAN SIEGEL: I think so, but we can -- well, does anyone disagree that we think of all the agencies we can think of at the moment, short of some brand new agency, the one we would recommend is DHHS?

I think we have consensus.

MR. CAMPER: Good.

CHAIRMAN SIEGEL: My way in viewing this is the person I would like to be responsible for deciding ultimately whether a radiation protection program in medicine is consistent with the overall needs of medicine is the Assistant Secretary for Health, who will advise the Secretary of Health and Human Services, who is less often a doctor.

MR. CAMPER: The other question I had is if I look at question number one of our issues, does the ACMUI agree with the preferred alternative chosen by -- I'm getting a no sort of.

CHAIRMAN SIEGEL: You are getting a no with a

modifier. We're opting for D and a half rather than straight D, which we thought didn't have quite enough teeth in it.

MEMBER FLYNN: Well one of us opted for E. Probably four of us opted for E.

CHAIRMAN SIEGEL: Well, two or four.

MEMBER WILLIAMSON: One non-binding voter opted for part of -- what was the one I voted, B? I've forgotten. What was the laissez-faire one?

CHAIRMAN SIEGEL: Yes, maybe three or four said E.

MEMBER FLYNN: I was E.

CHAIRMAN SIEGEL: Yes, but I think there also is not that much distinction between D and a half and E.

MEMBER STITT: Particularly since you are making D and a half up.

CHAIRMAN SIEGEL: Since I'm making D and a half up.

DR. HOLAHAN: Do you want me to identify the specific -- oh I'm sorry.

CHAIRMAN SIEGEL: Sorry.

DR. HOLAHAN: You had asked me about the other question.

CHAIRMAN SIEGEL: Do you have more, Larry, or is that it?

MR. CAMPER: No.

CHAIRMAN SIEGEL: Okay.

MR. CAMPER: No, I do have a question when you finish this discussion.

CHAIRMAN SIEGEL: Okay.

MR. CAMPER: The question is is the following question. Do the basis or rationale used by the IOM committee support their conclusion? We've heard a great deal of discussion that indicated that you didn't think that it did. Some of the criticisms were levied about the degree to which they answer some of these questions in terms of the state regulatory programs, for example.

MEMBER STITT: Well, I think that's one of the reasons that I am more an E person, because I don't agree that material was presented in the report tells me that what I think we should be looking at can be managed by the states. So therefore, I don't feel that D is a preferred choice to me.

MEMBER FLYNN: I agree with Judith.

CHAIRMAN SIEGEL: Although I think I'm not defending one position or another. I think what we may simply be suffering from is lack of data rather than a frank condemnation of the statement.

I'm not sure we know exactly what basis, and maybe John wants to comment on this, exactly what basis led the committee to conclude that they thought the states would in fact be able to do an adequate regulatory job under

scenario D.

One conclusion is is that they seemed to be doing what is perceived as an adequate regulatory job for the 90 percent that they currently control. It's hard to argue with that conception.

On the other hand, a more detailed sampling of actual state practices as a data base would have made for a more compelling belief that that conclusion was correct.

So -- Jack.

MEMBER WILLIAMSON: Well, another underlying theme of what the plus means, the D plus as I hear different people saying, and I've said in my own way too, is that there's a concern of having 50 different part 20s and part 35s. There is a concern about lack of uniformity and sort of basic standards. That is a different sort of D than it seems the Institute of Medicine had.

Their D was concerned with just reserve Federal authority in case no program existed at all. Here the preoccupation has been more concerned with consistency of the basic standards. No question maybe that the states shouldn't enforce them, but what are the standards going to be.

In fact, Larry has raised the concern that if part 35 goes, there isn't a nationwide part 20. It does seem to me that that's the kind of a standard that should cover as broad a geographic area as possible, and that really what is

needed is a sort of part 20 sort of document or regulation, a nationwide standard that covers all forms of ionizing radiation and isn't specific to whether it's medical use or industrial use or whatever.

MEMBER WAGNER: Well, just to support a couple statements there. The facts are that the IOM's recommendation to hand it to the states was under the assumption that with the organization set up under the guidance of the CRCPD, there would be more uniformity. But in fact, the NRC provides its regulations. The CRCPD has been set up for some time, so there is guidance on the Federal level already in existence. Yet two of the people here -- three of the people have stated that there really isn't a lot of uniformity in the states.

People who have experience from state to state to state said there isn't uniformity in the states. So it's quite clear that even with current guidance by the CRCPD, there's not uniformity. I don't think it's going to achieve that by just turning it over to the states and still having the kind of oversight that they are recommending. I think you need to have something that will be a little bit more authoritative. But that won't happen unless you focus on why the development of these regulations go sour.

CHAIRMAN SIEGEL: But we have said that already. Rebuild the medical regulatory program from scratch federally mandated, and let the states administer it with some teeth at

the Federal level to ensure that the states have to do it, and that the states are supervised in the way that they do it. That is D and a half.

That strikes me as stronger than just reserve Federal authority, which is call in the militia if the states are not doing their job adequately.

MEMBER WAGNER: Maybe you should call it E and a half.

MR. CAMPER: May I make a suggestion? One of the things that the Commission has asked us to do, and of course Barry knows this very well, is whenever possible, is to reach consensus within the committee. Or if you don't have consensus, to identify dissenting or differing opinions.

Maybe what would be simpler here would be to focus upon only the alternatives that were used by or identified by the IOM. Then specifically answer the question as to whether or not you agree with their preferred alternative. Address that question. If it turns out the answer is no, and I think that it is, then describe succinctly as you can, the preferred alternative, in view of this committee I mean.

CHAIRMAN SIEGEL: Didn't I just do it 30 seconds ago for you?

MEMBER BERMAN: But I think actually you articulated in the last 30 seconds very well, in a way that I

don't think I had heard before. I think it's more clear to say that we don't accept any of the alternatives the way they were put out, and that we actually proposed something that was a modification of one. You stated it so well in that last point, I think that's what we ought to --

MEMBER WAGNER: Yes. I would like to see a consensus vote from the committee in regard to what you said, just to see if there's a consensus with that particular statement of the program, because --

CHAIRMAN SIEGEL: Who wrote it down?

MEMBER WAGNER: I think your articulation was very good. I think we all know what it was.

CHAIRMAN SIEGEL: We'll have to come back in a week when we have the transcript in order to see what we said. No. Should I say it again, see if I can get it again?

Rebuild the medical regulatory program from scratch. I did say before but didn't say 30 seconds ago, that would be reassessing objectives. So that is the equivalent of what NRC would have done if it had redone part 35 from scratch.

So we are saying we endorse that activity, number one. Number two, federally mandate that program, but as a program to be administered by the states with a mechanism that essentially forces the states to comply and whether that -- I don't know what the legal mechanisms, the legal options

available are, but certainly one that we know works is tying it to reimbursement by HCFA. Then Federal monitoring of the states compliance.

That's essentially the concept. All of which of course also then contains the notion that we would magically transform the current quality by inspection, punitive mean-spirited system to one that is collegial and educational, and designed to help medical professionals do a better job.

How could you vote against that?

MEMBER STITT: Did you want to put an agency's name in there?

CHAIRMAN SIEGEL: The agency that would administer it at the Federal level is DHHS. I think we have already said that.

MEMBER BERMAN: And the agency to develop it would also be something within DHHS?

MEMBER WILLIAMSON: And it would cover 100 percent of the ionizing radiation medicine.

CHAIRMAN SIEGEL: Correct. Absolutely. So we've got lots of things. You want to add something else?

MEMBER SWANSON: As part of that process of reconstructing regulation, it is again the active involvement of the regulating community. I'm going to keep coming back to that.

As you just received a plaque in recognition of

the contributions that you've made to this advisory committee to the regulation of byproduct material, that process has to continue and it has to be stated.

CHAIRMAN SIEGEL: One can only hope that it will. I guess in some ways, the Federal Administrative Procedures Act provides a slightly higher level of assurance than do 50 state administrative procedures acts. At least that's my gut feeling about that.

All right. So we have a concept on the table now. We don't have to take a formal vote. We can see if anyone wishes to demure. Failing a demure, we've reached a consensus.

MEMBER BERMAN: I think if we rebuild it from scratch, taking into account ways in which it went awry in the past. He didn't say it this time around.

CHAIRMAN SIEGEL: Do we have a consensus? It looks like we've got a consensus on that. All right. Good.

Having reached a consensus on that important question, now you're going to give us 10 seconds more about the most important remaining questions. I'll tell you why I'm wanting us to focus on the most important ones in two seconds. They are?

DR. HOLAHAN: Okay. What -- I think it would be beneficial if the committee could at least comment on the dissenting opinions.

CHAIRMAN SIEGEL: Okay. Two?

DR. HOLAHAN: Then in terms of number three, four, five, those sort of all tie into if there's no congressional action taken. So I think in terms of looking at the basis, that NRC could make a finding that there's adequate protection of public health and safety either across the board or whether it's adequate protection of patient safety, which would then tie into question number four, to address that question.

Then again in terms of if we did follow, and I think you raised the question to Kate this afternoon, is under recommendation B too, would there be any uniformity in terms of Federal oversight. So that question may have gone away.

Then I think six and seven, if we can get to those it would help. Maybe seven and six, in that order.

MEMBER WAGNER: Can you give us that order again?

DR. HOLAHAN: Well, a comment on two, and then three and four I think can be combined to lead into a general discussion. Five I believe has been addressed. I don't know if there's anything additional the committee wanted to add to that. But then seven and six.

I think there was part of a discussion on 11 as you were discussing your D plus. I don't know if you wanted to address 10 if you have the time.

CHAIRMAN SIEGEL: I think 10 and 11 we have

already sort of addressed.

DR. HOLAHAN: Yes.

CHAIRMAN SIEGEL: In saying we're kind of unsure about 10 and --

DR. HOLAHAN: And I think you felt that there was a necessity for 11.

CHAIRMAN SIEGEL: That there needs to be some sort of mandate to make 11 work.

All right. The reason I'm wanting to make sure we're focused tomorrow morning is -- and I mentioned this to Larry, but I haven't said to you, I am hoping we can actually have a discussion of other issues to start at 1:00 rather than at 2:00. I plan to catch a 4:40 plane, so if we really go until 3:30, it may be pushing it. I mean I can do it in an hour, but I'd rather if we can get that other stuff out of the way an hour earlier if possible.

DR. HOLAHAN: I'll have to check.

CHAIRMAN SIEGEL: We can only ask. Then we'll plan on the morning in focusing on these remaining questions. Any comments?

MR. CAMPER: No.

CHAIRMAN SIEGEL: We can adjourn for the day. We'll see you all at 8:30 tomorrow morning.

(Whereupon, at 5:05 p.m. the proceedings were adjourned, to reconvene at 8:30 the following day.)

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