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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

(ACMUI)

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THURSDAY

APRIL 10, 1997

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ROCKVILLE, MARYLAND

The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3, 11565 Rockville Pike, at 8:00 a.m., Judith Anne Stitt, Chairman, presiding.

COMMITTEE MEMBERS:

JUDITH ANNE STITT, M.D. CHAIRMAN

JUDITH I. BROWN MEMBER

DANIEL F. FLYNN, M.D. MEMBER

JOHN GRAHAM MEMBER

ANDREW KANG, M.D. MEMBER

WIL B. NELP, M.D. MEMBER

DENNIS P. SWANSON, M.S.,B.C.N.P. MEMBER

LOUIS K. WAGNER, M.D. MEMBER

THERESA WALKUP, C.M.D. MEMBER

JEFFREY F. WILLIAMSON MEMBER

ACMUI INVITED GUESTS:

AUBREY GODWIN

LARRY SATIN, M.D.

BARRY SIEGEL, M.D.

ACMUI STAFF PRESENT:

WILLIAM B. McCARTHY

ALSO PRESENT:

EDWARD McGAFFIGAN

DONALD A. COOL

HUGH L. THOMPSON

LARRY CAMPER

CATHY HANEY

SUSANNE WOODS

SALLY MERCHANT

MARK ROTMAN

A-G-E-N-D-A

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

(8:30 a.m.)

MR. CAMPER: Good morning, ladies and gentlemen. I am pleased to welcome you to Rockville, Maryland, to the NRC Headquarters for this public meeting of the Advisory Committee on the Medical Uses of Isotopes. I am Larry Camper.

I am Chief of the Medical, Academic, and Commercial Use Safety Branch, and I have been designated as the Federal Official for this Advisory Committee meeting.

This meeting is an announced meeting of the Advisory Committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

This meeting was announced in the *Federal Register* on March the 25th, 1997. That notice actually said the meeting would start at 8:30; however, within our public document room we have an announcement saying the meeting will start at 8, so we just thought we would split the difference and start at 8:17.

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 the Council of this organization, of this committee, and we do appreciate and value the opinions of the committee very much.

The staff requests that the committee, whenever possible, reach a consensus on the various issues which you will discuss today. During this or any of

your meetings however, if you have dissenting opinions we would also like for those to be clearly identified and made part of your record of this meeting.

I ask that if you could, please clarify and articulate those dissenting opinions so they can be appropriately reflected.

As part of the preparation for this meeting I have reviewed the agenda for members and their employment interest. I have not identified any conflicts based upon the very general nature of the discussions which we are going to have today, which would pose any conflict. Therefore, I see no need for any individual member of the committee to recuse themselves from the discussions.

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 record, starting on my extreme left we have Dr. Jeffrey Williamson. Dr. Williamson is a medical physicist specializing in radiation therapy.

We have Theresa Walkup who's a certified medical dosimetrist; Dr. Lou Wagner representing medical physics, specializing in nuclear medicine physics; Mr. Dennis Swanson who is a radiopharmacist representing the radiopharmaceutical issues.

We have Dr. Barry Siegel with us today. Dr. Siegel is an invited guest representing the specialty of nuclear medicine in the absence of Dr. Alazaraki who's out of the country. We have Dr. Larry Satin who's not here yet but I'm sure he will be. Dr. Satin is a nuclear cardiologist.

We have Cathy Haney who is now our section leader for the Medical and Academic Section, and we'd like to welcome Cathy to her first ACMUI meeting. Of

course, to my left we have Dr. Judith Stitt who is the Chairman of the committee and is a specialist in radiation therapy.

Dr. Wil Nelp to my right, is a nuclear medicine physician representing Research. We have Dr. Andrew Kang who is representing the Food and Drug Administration; Mr. John Graham who is an Executive representing the Health Care Management perspectives; Dr. Daniel Flynn who is a radiation therapist; Judith Brown who is our patient's rights and care advocate.

We also have another invited guest; we have Mr. Aubrey Godwin who is the Director of the Arizona Radiation Regulatory Agency. He is a State regulator and is representing the State regulator or local municipality perspectives.

Our three invited guests are with us today because at this point in time we are recruiting, soliciting for nominations to fill those particular positions, but we felt that it was very important that the nuclear medicine perspective, the States regulator perspective, and the cardiologist perspective be represented, particularly at this point in time, as we embark upon a very challenging and interesting period of time as it relates to Part 35.

A couple of administrative points for all of our members of the public who are here, and we're glad to see you; thank you for attending. There are some restrooms at the end of the hallway on the left and right.

On the first floor of this building there is a full-service cafeteria where you can obtain everything from coffee and donuts in the morning to a nice lunch if you care to do so, and we ask you to please help yourself to that.

Two final administrative points. As you know, minutes are created for each of the Advisory Committee meetings. And in those minutes we ask you to try to

be very -- to exercise care in expressing your consensus opinions if possible, or to clarify dissenting opinions.

I would like to ask you to make a special effort during this meeting and future meetings, as we discuss changes to Part 35 or possible revision pathways to Part 35, to be as careful as you can to clearly articulate the positions of the committee and to express those dissenting opinions.

All of us on the staff and I'm certain the Commission and up through the management of our organization, will be looking very closely and carefully in the weeks and months ahead as we move toward revising Part 35.

So with those comments, I would like to take this opportunity then, to introduce Dr. Cool. Dr. Cool is the Director of our Division and will make the Director's Comments.

MR. COOL: We'll see if I can manage to get enough feedback to completely annoy our stenographer over there. Thank you, Larry.

And good morning. Let me welcome each of you to Rockville. I apologize for the somewhat unseasonable weather, but at least it is not snowing, so there are perhaps still some advantages. The wind has succeeded in blowing most of our cherry blossoms far out to sea at this point, and we apologize for that, perhaps.

We are now embarked upon what we have been waiting for, for a long period of time. I was groping for some sort of visual analogy as to where we might be in the process, and the closest I've come up to is that of one of big theme park rollercoaster rides where you spend a great deal of time waiting in the line in anticipation and not quite knowing what all it is.

You can see little bits and pieces and you think you know what maybe is going to happen. You finally climb in the car and you spend the next period of time

slowing clanking up this incline. And the anticipation mounts and you continue to wonder and anticipate what it is.

We are now at the top. They have released the brake, and we are now about to start what I suspect is going to be a very exhilarating, extremely interesting ride in our efforts to take a fundamental re-examination and re-crafting of the regulations of the Nuclear Regulatory Commission in terms of the medical uses of isotopes.

We're going to have a number of discussions throughout this 2-day -- all of this will be focused primarily towards initial discussions and thoughts related to how to do the revision of 10 CFR Part 35.

As you are aware, the Commission has been examining the issue in great detail through the last year-and-a-half or so, in a strategic assessment process. Took a variety of inputs, there were public comments associated with that, and various examinations looking at not only the Materials Medical Program -- which was but one of a large number of the direction-setting issues that it considered -- and has now reached its decision point and has in fact, put out a final decision and some directions to the staff on this particular issue related to Materials and Medical.

A copy of that staff requirements memorandum, which is the direction provided by the Commission to the staff to guide the staff and get the staff its marching orders to move forward, was included in your packages and hopefully you've had at least a little bit of an opportunity -- if only on the plane flight coming in here -- to examine some of those issues.

We'll talk about some of the direction we got in just a moment, but first I want to talk about the process. The process we're embarked upon, the Commission has asked us to pursue a process which is more open, includes more

input and comment, than would be the normal course of a routine notice and comment rulemaking.

However they, at the same time as part of that direction, also admonished the staff not to go so far as we once explored back three or four years ago in terms of trying to get a large amount of public input in our decommissioning criteria rule.

So we have been, over the last couple of weeks, been trying to devise a plan for how we will proceed with this rulemaking. What I'm going to outline for you today are the current staff views. We have not yet provided that back to the Commission, so there may -- almost undoubtedly will continue to be -- adjustments to the particular process that we intend to pursue.

But fundamentally, what we are intending to pursue very early on in this rulemaking process, beginning today with you folks as our Advisory Committee, is a first round of open solicitation of comments and ideas with regards to the revision of the rule.

Based upon the direction and the guidelines that the Commission has already provided for us, and based upon your knowledge, the agreement state knowledge will be discussing this with the Organization of Agreement States and the Conference Range Program Control Directors at the CRCPD's meeting coming up in just a couple of weeks in Tacoma, Washington.

Our hope is that we will publish this information for open comment and discussion within the next few weeks and have that available. Once we have gotten some early views -- what you could call a tabula rasa, a white piece of paper, whatever you would like; some open views -- starting from scratch, how would we do this over again?

Our intention is then to bring together a working group of individuals, hopefully comprising both members of the NRC staff and members of some of the States that will have to be involved in this process as well, using an approach which the NRC has used several times in the past in terms of a working group developing proposals and ideas.

A steering group of senior managers to very quickly examine those and provide reflection, obtain some additional input and discussion through that committee process with members of the public -- with you as Advisory Committees and with the States -- in order to have obtained, hopefully, a couple of rounds of opportunities for discussion, comment, and consideration, prior to taking the proposed rule to the Commission.

Our mandate is to have a final rule for the Commission to consider by June of 1999; that's slightly over two years from now. That perhaps seems like a long time. Let me assure you it is not, particularly for a task of this magnitude, of this complexity, of this breadth of scope and possible content.

In order to meet that, we believe we need to have a proposed rule for the Commissioners to consider at least a year before that; preferably a little bit earlier than that, yet -- say the April/May timeframe of 1998 -- so that there can be sufficient time for the formal round of discussion and the consideration of comments.

So this will be a very expedited process. It will need to move along very, vary rapidly. People will need to get involved quickly. There will be probably a lot of times when everyone is going to say -- and myself included, being in the middle of the process -- it would be really nice to be able to think about this just a little bit longer, or to grab yet another piece of information.

And we're going to have to discipline ourselves, I believe all of ourselves, to look at, to refine, and to very critically but quickly, review these activities. So that is the kind of process that we anticipate. I will anticipate that we will probably be asking this committee to review a number of documents and ideas at various stages.

I would expect that we would be trying to explore with you, not only in these formal meetings where everyone can get together, but probably also through correspondence and otherwise, in order to continuously get your views and ideas.

And I think perhaps for the first time, in recent history at least, it is our intention to probably send this group away with a homework assignment of providing some particular reviews and refinement, particularly because -- as I think most of you are probably aware -- we have scheduled a date for this Advisory Committee to brief the Commissioners -- about four weeks or so from now, on the 8th of May.

And so preparation for that and discussions will also be critical in terms of what you may want to present and consider with them, and some of the things that they may ask and test and sort of probe in terms of some of the ideas and approaches.

The Commission has asked us to fundamentally continue the program, to look at refinements that would move us to a more "risk-informed approach" -- you can put that in quotes if you'd like. Fundamentally what we're referring to here is areas which are of lower risk, of lower danger types of procedures -- to have some modalities-type of activities, to look at the regulatory requirements and to grade those requirements in accordance with risk involvement.

So that there are things that are of low-risk or simple activities, that they would correspondingly have relatively simple or fewer types of requirements, as

opposed to more complicated, larger dose activities, more risk associated with it; where it may be more appropriate to have more controls or more activities.

Part of what we are looking to you for is fundamentally to help us determine what types of modalities, what kinds of activities are in these various categories, and the kinds of requirements that you might apply to each one of these that are in keeping with their risks, their efforts in those activities.

You've been given a lot of specific items in terms of looking at quality managements, in terms of looking at various other aspects reporting in misadministrations.

At this point I'm going to stop because there are a lot of other things and you have probably read some of these. We are very pleased to have Commissioner McGaffigan here with us today. My understanding that he's going to give you, is not only his views but I believe the views from the Commission itself in order to help you get started.

Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: This is the first time I've met most all of you, so I hope to meet you in my office on less formal occasions.

I came here today just to give you some insights into how the Commission's thinking went the last several months on this issue. The best thing I can do -- some of what I was going to say Don has already said, so I am going to open it up to questions fairly quickly so that you can ask me some questions about why we did what we did.

My background is the Congress. I'm not from your world, I'm not from really, the NRC reactor world. I was once a physicist but the last 20 years I've served in government, worked in the White House Science Office when I was in the

Foreign Service, worked in the Embassy in Moscow, and 14 years on Senator Bingaman's staff, largely doing defense work.

So I came to this place with fresh eyes. I know a lot about government. I had a decently strong background in science at one point in my life, and that's what the President thought was a reasonable set of qualifications to be a Nuclear Regulatory Commissioner.

This issue is one that was brought to my attention very early. And I know one of the questions the medical community oftentimes asks is, you know, why is our advice not taken? So why don't I try to give you an answer to that.

I did read the Academy Report -- it's one of the volumes down there -- and read just about the whole thing. That's what I used to do when I was in the Congress. Senators don't necessarily read everything but the staff does.

I pored through it and I didn't pore through it linearly. I did at one point, get to Mr. Adler's comments, and I found myself agreeing with Adler's comments almost totally. I've met with people from the community. We put out the direction-setting issue paper. I read the comments, including yours.

By the way, I agreed with your comments on DSI 12; that it was the risk-informed performance-based paper; that it was pretty darn dense. And that actually led to my comment -- and I don't know whether the staff distributed each of the Commissioner's votes that led to the SRM -- I hope you get those; they are public information -- but in our comments, the original views of the Commission were, go off and do risk-informed, performance-based rules.

And we, in the final SRM say, go off and do risk-informed rules and performance-based to the extent that you can meet this 2-year deadline -- which as Don says, is fast for us -- but we don't rule our prescriptive rules.

Hopefully less prescriptive than the current prescriptive rules, but at times, you know, one of the things attached to my vote -- and I hope it's available to the committee -- is that during this process we asked the staff what did -- the words in the DSI about staff identified and staff suggested changes mean? And they gave us a 2-page paper as to what their thoughts were that have been pent up for four years is to how to change Part 35.

And one of the things I mentioned was, NRC has some prescriptive requirements that are not needed, such as weekly surveys for beta emitters when we also require daily surveys for gamma emitters. The gamma surveys will uncover any contamination that the beta surveys will have found. So there, whatever change that Don and you all, you know, that the staff comes up with and you all comment on, it's probably going to be still somewhat prescriptive.

You've got to go and make sure your facility is clean, but we're not going to be as prescriptive as we are at the moment, or stupidly prescriptive in terms of telling you to do something that something else has already uncovered.

So we do listen. But I'll tell you my view also, coming at this with fresh eyes is, we probably are never -- the regulator is probably never going to be loved by its licensees, and if we are loved by our licensees we're probably one step away from a Time magazine article about collusion. So I think we have to go about this very professionally.

I think we have to get on with -- as the Commission has directed -- get on with amending Part 35. We do Part 35 -- the staff knows -- our much-maligned staff in this area; Carol Marcus comes to mind -- our much-maligned staff is ready to work to make Part 35 a better document, and we want to get on with it.

You know, in looking at the notes of your last meeting, I noticed the frustration in this group with linear no threshold hypothesis and some of the radiation standards that get promulgated. And one of the first votes I had when I came to the Commission was the 500 millirem patient release criterion.

And it was at the same time a bunch of other papers were coming before me, and I voted for it and I think it's a rational public policy to provide that extra relief. But at the same time we see papers where at times, we are dealing with submillirem standards for cleanup.

The standard for baghouse dust from electric arc furnace releases -- you know, we worked a deal with EPA but the essence of the deal is that it's a one millirem per year standard that we are requiring them to clean up to. So there has to be -- as I say, I find some of the standards -- and they're all over the map, obviously.

You know, we have 500 millirem standard for patient release, 200 millirem standard for radon, a one millirem standard for baghouse dust, and everything in between, and sometimes below millirem per year standard.

I think that the irreverence that I found in the notes of this committee -- the committee's meeting last year on the linear no threshold hypothesis and the need to rationalize our radiological protection standards -- very refreshing. I mean, I've come to it -- as I say, I know more about whether to buy an F-22 or an F-18 as the next fighter aircraft -- and I won't bother to tell you which my view is -- but I came to this with fresh eyes and it's appalling that we have a standard for every case. I mean, you know, a new case comes up and we start from scratch.

And the very theory that underlies all of this is quite -- you know, there's really not much data and the data is confounding in many cases. And I've read a lot about it.

Dr. Pollycove here at the -- who's a Cal Tech alumnus about several decades before I graduated from Cal Tech -- has thought a lot about this and the degree to which -- and one of the things I read when I was a college student a long time ago was Thomas Koon's Theory of Scientific Revolutions. I forget the title of the book, but the -- you know, people hold on real tight, scientific communities, when there's about to be a change. I mean, they hold onto the old hypothesis.

And I get a little bit of a sense of that; that there may be -- as your community, as the medical community starts to understand how cells repair themselves and deal with much more serious events that occur -- free radicals and all that; that they have to repair themselves on every second -- radiation is a relatively small player perhaps. But we're not there yet.

You know, there's a whole community of people who just spend their lives thinking about radiation standards and they have been very, very conservative. And we in turn, have been very conservative. But I found the irreverence that you expressed quite useful and urge you to continue it.

Don has said what needs to be said about the rule. We want it done in two years, and unfortunately that's lickety-split for a regulatory body. I come out of the Congress and I'm known as the impatient Commissioner after seven months here because our time lines in the Congress are much shorter.

Sometimes we take years, but usually we have -- you know, a defense bill passes every year and you figure out what you're going to do on that bill that year. And so there's an annual cycle to things.

We here, will do well -- on a complex rule like this that does need to be changed, that does need to be made more risk-informed -- we will do well to get it done in two years. I would encourage the staff to be very open with you.

And one reason frankly, that I attached the little 2-page, December 10th memo that was sent up to me after I met with the staff, to my vote was to get it out to you all so that you all could see what the staff is saying to us in bullet form, as to what their ideas are -- which I don't think are very incompatible with your ideas as to what changes need to be made in Part 35.

My notion is that we might -- you know, we don't want to come out and say, here, we've got it all figured out, because we don't. But if we have ideas we need to communicate them to you, we need to get your reactions early, we need to see where the differences are early and where we're going to make a lot of progress early.

And then once we've done that -- they'll be hard issues, but get as much out and maybe, you know, the way our process works and the advance notice of proposed rulemaking -- get as much of our ideas out at that point so that people can really react to them. We go pretty close, and I think the Administrative Procedures Act requires it once we get into the formal process.

It gets very formal; people write us letters and we write letters back. And I think this informal process which is done -- this may last about a year -- is an opportunity to hopefully come together.

Bottom line is, we do listen to you, we don't always agree with you. I will tell you, one place where you had an impact -- I think you had an impact on the staff and then you had an impact on the Commission, and I don't know whether the final SRM is out but everybody's voted and the Commission unanimously voted against the Intentional Misuse rule, and so that rule will be withdrawn, as I think this committee encouraged.

The staff, frankly, was in a very tight place on that. You know, they sent us a paper that basically said, let's go out for another comment period -- having

tried to adjust to the comments they had heard from folks like you -- but there was also an informal grapevine came up to the Commission saying, we don't really mean it and we'd just as soon you withdraw the rule.

And you know, all five Commissioners did vote to withdraw the rule. Although I think there's a problem still there. It isn't clear to me -- and Commissioner Dicus voted and I agreed, and I think Commissioner Rogers agreed -- that there is still a problem as to whether people really do -- we want the licensees to investigate misuse, but we also want them to investigate misuse below 5 rem.

You know, it isn't clear to me at the moment that everybody's radiological protection programs, radiation safety programs, if there's an intentional misuse event and if it's de minimis in the view of the radiation officer, whether it's looked at -- I think you still may want to -- if the rules aren't clear at the moment -- and several commentors said they were -- at the moment, if such an event occurred it would be investigated by the licensee.

They don't need to be recording it in 24 hours and bringing in augmented inspection teams and all that. Let us do our job; as a licensee we will do it and we will deal with it. But I think we may want to just know that we have some visibility into the fact that you did it after the fact and that you've taken appropriate action and we have an appropriate program.

But that's not the rule before us, and whether that rule ever comes out of the staff we'll see. You are listened to, and we won't always agree with you, but let's get on -- having had this great debate for four years with the parking brake firmly fixed on the car -- let's now start moving and see if we can't redo Part 35 in a rational way.

I'm happy to take some questions. I don't want to hold up Hugh, but I'm happy to take some questions from you in case you want to get any more visibility into what I understand is sometimes -- you know, you sit there doing criminology on the Commission. We're not Brezhnev and company lined up on the Kremlin wall. You don't have to figure out who's standing next to whom. We are accessible and we will answer questions if you have any.

CHAIRMAN STITT: Now's not the time to hold back. I think it's that side of the room that tends to be the irreverent side, and I want to encourage you -- there are some irreverent-looking folks over here -- I want to encourage the committee just as the Commissioner has.

I had a question. I hear you say that you had comments -- individual Commissioners had comments that we --

COMMISSIONER McGAFFIGAN: Yes.

CHAIRMAN STITT: -- might be privileged to see? I haven't seen those. Anybody on the committee? If I could ask --

COMMISSIONER McGAFFIGAN: Well, I've got my copy. If somebody has a xerox machine, I've got the individual Commissioner's comments with me and I'd be happy to get them xeroxed and passed out to you all. I walk around with my DSI book that has every Commissioner's comments and every final SRM, and we've got just about everything finished now.

You might, you know -- I would encourage you not to read the DSI 12, risk-informed, performance-based stuff because it will only confuse you. And I don't think it's relevant, really, to anything that you're going to be doing in this group. But if you want to see how we dealt with that confusing paper you're welcome to that as well. But I'd stay focused on DSI 7.

CHAIRMAN STITT: Thank you. And I'd like to say that whatever staff member is making those copies, I think we appreciate our staff and -- at least I'll speak for myself -- to say we try not to hassle them too intensely, too frequently.

COMMISSIONER McGAFFIGAN: I think the staff -- the malignment that the staff routinely receives from Carol Marcus is not typical of their interaction of the community as a whole, I hope. And I don't know whether you all have seen the letter that we sent back to Dr. Marcus last month, but if you haven't you're welcome to get a copy of that.

That was drafted by the Commission. The staff -- the sort of letter that the staff probably would not have drafted. It was drafted by the Commission to send back -- a very firm letter.

CHAIRMAN STITT: I would appreciate that. I actually get copies of those letters from her but I have not seen any reply, and it would certainly --

COMMISSIONER McGAFFIGAN: We'll supply --

CHAIRMAN STITT: If you happen to have that with you I'll copy it for you.

COMMISSIONER McGAFFIGAN: Well, we'll get that for you by the end of the day.

CHAIRMAN STITT: Thank you. Comments from the committee? Questions?

COMMISSIONER McGAFFIGAN: Yes, right here.

MEMBER WAGNER: Commissioner, you made one comment that I took note of which is, you said that there's not much data. Did you really mean to say that there's not much data on radiation effects or what did you mean by that?

COMMISSIONER McGAFFIGAN: Not at the one millirem -- I mean, I think that there's a lot of data and I've read some of it, but I think that the -- you know, I went back with the help of Dr. Pollycove and looked at the latest data on Hiroshima and Nagasaki -- which is of course, high dose rate and high dose.

And I'm not sure, you know, looking at the tables, that they have proved anything below about 50 rads. You know, they claim that they're now showing effects to 5 millirem -- or 5 rads -- but it isn't clear to me that that's what the data shows. And we do have a lot of, as I say, confounding data.

You know, the State of Pennsylvania -- I think it's one of the Pennsylvania schools has looked at radon and you know there's data that show if anything, a beneficial effect at, you know, being exposed to a couple hundred millirems a year of radon over -- I mean, I don't believe that there's a beneficial effect but the data doesn't -- there isn't any big effect at that stage.

I think that the extrapolations that we do from where there's a real effect that's discernible, to the one millirem, or 10 millirem or 500 millirem even, range, is a very, very conservative approach. The Academy itself over time has occasionally deviated to linear quadratic from linear no threshold -- linear quadratic no threshold.

I don't know what the right answer is. I just -- I haven't seen -- I think the data below -- in the range that we regulate at, is basically non-existent.

MEMBER WAGNER: That's an interesting comment, and I guess if I were going to get on the bandwagon I'd like to start trying to break down the idea that there's not much data. We have over 100 years of research in these area. There's many, many thousands of -- hundreds of years --

COMMISSIONER McGAFFIGAN: But does it all support the linear no threshold hypothesis?

MEMBER WAGNER: It isn't a matter of whether it supports it or not. The NCRP recently had a meeting here in Washington and they went over a lot of research, a lot of the history, a lot of the effects. And to a man, the conclusions of the talks are, down at the low levels, we just don't know.

COMMISSIONER McGAFFIGAN: Right.

MEMBER WAGNER: Well, the point is, is that if you've researched it this hard, this long --

COMMISSIONER McGAFFIGAN: And you don't know--

MEMBER WAGNER: -- and you still don't know, there mustn't be much of an effect. That's the whole point.

COMMISSIONER McGAFFIGAN: See, but that -- I agree with you, there probably isn't much of an effect, but when you go and extrapolate -- what we routinely deal with here -- you know, we use $3,000 per person rem in making calculations. We're dealing with a decontamination rule at the moment, and if you have a tiny effect but it's a large number of people, when you do multiplication you end up with, you know, effects.

And then the question is whether -- you take medical release. You know, we probably are getting more exposure -- I think there was -- the paper said there were 38,000 patients a year for whom this rule would likely apply; 500 millirems per possible exposure of family members or others sitting next to them in the airplane going home or whatever. I mean, that's a lot of person rem and a lot of dollars.

But that's the sort of calculus we get into -- and it gets even worse in the decommission rule when you get down to, you know, 15 or 25 millirem or possibly applying MCLs, which in some cases are submillirem -- you know, the staff is

recommending that we not do groundwater standards -- we have all pathways standard for decommissioning.

But we're dealing with effects that are very small, and if you believe that they were significant, we should be doing something about flight attendants who routinely are now more exposed than nuclear power plant workers. They get 500 millirems a year.

We should be doing something about -- I don't know whether Paperiello's here and he can defend himself -- but you know, Carl has told me and I've said at a public meeting, reg info conference last week -- if you really believe in millirem matters you'd better start thinking about double beds because of the Potassium-40.

I agree with you. There's a vast amount of data and at the levels where we regulate it is confounding and you're trying to find a very small effect. That's the trouble with the Hiroshima and Nagasaki data. The fundamental problem in that paper is, you know, they count the number of cancers they see and then they have an expected number of cancers. Well, that expected number of cancers has a wide -- as you guys know better than I -- has a wide range to it. It isn't a fixed number.

So trying to find a small effect -- and you guys know better than I -- trying to find a small effect even with a vast population, is very hard. And so I agree with you, but I don't know how to deal with it. I mean, if the NCRP sits there -- the way the NCRP is interpreted by EPA is, you know, they have the right to go to submillirem standards, or certainly very low millirem standards, if they just apply the hypothesis.

MEMBER WAGNER: It would seem to me that what we need here is a real change in philosophical attitude toward enforcement of these kinds of numbers. I mean, when you're working in an area where this much research can't come up with

any definitive conclusion that there really is an effect, you must be dealing with some very small risks compared to other things in life.

COMMISSIONER McGAFFIGAN: I tend to agree with it. Dr. Pollycove points out -- and I've actually been taking Vitamin E the last month or two as a result -- I mean, he points out that the effect of free radicals in the cell -- I mean, I actually studied -- when I was a graduate student at Cal Tech, I'll tell you, the first person I ran into was -- I was a physics graduate student in theoretical particle physics -- I went there to work for Feinman and Gelman -- and the first person I ran into was George Zweig who had co-invented the quark with Gelman, the SU-3 model at the time for elementary particles.

And he said, why are you in physics? Come on over and work in the biophysics of the ear with me because particle physics is basically not going to make a lot of progress. And he was right and I ended up -- I wasn't smart enough to go work for him in the biophysics of the ear, but I did go and take some course in molecular biology at the time and I've stayed abreast of it.

And the cell has -- you know, as Pollycove says, the trouble with a lot of these standards is that physicists had a lot to do with them, and they are very simple-minded models as to how the human body works. I'm not going to defend physicists because I think that's probably right.

But those with the most sophisticated view understand that we're constantly subjected to stress and our body is this remarkable institution that 99.9999 percent of the time or more manages to deal with it and repair itself. So --

CHAIRMAN STITT: Being the taskmaster I'm going to jump in here. I'm glad to see there's a reverence on more than just the committee. People are

raising their hands and I've got a few people that I'm going to allow to make short comments.

COMMISSIONER McGAFFIGAN: Go ahead.

CHAIRMAN STITT: Dan, two physicists -- well, nuclear medicine physicist and Graham. And if you're not short I'll --

COMMISSIONER McGAFFIGAN: Okay, sorry. And I'll try to be short.

MEMBER FLYNN: I think when you use Hiroshima and Nagasaki as an example it's also -- I think it's important to be able to react to new data as it comes out. For example, Hiroshima and Nagasaki, the latest data I've seen and it's been supported by other major studies is that, for example, radiation-induced thyroid cancer is not a risk for adults in Hiroshima and Nagasaki, but it was a risk and is a risk for children. You see that in Chernobyl.

So I think, unless you have any radiation workers that are under 15, we're not -- you should be able to concentrate what's important as new data becomes available. And I don't think the regulations -- it's hard for the regulators to react in a timely fashion as data comes out, to let's say, maybe we shouldn't be worried about one particular area as much as something else.

COMMISSIONER McGAFFIGAN: I agree with that. I mean, actually I'm not sure where the Commission is on this but on potassium iodide the Chernobyl experience with the French -- the French have now reacted by deciding to distribute potassium iodide to the 600,000 people living within, I think it's 5 miles of French plants.

I personally think we should relook at our policy; not that we shouldn't focus on evacuation, but that is an additional precaution to have potassium iodide distributed, basically to protect children, would be a useful thing. But that's an issue that's going to come to the Commission sometime later this year.

CHAIRMAN STITT: Dennis Swanson.

MEMBER SWANSON: In looking at the IOM Report, the ACMUI actually recommended that they feel that the medical use of ionizing radiation would be regulated by a federal agency but we recommended that that should be a federal agency with some type of a health background.

Clearly, the NRC is going to continue to regulate this. I think my concern and question deals with, how can we get medical representation at the Commission level? As you pointed out, you don't have a background in this area and I think it would be important that --

COMMISSIONER McGAFFIGAN: I think Commissioner Diaz has at least some background in your community. I mean, not that he's a health physicist but that he, because of his broad role in the university, had to deal with this issue.

MEMBER SWANSON: I think what's important here though, is to have somebody at the Commission level that understands patient care as it is related to the use of ionizing radiation. I think that that input would be important at the Commission level, and how do we go about trying to make sure that that input is present at the Commission level?

COMMISSIONER McGAFFIGAN: Well, I think that you're probably -- given that our main role -- the reason I'm there is, you know, I know a lot about nuclear reactors even though that wasn't what I did. I reported on them when I was in Russia and I've had -- there is a focus on the reactor side of the Agency and there's no getting around it. That's where the bulk of our resources go.

You know, you talk to White House personnel, I mean, there's a Republican slot that Commissioner Rogers will be moving off the Commission, and there's a Republican slot available if they ever get around to it, as of July 1 of this year.

But I think, don't sell us short. I showed up -- you know, people like me routinely make decisions on F-18s versus F-22s, or whether the airborne laser lab makes any sense, or whether -- and a background in high energy particle theory is not necessarily what you need to make those decisions.

You need to be smart and able to absorb technical data and be able to tell when you're being BS'd and sort things out. We can learn a lot and I'm happy to learn from you all. You've got the Commission you've pretty much got, and so you know, there will be a vacancy this year but the way you're going to get that information -- you know the way you're going to get a Commission that can deal with these issues is to try to continue to educate us.

If there's somebody on the Commission who happens to have a health physics background or a background from your community, patient care community -- an M.D. who would want to be on the Commission -- he should be lobbying the White House at this point, or she should be lobbying the White House at this point to get -- if she's a Republican -- the slot that's coming up. But that's politics.

I mean, I'm on the Commission because Senator Bingaman and other Senators -- bipartisan Senator Domenici -- helped support my nomination to the President. It's a political process, getting people on the Commission.

CHAIRMAN STITT: Jeff Williamson, and then John.

MEMBER WILLIAMSON: Yes. I think the Commission's past efforts to try and regulate and control medical practice with respect to quality of medical care rendered to the patient and safety of the patient, have been among the more contentious things.

So I wanted to ask you, on what basis do you think radiation medicine should be singled out for, you know, this kind of management of its clinical practice

compared to other areas? I'm from the therapy area so I would compare radiation oncology to other procedure-based medical specialties like anesthesiology and surgery.

So why do you think inherently, radiation medicine is so risky that it's spelled out for the special federal regulation, just because we use radioactive materials?

COMMISSIONER McGAFFIGAN: First of all, there's a statute that requires it, and I think that it would be unlikely that Congress would repeal that statute. You know, you could try that but I don't see the Congress repealing the statute. Congress does not make laws that are uniform.

You know, one committee makes laws with regard to radiation medicine and another committee makes laws with regard to medical practice more broadly. And to expect uniformity in our legal framework is just -- it's never going to happen.

But I also think that, you know, I actually -- I think there's a benefit to us being involved in doing our job well. You know, when these cases, the misadministration cases or whatever come up, having us there can actually be beneficial in terms of public confidence and the practice of medicine in this area, I think.

And I think one of the problems the medical community get into -- I mean, you all -- if 60 Minutes needs to round up a story, you know, the practice of medicine is one of the places that they routinely go. And there's great irreverence in the public, as you know, with regard to whether State medical committees -- I'm not sure the proper title -- properly discipline their fellow M.D.s.

It's anecdotal, it's 60 Minutes-type stories, but there's no end to 60 Minutes-type stories. I remember seeing one last year about people -- was it in Texas -

- who were in the operating room acting as surgeons and they had no medical credentials whatsoever, and somehow that got past the system.

I think our job is to do a good job in the area that Congress has given us the job to do, and our job is also to try to strike the right balance between not getting involved in medical practice but also do our job as a regulator. And there's a balance. You know, you guys talk about the 1979 Medical Policy Statement. I think that's, you know, I try to strike that balance.

CHAIRMAN STITT: I'm going to ask John to make a comment and then thank the committee for their input and then we'll keep moving on.

MEMBER GRAHAM: I think as a relatively new member of this committee, part of the irreverence appears to be related to frustration; frustrations related to limited feedback.

COMMISSIONER McGAFFIGAN: Right.

MEMBER GRAHAM: And understanding of why the recommendations that come out of the ACMUI are not implemented. And I think that fundamental problem becomes communication, 2-way communication, but I would encourage that the routine distribution to the ACMUI members of Commissioner votes, of staff memos that affected those Commissioner votes, and any other relevant communication would occur. That this -- I would thank you for coming here this morning --

COMMISSIONER McGAFFIGAN: I think that that's what's needed --

MEMBER GRAHAM: This is a feedback loop we've not had.

COMMISSIONER McGAFFIGAN: And I'm happy -- you know, I don't want to become the Commissioner for ACMUI but I am happy to try to encourage better communication. I mean, we really do listen to you. We really -- I at least, read your

minutes, and I did read your vote on DSI 7, and we did read your conferencing in thinking about what we should on the Intentional Misuse rule. So you are listened to.

I can't tell you that in every instance -- I honestly think that the community really would like to have the same degree or a lack of it, of regulation as they have in the rest of the medical community. That is not going to happen, but we can try to be rational about our regulations, have them be risk-informed. I think the staff wants to do it. I mean, I think the staff wants to get on with meeting you all halfway.

And we also want to do it frankly, with the reactor community. You know, we talk much more routinely in the Commission about reactor regulation, and we recognize that we have a body of regulations built up over four years, some of which we really need to get on with changing, or even getting off the books, because they're not really very important from the point of view of the safe operation of the 108 reactors we have operating.

We heard Don talk -- our processes -- and it's great frustration -- our processes take two years to do a rule. You know, we have a rule in that area, 50.59, which we're going to have to do a rule on, and we'll do it lickety-split if we do the 50.59 rulemaking in two years. But we have to get on with it.

And especially during this period over the next year, that there's no amount of communication between this group and the staff -- and frankly you're welcome to talk to me and other Commissioners -- that will be too much. You should take advantage of every opportunity to communicate, and I for one will be happy to do that.

Thank you.

CHAIRMAN STITT: And thank you for coming. I think your year in as a politician are showing. You didn't come here to press the flesh and make us feel better about our work. Thank you very much.

COMMISSIONER McGAFFIGAN: Okay. Should I introduce -- is Hugh the next speaker? Come on up, Hugh.

MR. CAMPER: Hugh Thompson, the Executive Director of Operations -- the Deputy Executive Director of Operations wants to talk to you about the Advisory Committee process.

MR. THOMPSON: Well, I'd like to welcome you today. It's always a pleasure to have the opportunity to discuss issues with you. The one issue that I really wanted to come to talk today was a letter that I received, which Dr. Stitt indicated that there was a high degree of frustration expressed by the member of the Advisory Committee about whether or not we were really taking their advice, their recommendations.

I think Mr. Swanson's letter was the key factor in that. I know a former member, Dr. Marcus, had a history of writing a large number of letters. And rather than writing back -- and I will write back just to make sure the record is clear -- but what I wanted to come and let you know that the Commission really did.

Well, at the time that I said I wanted to come down and put myself on the calendar, I didn't know Commissioner McGaffigan was going to come down here. And I think his presentation and his words clearly demonstrate, not only that the Commission has an important role and really welcomes your reviews, your information -- and I think it really does turn down to the issue of communication.

There are decisions that the Commission has to make. We won't always agree with the committee; we don't always agree with all the Advisory

Committees. If you kind of look in the history of the Commission's appreciation for this Advisory Committee, it started back one time as almost being co-chaired or even be chaired, by the NRC staff. It was the only Advisory Committee that had that.

And when I became involved in the nuclear materials area I said hey, we really want this to be advice from the committees and not from the NRC staff giving advice to the NRC staff. And I thank Dr. Siegel for his leadership in making that change, and Dr. Stitt for continuing the efforts along those lines.

But I would just like to reiterate, we really do value your comments; we really do recognize that they provide a perspective that we are not able to get otherwise. But part of the difficulty we have is in -- the Commission, as you say, has their rules and regulations.

They get advice from a number of people. They get advice from the staff, they get advice from the General Counsel, they get advice from all our activities, and they're often conflicting and the Commission has to make their decisions based on the best advice available.

What I think I've heard today, and I think what Larry has commented back on I think, in his letter back to Mr. Swanson was I think, we need to improve our process in communicating with you where the differences are, where the -- so you can understand that we heard you and we didn't necessarily agree. Or, we heard you and we agreed, but there are other issues that preclude that.

Part of the difficulty we have -- we obviously don't necessarily agree with our other sister agencies. EPA, we're at loggerheads with EPA frequently over recommendations on standards of protection for public health and safety. So it's not unique in that regard.

The Commission was earlier asked to reduce the number of Advisory Committees, and if they clearly had the opportunity if they didn't want to hear your advice to say, the President issued an Executive Order -- we must reduce Advisory Committees. We can't reduce the Advisory Committee on ACRS; it's a statutory requirement. You know, you're it.

They elected not to do that. We went back and said, no, no, we need the advice from the Advisory Committee, and this one was included as one of the ones that they really wanted to do. So I guess what I would like to, in my few minutes that are still remaining, we've committed to, I think respond back to you, both in the rulemaking phase or there may be other avenues that you would like to hear back from us on addressing your recommendations.

Let me tell you what we do in the Advisory Committee on Reactor Safeguards. They send letters more along the line of the letters we're going to be asking you to provide -- at least on this one -- saying, give us your specific recommendations.

When those letters come in they're assigned to the staff and we write back to the committee saying, we agree with this, we agree with that, we don't agree with this because. Fortunately, or unfortunately as the case may be, they spend about half of their time working as committee members. They have a full-time staff that work on them.

And the infrastructure that support their activities and their efforts are probably not something that's available, number one, to you; or number two, you probably don't have the time to spend half of your time -- or even a quarter of your time -- working on NRC activities.

Now, maybe some of you do and maybe we can talk afterwards of this and we'll find out that there are ways to do that. But in essence, it really is an area that the Commission wants to hear from you. In fact, I've talked with Carl and Don on where we're headed on this rule.

That's one we talked about the approaches -- look, does it make sense to give you a blank sheet of paper? I said look, a lot of times we ask you to comment on things because we know how valuable your time is and we try to work on that, but we're willing to try something different.

You know, start with a blank sheet of paper, you write down what you think the regulation ought to be consistent with the Commission's decision, and let's start from there. That way we aren't trying to give you any constraints, and previously you may have felt constrained to comment on some proposal that the staff had to have there.

So with maybe, I know we want to have some continuity of schedule here, so I guess I will kind of stop for a moment and either respond to any questions or maybe take some advice that you want to provide to us, and we'll obviously respond back in more detail. But Dr. Stitt or Mr. Swanson?

I'm here to tell you, that personally -- and I can -- the Commissioner did better than I obviously can do, of conveying the importance that the Commission feels. But I personally feel -- because I sign all the papers or concur on all the papers that go through the EDOs Office up to the Commission -- and this is an area of which I am personally committed to receiving your advice, and as I guess one of the leading staff people in this area who have no medical background, who takes vitamin E.

CHAIRMAN STITT: We're flattered by all the attention we're getting today. I think that, number one, we tend not to be a letter-writing group. We tend to, I

think we're relatively cohesive. We're all online which gives us some advantages over prior years where communications were in other modes and slower. I think the letter that Dennis wrote was considered very carefully by a number of people. It wasn't an emotional --

MR. THOMPSON: No, I mean, I took it for the value that it had, or otherwise we would --

CHAIRMAN STITT: I think the entire staff did, and in effect it was considered by a number of people. And I like John Graham's comment that I believe this is a communication we put a lot of emotion, time, and effort into that. I don't expect that the staff or the Commissioners would agree with what we say, but it's not having that feedback.

To say, number one, we did observe this, number two, we strongly disagree and here's some things why, certainly completes that circle. So I would also like to comment that I've been thinking that intellectual skepticism or intellectual skeptics might be -- sounds better than irreverence.

But are there any intellectual skeptics that would like to -- I can make euphemisms -- go ahead, Dennis. You were the one that had your name on that letter.

MEMBER SWANSON: I just might make one additional comment. I think that the NRC has to remember that each of us on this committee represents a certain constituency, and I have to report and I am basically reporting to my constituency, okay, and I need the information back.

I think it is a communication issue, so when -- you know, the advice that we give or my, you know, to represent -- the concerns of my constituency isn't taken, I need to be able to provide them with some explanation for that. Otherwise it looks as if I'm not doing my job.

MR. THOMPSON: Right, right. And I think that's real and I'll work with the staff to make sure we find better ways. I mean, there's probably no end to additional pieces of paper, vote sheets that we can give you, and I think we owe it to. Maybe this time we'll err on the side of giving you a little bit more than you maybe want, and in the past, you know, maybe we'll get the right balance.

But that's certainly -- we have no problem providing information that you need to have to understand and communicate with your constituency as well as just understanding what happened on one of your recommendations, and the staff will certainly be able to do that.

CHAIRMAN STITT: Lou Wagner.

MEMBER WAGNER: I guess my biggest concern is that this Advisory Committee does represent a high concentration of health professionals who are very dedicated to the advancement of health in their patients and in the patient population. And when we make recommendations we carefully consider those based upon the effect we perceive it's going to have on that population.

When those recommendations that are very carefully considered and voted on appear to us to be ignored by a constituency of Commissioners who don't have the benefit of that background, we get very concerned. And I get very concerned because I feel that we are trying to do the best for the patient, and when it comes out that we end up with a regulation that we know is going to be more of a burden to us in trying to manage that patient care, it's a problem.

So I'd like to see the feedback which really gives us the idea of why, based upon patient care, many of our recommendations are rejected.

MR. THOMPSON: Well, I think there is a balance that -- Commissioner McGaffigan says, sometimes it's a balance between public health and

safety -- that's other people involved as well as patient care. I do understand that that's the reason. The Commissioner approves everybody on here because of their expectation that, you know, you bring that view and bring that value to your advice.

So you know, we've committed to try to give you better feedback. As the feedback, I don't know that we're able to specifically address the "patient care" in the stovepipe -- because there is a patient care stovepipe, there's a public health and safety stovepipe. You know, there are other kinds of issues that the Commission has to get involved. To the extent that we can fully describe those issues, I think we will get to you.

Well, with that I will now write an answer back to you.

CHAIRMAN STITT: Thank you and thank the committee. All right.

MR. CAMPER: Well, good morning again. I want to pick up actually, on the things that Mr. Thompson was talking about. Last time we agreed that we would give you some insight into the committee process. Obviously, Dennis had a lot of concern about that; he talked about it during the last meeting.

Dennis did write me a letter. The response that I prepared to Dennis' letter is contained in your briefing book. Hugh did reference that. We are getting a copy for you -- I don't think you have it yet -- Dennis' incoming letter. Dr. Williamson had asked for that so you'll have both sides of the equation to look at.

What I thought I would do is just take a few minutes and explain the Advisory Committee process to you as it relates to this committee. That will be beneficial for a couple of reasons, I hope.

One, for some of you who are relatively new to the committee, or perhaps are not familiar with how the process works, perhaps it will be a bit of an

education for you. And more importantly, I want to try to tell you how things are currently reviewed and addressed that your committee provides to us.

And then at the end I want to show you a couple of things we intend to do to go a step or two farther than we have to-date. So I think you'll find that end of it interesting as well.

Well, obviously, there's a Charter for this particular committee. This committee -- and the Charter is very brief and basically it says why you exist. This committee is not a Commission-level committee; rather it is a committee that reports, actually, to Dr. Cool as the Division Director for IMNS.

It's unlike a couple of other committees that exist which are Commission committees. Hugh mentioned that a couple of years ago the Commission was asked to look at committees in general, and there was an effort by the federal government to reduce the Advisory Committees that existed.

And at that time the Commission looked at the question of, do we keep this committee, do we get rid of this committee, do we change this committee to a Commission-level committee? And at that time they made two very important decisions about this Committee.

One was mentioned already; that was to keep it. It was felt that the advice provided was terribly important. And secondly, it was also decided to keep it at a staff-level committee; however, the way in which the committee conducts its business, the way in which it interfaces with the Commission, did undergo change. Which made it look a lot like a Commission-level committee but not quite a Commission-level committee.

Obviously, you have a set of bylaws. This is a fairly recent addition to your process. It is in your books if you want to take a look at it if you haven't. Basically

it's designed to tell you, as all bylaws are, of how to conduct your business in an orderly manner. And I think one of the most significant changes to those bylaws is that as a result of those bylaws is that we formalized your recommendation process.

Dr. Siegel knows very well during his term as the chairman of the committee the committee underwent a lot of changes, and one of the things that was most significant in terms of changes was the way in which you formalize your recommendations and dissenting opinions for consideration by the staff and by the Commission. That is a fairly recent change; something on the order of three, four years now.

The Commission direction has been provided to us in what we call COMSECYs which is a communication from the Commission back to the staff as a result of communications from the staff to the Commission in Commission papers. They're cited there. I won't go through them in great detail. They're in your books, again, if you want to look.

But if you look at these COMSECYs what you'll find, from 1989 to 1993, the Commission gave the staff a lot of direction about this committee. For example, a few things. It told us to keep the size of the committee about 12 members; it told us to make sure that the committee met at least twice a year; it told us to expand from what was the previous size of the committee to the size we now have -- about 12, 13 members.

They asked us to expand the specialties and modalities that were represented in the Commission. They asked us to make sure that the committee would interface with the Commission on an annual basis -- an informal interaction, a briefing, if you will. So there were a lot of administrative changes directed by the Commission to the staff with regards to this committee.

Now, I think that Mr. Graham has made a very good point about communication, and I'll come back to it as I close here. But I also think in addition to communication, there's something else that has gone on and is going on here -- and I know Dr. Siegel and I have talked about this.

If one goes back to the ACMUI of the '70s and the '80s, up until about 1990, you would find a dramatically different committee than you have today. It was a committee that was previously chaired by the Division Director for IMNS, which was Mr. Cunningham. It was a committee that the staff took information to, primarily technical issues, and it was sort of a -- you sort of get a blessing by the ACMUI that this is okay.

Well, about 1990 that changed tremendously. And what's happened over the last six to seven years is that the composition of the committee has changed, how you conduct business is changed, what happens to your recommendations and how they're documented, how they're reviewed by the Commission has changed.

Obviously, Part 35 has become volatile over the last few years. The Quality Management rule certainly did a lot to cause that. So what I see is, I see a committee that's undergoing a dynamic process, a more involved process, and frankly I think this committee now functions like a true Advisory Committee.

We now bring to you concepts, not just the finished product. We now bring to you guidance. We last time discussed with you inspection guidance. So you're blazing a trail all the time and I think that what needs to be done now, the next step is to further enhance the communication. And we have a couple of ideas about how to do that.

But anyway, with regards to the process, the responsibilities of the committee include providing us with guidance and comments on current or proposed regulations and guidance; evaluation of byproduct materials for medical use.

That's actually something that you really no longer do; that goes back to the days pre-1976 when we used to -- the NRC used to establish safety and efficacy of radio-pharmaceuticals. This committee was involved in that in the old days. It's obviously something you don't do any more.

Evaluating training and experience of proposed authorized users. As you know, there are times when we bring to you an individual applicant that the staff has not been able to reach closure on as to whether or not the individual is qualified to be an authorized user consistent with our regulations, and you help us make a call as to that individual's training.

You also work with us to provide the training guidelines. We've worked on a policy and guidance directive, oh, within the last couple of years, on that topic and you helped us to formulate how training and experience should be administered by our regions.

You also provided us with technical assistance with regards to your area of expertise. Obviously, the composition of this committee is such that you have different technical expertises, different practice expertises, and so we draw upon that. And one of the most important areas that we try to capture and have certainly tried to capture in the last few years and we'll continue to do so, is to address the emerging technology.

I mean, there's obviously a lot of things going on today involving byproduct material in medical use and we're trying to make sure we capture expertise to deal with that. We asked you to provide us with guidance on NRC's role relative to other federal agencies and professional organizations.

What is it they do; what is it that we do; what is the marriage between those two; where should we draw the line; what is the best way to communicate and

you share with us, what professional organizations are doing? And hopefully we can factor that into our overall process.

The membership scenario, the process for bringing members onto the committee is one of the things that underwent a lot of change in the last four or five years. As I said, we have about 12 members -- technical expertise is certainly one of the bases. The capacity to provide key perspectives on current or emerging issues is something that we look for as we screen potential members for the committee.

There is a 6-year limit now; that's a major change. There was a time when previously, if one goes back in history, committee members were on this committee for 10, 15 years. There was no process for changing. Now we have a 2-year term, a possibility of three terms, it's a basis of -- Commission need is a factor and whether or not a particular individual continues.

That's a function to some degree of the technical discipline which that person represents. So we now have a process of bringing more players to the table to represent industry within its process in your practice of medicine.

We go through a public solicitation in the *Federal Register* to bring you on board. Typically, professional organizations nominate you; sometimes more than one nominate you, although there can be personal nominations as well. There is a staff review that is conducted.

My staff does the first review of all the curriculum vitaes that are provided. They categorize them and rank them based upon their perception of what the Commission is looking for. There is then a panel meeting that occurs in which either Dr. Paperiello or Dr. Cool participates, along with myself, along with the section leader for the Medical Section and cognizant staff person, and another representative from the federal government, not NRC, that is in that specialty.

For example, if we're looking for a nuclear medicine position we will typically get a nuclear medicine position from say, NIH or Bethesda Naval Medical Center, that will sit on that panel. That panel will then review the various nominations that have been provided.

We will rank them in terms of a recommendation to the Commission. We forward our recommendation and our rankings along with all curriculum vitaes to the Commission, and the Commission ultimately approves the committee membership.

The process that we use with this committee in general terms, to the maximum extent possible, is one of open public dialogue. Clearly, your meetings -- you cover a lot of ground in your meetings. I mean, you have a lot of very interesting discussions. Some of them are heated, some of them are irreverent or in pursuit of intellectual differing opinions, but you certainly have an open public process, and that's key to the function of the committee.

We do ask you to formalize your recommendations and your concerns. We've increasingly asked you to do that. At the beginning of this meeting I asked you to take care today as you reach some of your opinions and consensus and so forth, to formalize them so that we can review them and react to them.

Identify dissenting opinions. We do now of course, have a preparation of formal minutes. The minutes, as well as the transcripts, are reviewed by the staff, reviewed by the Commissioner's assistants -- their technical staff -- and by the Commissioners themselves depending upon the issue, their time, their interest in the issue, and so forth.

So I want you to understand that the minutes and the transcripts are provided to the Commission. We do work with the Chairman to prepare the minutes.

We don't filter the minutes. The minutes are processed and signed by the Chair and then we forward them in a transmittal memo to the Commission. So they see firsthand, the outcome of the conduct of your business.

We do have obviously, public meetings of this committee under the category of interaction with the staff and the Commission. As I said, you also have subcommittee meetings. You recall that we discussed the modules to Regulatory Guide 10.8, and you worked with us in subcommittee format.

I think that there will probably be, as Don pointed out in his opening remarks, there will probably be a need for some subcommittee meetings as we move on Part 35 over the next several months and next couple of years.

We interact with the Chairman a lot. We talk with the Chairman prior to the meeting to discuss the agenda. We talk with the Chairman about pending Commission briefings. As you know, there's a Commission briefing on the 8th of May. So we do interface with your Chairman outside of the normal business that we interface with you here on.

There is the preparation of the minutes which I've already, you know, talked about. Continuing with interaction, there's a transcript of these meetings. These are put into the public document room. Professional organizations can obtain them if they choose to do so, or any member of the regulated community.

And the Commission has asked that there be an oral report or a meeting with the Commission, annually. And that is going to happen on the 8th of May for this year. And it will be, obviously, a very timely meeting for you. You'll have much to say, I'm sure, about some of the things we're going to talk about today.

I think, getting to Dennis' concern is sort of where we are now. You know, what happens with all this stuff? What do we do with it? Well, first of all,

depending on what the topic is -- if we're working for example, on a policy issue. Let's say for example, we're in the early stages of considering a regulation, or even working on a regulation.

The program office, NMSS, Nuclear Material Safety and Safeguards -- Dr. Paperiello's office of which Don and I are part of and our staffs are part of -- we review what -- we go back and literally examine the transcript and your minutes and try to bring to bear what it is that you have said and what it is that you have recommended.

Now, as Hugh pointed out, we don't always take your recommendations entirely; we don't always take them. Sometimes we do take them; sometimes we take them in part. There have been, I think, a number of examples in the last two or three years in particular, where our recommendations have clearly shown up in the regulations when it was ultimately finalized.

The staff, the Office of Research which is charged currently with actually doing regulation development, their staff also looks at the minutes, the transcripts of the meeting and the recommendations that you make. Oftentimes, the NMSS and Research staffs are working together as a team on a particular regulation or a particular guidance document. So that team examines your recommendations and brings them to bear.

Management consideration. As the document goes up the channel, at my level of concurrence I'm reviewing it, I'm cognizant of what you had to say. There are times when I will go back and pull up the transcript or your minutes; I will look at what you had to say; I will look at what the language and the rule or the guide says.

There are times when I raise concerns to the staff about recommendations that you have made. There are times when Don does the same thing. There are times when a rule is making its way and we'll have a meeting with Don

-- he's to review the document at his concurrence level -- and he'll call us in and he'll want to talk about it. What about this, what about that, how do we get to this position, what are we going to do about this, I have concerns about that. And the ACMUI, how does this coincide with he ACMUI recommendation?

So at each level of management review or concurrence, we take a look at your recommendations and your comments to varying degrees. Again, it's a function of the subject matter and what's going on.

And then ultimately of course, Commission consideration. The Commissioner's assistants who work closely with their Commissioners, have the minutes, have the transcripts. Many of them are often here in the audience during various parts of the presentation, depending upon what their schedule allows and what's going on at that particular time. They review your recommendations firsthand.

And there are times when we will brief the Commissioner's assistants. They'll want to know how the staff is proceeding on a particular or how we got to where we are, and they will raise questions about, well what did you do about the ACMUI recommendation? So that kind of process goes on. So I think it's certainly fair to say that we do consider your recommendations and comments.

I think what's lacking though, is feedback; what do we ultimately do with it? I'll be the first to tell you, having been involved actively with this committee sine 1990, or having seen the committee function for years even before that, I think it's clearly fair to say, to step up to the plate and say that we have not done as good a job as we can of giving you feedback. Your criticism and your concern is legitimate.

I think the front end, we've increasingly worked very well, and I think most of you agree that you do have input and it is listened to. What comes of it, you don't know, and we owe you that.

Now, what we've decided to do then, about that, to try to take another step in this process, is to do a couple of things. With regards to rulemakings, if you look at our rules you note that comments are always addressed in the rulemaking process. And we have certain sections where, for example, agreement state concerns are specifically addressed, our comments are addressed.

What we have done is, we have prepared a memo from Don to the Office of Research who currently has responsibility for rulemaking, and we have asked them to modify the process to now include in the future rulemakings, a section within the Statements of Consideration that will specifically address ACMUI comments: how they were addressed, what the staff did or didn't do about them, and the rational. That's for rulemakings.

With regards to non-rulemaking activities -- such as guidance, documents, inspection procedures, conceptual issues that we are beginning to explore, things that we will discuss today with regards to the DSI 7 and Part 35 -- we will provide you routinely, in following meetings -- either the next meeting or when it's appropriate, once the issue has materialized and we can give you legitimate feedback -- we will provide you with a status report on what we did or didn't do and why, with each and every recommendation that you make to us.

We will clarify how we utilized it, and as I said, if we use it we'll explain that we did that; if we didn't use it, we'll explain that and why. So you will get more formal feedback, and we'll do that under the section where we normally provide you with status reports on ongoing rulemakings, etc. There will now be a component to this meeting that will be status reports and feedback on your recommendations.

So we think those two additional steps will go a long way to address the communication problem that Mr. Graham has raised, and we think it is one more step in what has been a, clearly in my mind, an evolution of this committee over time.

We think your points are valid, we think your criticisms are just, and we are going to take some steps to do something about it. I think it will enhance the communication process a lot.

We'll try this over the next few meetings; we'll see how it goes. I'll ask you to tell me if you feel like you're getting feedback. Are you really getting to know where things went? I clearly will ask you to understand up front that there will be times when we won't agree with you; there will be times when we'll take your recommendations in part; but at least we'll give you an explanation as to what we do with it and why.

Any questions or comments about the advisory process?

CHAIRMAN STITT: Since I'm the Chair I get to start --

MR. CAMPER: Sure.

CHAIRMAN STITT: -- and then I'll call on you guys. Two comments that come to my mind. One is, I think in the past we had talked about -- I'm not sure we did anything formal -- but I would like to put together something that would be termed a new member packet, and I'd like to be involved in that.

Several of your early slides would be a nice way for a new member to figure out how we work and what we do to bring people up to speed faster. And that person should probably talk with me and probably a session with you could be done by phone as they come on. So I can work with you and the staff on what the contents would be.

And then --

MR. CAMPER: Excellent suggestion.

CHAIRMAN STITT: -- relating to that, can you give us -- other than I know we're in process -- where do we stand on replacing the members for cardiology, agreement states --

MR. CAMPER: Right. We're looking for a cardiologist, we're looking for a State or Local municipality regulator perspective, and we're looking for a patient's right care advocate. That was published in the *Federal Register*, soliciting nominations. Cathy, do you recall the closure date? Or Bill?

MS. HANEY: May 25th.

MR. CAMPER: May 25th, the solicitation of nominations comes to closure. Once that happens we'll then go through the process that I briefly described. I would hope that we would have recommendations -- assuming we get an adequate number of nominations. Sometimes we don't get enough nominations and we have to go back again. But if we get enough nominations I would hope that we would have our recommendations up to the Commission sometime in June.

CHAIRMAN STITT: Thank you. All right. Who's -- I'm getting some attention over here. Our illustrious past Chairman who's been shuffling his papers, sitting on his hands, chewing gum, doing whatever he could do not to interrupt. He promised me he would not take over. I will recognize him --

DR. SIEGEL: Okay, I promise.

CHAIRMAN STITT: I haven't recognized you yet; just cool it. Exert my control; see how long I can string you along. All right, take it away Dr. Siegel.

DR. SIEGEL: Yes, I promised to be very quiet today. A comment and a question. The comment is for you and for the committee. One of the things that

-- in terms of communicating that you did not include, is a form of, sort of 24-hour alert minutes.

If there's something that the committee thinks is really important, that it wants to make sure gets into the staff and then to the Commission very quickly, you can, immediately following a meeting, release several bullet points and get them into the building very quickly.

And I would suggest that you might want to consider that for this meeting because of the fact that you've got a Commission briefing in only four weeks and the minutes might not be done in four weeks. I'm not trying to make work for you but it's a point to at least keep in mind. It's an option that's always available.

Then I have a question for you which is, so why did the word "consequence" get left into the Patient Release Rule with respect to breast feeding?

MR. CAMPER: Well, I can run but I can't hide.

DR. SIEGEL: Since there are no consequences.

MR. CAMPER: Well, I think that there were certainly those of us who felt that another word, another approach would work, and we make our point along the way. Ultimately, it was kept in. We're all in this together. I mean, I'm not going to point at my colleague's in Research or say that NMSS had the right way to do it and Research didn't do it; I'm not going to say that.

But I can say that there's -- certainly a lot of us in the Program Office felt that the suggestion by the committee was a worthwhile way to do it. There were others who felt that it -- you can explain that there is no consequence or there is no known consequence, or there is minimal consequence, and address that point that way.

And the feeling was in the final analysis that it wasn't particularly burdensome to address it in that manner. I believe that's the best explanation that I can give you. I mean, we did discuss it, we did specifically react to the committee's recommendation, but in the final analysis that argument didn't prevail.

DR. SIEGEL: Was that specific word change -- get to the level of Commission discussion in their vote on the rule? Do you recall?

MR. CAMPER: I don't recall that being discussed at the Commission level. No, I believe it was resolved further down the line.

CHAIRMAN STITT: Dennis.

MEMBER SWANSON: I don't want to drag this out any longer but let me make one comment. What led to the frustration I think that was expressed in my letter is the fact that, I do think that this ACMUI committee has a very respective, if not good working relationship with the medical use staff. And I've seen that evolve over time to something I appreciate both at a staff level and at a personal level -- those relationships evolved to good working relationships.

We have discussions here, and certainly the medical use staff are part of those discussions, and I think become part of the understanding of our recommendations. And the two specific issues that led to my concern, in both cases I think the Medical Use staff and the committee came to sort of a mutual agreement that consequences shouldn't appear in this one.

And then the other incident dealt with whether we should refer to the MIT incidents and NIH incidents in the introduction of the proposed rulemaking on the broad license. And so now we've got a situation where the ACMUI and the Medical Use staff are sort of agreeing and coming to this final recommendation.

And what's particularly frustrating then is, well what happens to that? I mean, it's back to communication again. You know, we've got some agreement here and then all of a sudden it's like, it disappears.

MR. CAMPER: Well, let me be candid. I mean, it was alluded to I think by Hugh, that you know, we have differences of opinion for example, with the EPA. I mean, that's clearly a mild understatement. We have substantial differences of opinion with EPA. We have differences of opinion amongst ourselves.

I mean, there are sessions which I take part in where there is strongly different opinions expressed. We have our colleagues in Research who come from a perspective of, we write a regulation from an arm's length, and we're driven by quality assurance considerations, and is this consistent, and how are we doing this in one rule as compared to another? And bear in mind that they write rules across the board, not just for medical uses.

By contrast, you have a Program Office which we're in. We're very concerned about how do we implement this? How do we license this? How do we inspect this? Is it reasonable? It is practical? Is it enforceable. So we come at it, really with different mindsets. Our colleagues in OGC, there's is a purely legal perspective, plus they're charged by the Commission with a very broad mandate in terms of consistency and quality assurance as it relates to regulatory rule product.

So we as staff members and managers, we come at these these things with totally different issues. I think it's fair to say that my program staff in my branch certainly, and Don's Division, we are extremely sensitive to the advice from this committee, because we know you're out there on the front line every day, using these materials, supervising people who do use them, and we fully understand that -- I mean, your goal is our goal.

You want public health and safety just as much as we do. You don't want misadministrations, you don't want bad press, you don't want people to look at radiation any different than they do any other aspect of medicine, which troubles Dr. Williamson a lot. We are very sensitive to that. So we take that into our deliberations and interactions with the various players in the Agency as well.

They on the other hand, they share some of the same concerns and issues as well, but their perspective, or what drives them, or what's -- that the top execution might be different than ours as a Program Office. That's entirely understandable. That's the process and that's not bad.

What I think is lacking though, and I think what you're now going to do is, you're holding our hand to the fire -- and that's okay, because it's a reasonable thing to do. You're saying, okay, you've got this process and we know you don't always agree, and you know you go through this deliberation, but you tell us, you owe us an explanation.

It is, if you took it, great; if you didn't take it, why; if you took it in part -- you owe us at least a gentleman's or gentlelady's explanation as to how you dealt with our recommendation. That's a reasonable request; we will do that.

MR. CAMPER: One comment on the minutes that Barry raised.

We are doing something a little different this time. Because of the briefing the Commission has expressed a great deal of interest to the staff in knowing what's on your minds in advance of the May 8 briefing to accommodate that, and we've already talked to the chairman.

We have various members of the staff today taking notes as we make our different presentations, and I've asked the staff to prepare their version of the summary of the minutes by COB, close of business tomorrow, to get back to Dr. Stitt

promptly so she can do her work as the chairman. Our objective is to get the minutes wrapped up next week.

CHAIRMAN STITT: Barry, they're sending them to my home, so I can spend the weekend curled up with them.

DR. SIEGEL: You can do it by e-mail. No, I'm kidding.

MR. CAMPER: We're in a crunch on this one.

CHAIRMAN STITT: This side of the table.

Let's try our guests from the states.

MR. GODWIN: Madam Chairman, this sort of reminds me of attending an agreement state meeting here to some degree.

The staff has had problems from time to time communicating with various groups, not just this group, and at least in the case of agreement states, in some cases they have improved, so I think that's hope for things to come down the line.

The question I had related to your presentation.

I noticed in Commissioner's sign-off sheets or voting record sheets, there's several comments in here relative to perhaps expanding the authority of the NRC.

Will this committee be expected to comment on it and follow the procedures as suggested there?

MR. CAMPER: One of the things we're going to do today, in fact in the next session, is I'm actually going to step through the Staff Requirements Memorandum with you, each of the line items in the SRM.

What we're going to ask you to do today is to provide us with your preliminary reactions to the SRM. The SRM as for all of the various DSIs, will be

released publicly in the near future, however we did get permission from the Commission to share the SRM dealing with DSI No. 7 with you today.

So we're going to actually step through the SRM. I'll sort of lead that discussion, just stepping through quickly what the line items are that is within the SRM, and we are going to ask you to provide preliminary views to the SRM.

The other thing we're going to ask you to do that we've never asked you to do before that I can recall, is we're going to ask you to prepare for us -- We're going to give you a take-home assignment.

We're going to ask you, given the limited time that you have today to provide preliminary views, we're going to ask you to give us your views in writing on two very important things.

We'd like your views in writing on the Staff Requirements Memorandum, and how the Commission has directed the staff to proceed, bearing in mind that the Commission has made a decision as to how it wants to proceed. It's no longer deliberating. It's not longer debating the issues. It's decided how it wants to proceed, and it's directed the staff how t proceed accordingly.

We'd like to get your reaction to the direction by the Commission to the staff, and in particular, how we might best go about implementing the direction that the Commission has given us.

We also want you to get us -- If there are issues that didn't surface during DSI 7 or that aren't addressed in the SRM, we'd like for you to provide that to us.

And then what we're going to do is, when you prepare this written report for us we would like to have that before the Commission briefing on the 8th of May.

The other thing we'd like for you to do in that written assignment, if you would, is in keeping with the clean paper from scratch approach, we'd like for you to tell us what's good or bad about the existing Part 35 and/or what would you recommend that Part 35 look like. How should it be structured?

We're going to discuss today some particular questions. We're going to ask you to rank some things by risk, and what the criteria for doing that is. We're going to talk about the medical policy statement and so forth and so on. You can factor all of those things into your written comments. But we are looking for a written perspective from this committee.

Today you'll give us your preliminary views, obviously in the time that's all we have time to do. You'll put some recommendations, you'll reap some consensus, you might have some dissenting opinions, etc., etc.

But in addition to that, we're looking for something in writing in a short time frame for you to express, for the record, your preferences for Part 35, what it should be like and so forth. And we're going to ask you to do it in such a fashion that it could be subjected to being published, perhaps at an FRN, or to solicit public comment, or certainly for consideration by the working group, if we go that way, that we'll be working on Part 35.

But yes, you'll have an opportunity to provide a preliminary view on that particular issue today.

CHAIRMAN STITT: I think Dan had a comment.

MEMBER FLYNN: I think in response to Dr. Wagner's point, I think he has a good point. And also what the commissioner stated that, the Commission seems to be very heavily still reactor focus. That's where the beef is. And the

comment was made would it be appropriate that there would be at least one medical person on the Commission given the interest in the medical use program.

An alternative would be, if for example this committee could have another corner to the triangle so to speak, dealing with the staff, the committee, and then also perhaps beefing up the medical fellow program where you have full-time people here on staff.

For example, I don't know what the status is now, but if there was a radiation oncology physicist or a radiation oncologist here full-time with the staff that I could speak in terms of clinical patient care sorts of things to as sort of having a triangle, because the medical fellow program seemed to work really well -- and I have the impression that would be expanded, but maybe either I have misread it or I don't understand what the current status is. But I would strongly encourage even a more expanded medical fellow program, and individuals that in the past -- I've talked to Dr. Pollycover -- that members of this committee can communicate with in addition to communicating with the staff.

MR. CAMPER: Okay.

Well, the Medical Visiting Fellows Program -- some of you may not be familiar with that. It's something we started back in about 1991 or so, 1992 I think, in that time frame.

We have had two medical visiting fellows. We had Dr. Mark Rotman, who is a pharmacist, who is in the audience today, spent almost 2 years with us as a medical visiting fellow.

Dr. Pollycover, who is still with us as a medical visiting fellow, and is doing a lot of work these days, during a lot of research for the agency to follow the

developments that are going on in the scientific community as it relates to the L&T model, and also the issues of hormesis and related topics.

We have not recruited. We have not solicited or pursued in further medical visiting fellows since 1991-1192, the first batch.

I can't say that we've ever sat down and said, well this worked or it didn't work, or it was good, or it was bad, or we would change this, or we would change that. I think that time has gone by and we haven't pursued it any further. Certainly your recommendation would cause me to go back and examine that issue, and we'll do that. We just haven't taken a look at that critically for some time, but we should do that.

CHAIRMAN STITT: Well, we need to discuss some serious business, like the coffee break.

How do you want to manage that?

MR. CAMPER: Where are we now, about an hour? How far behind are we?

CHAIRMAN STITT: We are --

MR. CAMPER: I'd give them 10 minutes.

CHAIRMAN STITT: Can you all be back here at 10 after?

(Whereupon, the foregoing matter went off the record at 10:10 a.m and went back on the record at 10:30 a.m.)

MR. CAMPER: Thank you for looking out for me, especially Judith. Fortunately, I didn't say anything about Dr. Flynn or Dennis Swanson or anything. Or John Graham.

MEMBER FLYNN: Just all those commissioners.

MR. CAMPER: Let's try to move on. I want to move two comments of correction before I actually get into DSI 7.

The staff who is in the audience -- and the staff will always keep you honest, fortunately.

Two things. I said there were three 2-year terms. That was recently changed to two 3-year terms. And on Dr. Flynn's issue, this idea of a medical visiting fellow, I was reminded that we did in fact provide a solicitation of nominations for a medical visiting fellow in radiation therapy. We got like two or three nominations I think. And then ultimately, about the same time that we had received minimal nominations we went into a budget issue with that program.

I did not recall that, so the staff reminded me of that. I thank them for that. They always try to keep us honest when we say things that are a mistake.

But having said that, based on your comment we will re-examine that issue.

DR. SIEGEL: If I may. If you change the terms of membership to 3 year from 2 years, the committee probably needs to amend its by-laws, because the by-laws say 2-year terms.

MEMBER GRAHAM: And I guess it was implied in the by-laws that this committee had direct input on changes of that type.

DR. SIEGEL: The committee has no input, but the by-laws ought to at least be consistent.

MR. CAMPER: The change was a recent one and your administrative point is very good. We need to do that.

All right.

In your briefing books you have the Staff Requirements Memorandum on DSI No. 7.

The brakeman is about to turn you loose. We're up at the top of the rollercoaster to facilitate your discussion. What I want to do now is actually step through the Staff Requirements Memorandum dealing with DSI No. 7, and let me just kind of get you thinking about what we need from you.

We'd like for you to today to provide your preliminary views on the Staff Requirements Memorandum. Again, I would ask you if you could, bear in mind that as Commissioner McGaffigan has says, let's get on with it. The Commission has done its deliberation. The IOM is behind us; previous public comments are behind us. The Commission that is charged with this public responsibility has made a decision. They've now directed a staff to proceed. They've told us how to proceed. We need your help in proceeding, and that's the types of things I think you should focus upon.

We would ask you if there are other issues that are not contained within the SRM, in the directions to the staff, that you would raise those. As I said before, we're going to ask you in addition to your preliminary views that will be contained in your minutes, that you would also provide us with a written summary of your comments. Dr. Stitt will talk about how she wants t proceed to achieve that.

And then of course this discussion today will help you as you formulate your ideas tomorrow morning in particular in preparation for the commission briefing which comes up on the 8th of May, and that will be here just like that. So some of the things that you're doing today will help you tomorrow morning as you prepare for that particular briefing.

I hope that you've all found the Staff Requirements Memorandum in your briefing book. And what we have done is, you have the actual SRM itself, and just

before that you have a summary sheet that the staff prepared to facilitate the discussion, and basically it lists the key ideas out of the SRM, and so we'll step to those one at a time.

First of all, the SRM points out that the Commission continues to support Options 2 and 3. Options 2 and 3 were contained in DSI 7 which was released in September. This is consistent with their preliminary view, which we discussed with you during the last meeting.

These two options involve continuing the program with improvements, and decreased oversight of low risk activities with continued emphasis in high risk activities. That's Option 3.

The Commission expressed its position with regards to the NAS/IOM report, and they said the following with respect to the medical program the Commission was not persuaded by the National Academy of Sciences, Institute of Medicine report that recommends that NRC should not be the federal agency involved in the regulation of ionizing radiation in medicine. The Commission continues to believe that the conclusions in the report were not substantiated, and that the recommendations should not be pursued.

The Commission made it very clear that it continues to support the use of this committee, the ACUMI, and professional medical organizations and societies in developing regulatory guides and standards.

The Commission also directed the staff in a longer time frame to provide consideration for broadening NRC's regulatory oversight to include one or more of the higher risk activities identified in Option 1 of the DSI 7. You might recall that was things such as linear accelerators. I also believe that the voracity was in that section.

In making this direction to the staff though the Commission said that it would be willing to consider taking on broader regulatory responsibilities for higher risk activities involving other sources of ionizing radiation, but such efforts should not divert resources from 10 CFR, Part 35, Rulemaking, discussed below. In other words, we'll revise Part 35 first over the next 2 years, then we'll go back and take a look at whether or not we should be doing anything more or making recommendations, and so forth and so on to the Commission about some of the other activities in Option 1, such as linear accelerators for example.

There is a methodology described to the staff by the Commission, and in this methodology the Commission said, "In lieu of a rulemaking plan, in the context of Management Directive 6.3, the staff should submit a program for commission approval for revising 10 CFR, Part 35 and associated guidance documents. And the Commission's 1979 Medical Policy Statement if necessary."

We have a management directive, 6.3, that directs the staff how to proceed with rulemakings. Well, one of the things that we do in that process is to develop a rulemaking plan in which we lay out the various issues on the table, generally how the staff intends to proceed. That document is then made available for public consideration, review by the agreement states, and so forth.

The Commission in this case said though, don't develop a rulemaking plan. And as we go a couple steps further here in a moment, you'll see why, because the Commission is very explicit in its direction to the staff as to how it wants to proceed in revising Part 35. So you really don't need a rulemaking plan when the Commission has said we want you to do this, and do this, and do this, and this is our concern, and so forth and so on. So we really don't need to develop a rulemaking plan; rather what we need to do is incorporate the Commission's direction into a program.

The staff's program to implement the above should be submitted to the Commission by the 6th of June of this year -- very quick, very quick.

The program should describe how 10 CFR, Part 35 can be restructured into a risk and formed, more performance base regulation by a suspense date of June 30, 1999.

MEMBER WILLIAMSON: Excuse me. Could you explain the difference of a rulemaking plan and a program?

MR. CAMPER: Yes, I will. In fact I'm going to do that in just a moment.

The Commission has directed the staff that the program should consider the following points. And again, as you read these this removes a necessity to develop a rulemaking plan, because as I said, the Commission gives the staff rather explicit directions as to where to and how to spend our energies and what to focus upon.

So the program that the staff is going to develop to revise Part 35 should consider the following things, and I will come back and talk more about the program itself in a couple of slides.

First, the Commission tells the staff to focus Part 35 on those procedures that pose the highest risk. If you recall from your readings of DSI 7 there were some discussion in there in which the Commission for example points out that diagnostic nuclear medicine should be throttled back. The level of regulatory presence is not consistent with the risk, but by contrast some of the therapeutic modalities that we regulate, such as HDR or teletherapy pose a much higher risk. So the point is, focus Part 35 with risk in mind, and set up the regulatory presence accordingly.

For diagnostic procedures the staff should consider regulatory oversight alternatives consistent with the lower overall risk of these procedures. That might mean for example, clearly moderating the requirements in Part 35 as they relate to diagnostic uses.

That might mean for example, changing the process that we use in licensing diagnostic material uses. It might be that the regulations will ultimately be structured in such a way that we would not a limited specific license for diagnostic use for example; we might issue a general license, or we might issue a general license with some type of acknowledgement, or we might issue a registration. Or in the final analysis it might be that it should continue to be a limited specific license, but with fewer regulatory burdens imposed upon the diagnostic uses.

So clearly the Commission is sending a signal to the staff, change how we regulate diagnostic uses of materials. We hope that you will help us figure out what's the best way to regulate diagnostic uses of materials.

The staff should address how best to capture, not only relevant safety significant events, but also precursor events.

Now, this is really about mis-administrations of course. Most of you know -- I'm sure all of you know in fact -- that most mis-administrations are not a safety significant event. A very large percentage of them are under-dosing. That may have a medical consequence of course if you don't catch that problem and go back and administer the correct amount of radiation to the tumor site for example, but from a radiation exposure standpoint it's a non-event.

So the Commission is saying to the staff, look, we want to capture safety significant events, but we're also interested in seeing precursor events. As you know, mis-administrations today are reported as a function of percentive error. The

threshold is currently 20 percent for most of them; 10 percent for gamma stereotactic radiosurgery with 20 percent for the others. So they're interested in seeing both kinds of events.

And again, I think one of the most intriguing discussions that we're going to have in this committee over the next several months, is if we keep something like a mis-administration, what is the appropriate level to trigger such a report.

For example, changing the nomenclature from mis-administration to medical event or comparable terminology. The Commission is saying to the staff, change the term "mis-administration".

We suggested this when we did the quality management rule. At that time the Commission opted not to do that. They did not agree with the staff's suggestion to change the term to a medical reportable event. Clearly this commission is saying, not only are the considering the staff's suggestion, but they're saying to the staff, change the term. So we're going to change the term.

Part 35 should be redesigned so that it can incorporate necessary regulatory requirements for new treatment modalities in a timely manner.

Last time I briefly alluded to, and will show you an example of something today that we have come up with thus far in our preliminary deliberations, what we call a modality driven approach. And the idea that a particular modality, whether it be HDR or radiopharmaceutical therapy, would have all of the components about that particular modality within one section of Part 35.

If one looks in 35 today, 35.600 teletherapy, I would argue that 35.600 is fairly modality driven, and it's easy to go in and change that modality only; that component of Part 35, without having to change all of Part 35. And so the Commission is saying, look, let's structure Part 35 so that as new technologies come along we can

add them to Part 35, or if new developments occur we can go in and adjust that modality to make the regulations consistent with what is going with us going on the technology, without having to go through the entire process of revising Part 35.

Part 35 was last revised in 1986; it became effective in 1987. We're not quite 10 years into it, and it's only for the next 5 years all of us have known we needed to revise Part 35. So let's try to make Part 35 accommodate future modalities and changes.

The quality measurement program provisions of 10 CFR 35.32 should be re-evaluated and revised to focus on those requirements that are essentially for patient safety. For example, confirming patient identity, requiring written prescriptions and verifying dose. That's objectives 1, 2 and 3 of the current QM role.

To the maximum extent possible the requirements should be revised to be risk informed. Given this objective a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued.

What I'm reading when I read that is I'm hearing the Commission saying, we think that there are aspects of the quality management rule that are worthwhile, and should be retained. And in particular we're saying we think that Objectives 1, 2 and 3 of the existing QM requirement are worthwhile retaining. However, staff, to the extent possible, make the QM rule, or whatever you want to call it, as performance oriented as possible; move away from some of the prescriptive requirements, and recognize that you'll probably end up having some combination of performance and prescriptive.

The staff should consider the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they meet NRC needs.

Clearly they want us to bring industry standards to bear. Now later on today we have a discussion about industry standards, and we're going to ask you some questions about how we might best bring those industry standards to bear within the regulation or guidance, and more importantly, if we did that how might we work with the professional organizations that create those standards and guidance along the way. It's sort of a pathway of partnership, if you will, where we can make sure that our regulations and their standards coincide, and they're timely.

And I'll share you an example with you later in another part of the regulations dealing with industrial radiography, where we brought an ANSI standard to bear in the regulations, and I'll share with you some of the problems that we're having with it today in terms of implementing it.

So, we want to use industry standards. The Commission is saying you want us to use industry standards. Aubrey's laughing about the industry standard.

But bringing industry standards to bear raises some issues and problems. It's not as simple as snapping your finger, but we want you to help us do that.

The staff should consider a rulemaking process that provides more opportunity for input from potentially affected parties that as provided by the normal notice and comment rulemaking process, but would be less consumptive of resources and time than the process recently used in the development of NRC's rule on radiological criteria for license termination.

In other words, do more than the normal publishing of a proposed rule, solicitation of public comments, and publishing of final rule; do more that. But that's what has to be done with the rule. Do more than that, but don't go to what is known as an EPR, an enhanced participatory rulemaking.

There are guidelines and rules that are followed when you do an EPR, so do something in between.

Now, what we interpret that to mean is, go get lots of input, provide multiple opportunities for public comment, hold public meetings, and let the community and the public get involved, but don't go all the way to an EPR and the groundrules associated with an EPR.

And to address that I think it's a good way t pick up on Jeffrey's point. By anyway, that's the last two or three points I made.

Aubrey.

MR. GODWIN: I do not see anything addressing the enforcement issue in this plan.

Are you going to talk about frequency of inspection and things of that nature somewhere in the plan?

MR. CAMPER: You are correct. There's nothing in the SRM that specifically identifies enforcement. However, if you look at DSI 7 there was some comments in there that this effort toward risk-informed performance orientation should also be brought to bear in terms of implementation as it relates to inspection, as it relates to enforcement.

MR. GODWIN: You've got a diagnostic on the facility should not be inspected at the same rate that say, teletherapy or brachytherapy units.

MR. CAMPER: Right.

That's right. There's another effort that's going on -- let me just digress for 30 seconds.

We have another effort going on right now. There was a working group that provided a report to the Commission on the general license device

problems, and we're working on a plan to address direction from the Commission on that.

But one of the things under that particular umbrella, is we're going to be doing a risk assessment that will look at materials uses across the board. And one of the things that we're going to propose back to the Commission in our plan, is that ultimately there would be a risk re-rack, if you will, of all materials uses in which this risk assessment would identify the risk criteria. We'll take all the various uses that are existed in our program. We plug into the matrix based upon the risk criteria, defining that risk assessment, and then ultimately the entire regulatory program -- everything from licensing, to inspection, to enforcement and so forth, would be adjusted accordingly.

Now, it turns out that that risk assessment, our time line -- and we're suggesting to the Commission to do that is '98. So that risk assessment and re-rack of all materials' uses probably will have some bearing on what we do here ultimately as well.

But your point is that obviously if you change your regulatory presence in terms of your regulations for diagnostic, you would naturally in turn expect to change your inspection presence?

MR. GODWIN: I would hope to.

MR. CAMPER: Frequency, nature of, and you're obviously right.

Yes, certainly we will be changing ultimately how we inspect how we inspect diagnostic facilities and so forth and so on, both in terms of content of the inspection and frequency of the inspection.

Okay.

What are the major activities that are going on? I'm trying to get back to Jeffrey's point about tell me what a program is.

What's going on? What are the major activities? Well, obviously we have this meeting. This is sort of the kickoff. We're letting the brake go on the rollercoaster; this is the kickoff.

You're first. That's good. It's timely. It's appropriate. So this is going on, and then of course you're going to brief the Commission.

We are currently developing an issues paper. We owe the Commission the plan by June of this year. It will not be a rulemaking plan in the classical sense, in that a rulemaking plan typically lays out what the issues are that you're going to address in the rule and generally how you intend to proceed to address them.

This plan by contrast lays out a process that the staff intends to follow as we move to revise Part 35. This plan is due in June. We're also developing an issues paper. What we're doing is we're going through; we're developing something like what's called an ANPR, and advanced notice of proposed rulemaking, but it's not an ANPR, it's an issues paper, but it look something like that for those of you who've seen that.

And we're going to say, okay, here's a whole bunch of issues that have been identified. Here's a whole bunch of questions that fall out of those issues, and we're going to publish for public comment.

In the commission paper that we are currently developing that will contain the plan and the issues paper, we intend to provide the Commission with what's called a negative consent paper, where we go to the Commission and we say, okay, this is a program the staff has developed to proceed to revise Part 35. Here's an

issues paper that's been developed early in the process to solicit public comment is part of that overall process.

Tell us Commission if we may proceed with the plan, the program, and may we proceed to publish this document.

One of the things that I think that we need to do as we develop that issues paper is, somewhere down the line, between now and the time we present that to the Commission in June is, we ought to let this committee take a look at it.

So you will be seeing a draft of the issues paper in the not-to-distant future, and you will be afforded an opportunity to provide some thoughts and insights to that issues paper.

The issues paper is designed to be an early mechanism to bring this issue to public attention and to stimulate comment development on the issues that the staff has identified to date.

So, again, the Commission paper under preparation, it will contain the plan or the program, as it's referred to in the SRM. It will also contain this issues paper. It will be a negative consent paper, and we'll be asking the Commission for permission to proceed accordingly.

DR. SIEGEL: At this stage is this stuff you all are working on a joint effort between NMSS and --

MR. CAMPER: This is a NMSS lead.

DR. SIEGEL: Okay. So Research is following at the moment.

MR. CAMPER: That's correct.

DR. SIEGEL: Okay.

MR. CAMPER: Two things on that point. One is that NMSS is preparing the program -- the plan -- I can almost use those terms interchangeably. Just don't call it a rulemaking plan. I call it a plan.

We're developing that. We have the lead on this rulemaking initiative, rather than Research. In addition to that you should be aware that the Commission in separate SRM has directed that rulemaking activities will be moved from Research to the Program Offices, and that's across the board. And the staff is currently tasked with developing a plan to do that, and owes the Commission that plan by August of this year.

So the Commission has decided that it wants rulemaking activities, the creation of rules, to be moved from Research to Program offices. Research will continue; Research will focus more upon the classical research activities and support of regulatory development, contract management and so forth, but the rulemaking function will return to Program Offices.

We have met with Research. They will be providing support to the staff. They will be providing some resources to aid the program staff in developing this. They will be providing some contractual support in terms of a contract to do comment analysis and development of the regulatory analysis.

We intend to use the research Web site as another means of getting the information out to the public to allow comment gathering via the Net. But the lead for the rule will be with Program Offices.

CHAIRMAN STITT: Larry, what do you see as differences in how things would come out of NMSS versus Research in both those issues; development of this as well as rulemaking?

MR. CAMPER: What is the difference?

CHAIRMAN STITT: Yes. Is it something qualitative, something --

MR. CAMPER: Well --

CHAIRMAN STITT: Is there a different focus from one group to the next? Would it look different for me?

MR. CAMPER: Well, if you look at what Research would have done in terms of the rule, what it meant was that Research under the way it was structured -- well, it's still currently structured, but about to change -- Research would actually develop the proposed rule and the final rule.

The kinds of things we're going to talk about here the Program Office would be taking the lead in. However, let me just say this, in January we did provide a user need memo to Research, in which we asked them to take a lead in doing all these kinds of things. That has now changed. The Program Office has the lead.

So the fundamental difference, Judith, is that the actual development of the rule itself, both in terms of the proposed rule and the final rule will be developed and led by the Program Office, NMSS, as opposed to Research.

I think that some of you, based upon our discussions earlier today, probably feel that the Program Office is a bit more sensitive to your concerns, although I think the people in Research try very hard to factor your concerns in as well. But I suspect that some of you feel that because we interface with you, because we implement, because we have to inspect, because we have to license and so forth and so, that we're a bit more sensitive about what should be done, and you might get a more reasonable rule.

Again, it's not to knock my colleagues in Research because they work very hard at what they do and they try to be sensitive to the community as well. But certainly the Commission has decided it feels that Program Offices should take the lead in rule development.

Let me try to finish up answering Jeffrey's question.

In the plan that we are developing; that we will submit to the Commission in June, the staff's preference -- caveat that accordingly. It's the staff and management's preference, suggesting to the Commission -- and I don't know what the Commission will do, so please bear in mind where we are. But our preferred mechanisms would be to use a working group/steering group.

We would like to have a working group that would consist of NRC people from the Program Office, perhaps someone from Research on the working group. We'd like to see agreement state and non-agreement state participants. We would like to see this working group actually be the ones that take all the input that will be coming in.

For example, the working group would take the paper that you're going to develop, and would consider it and factor it into the overall process. And that that working group would also be accompanied by a steering group, and the steering group would consist of three or 4 managers at Dr. Cool's level or higher that would interface with the working group on a routine basis, and steer the process as steering groups do. The working group is getting all the comments, analyzing the comments. Ultimately we will develop a proposed rule, and the steering group works that along the way.

Another thing we're going to propose to do is the use of consultants, at least one consultant, perhaps two or three; that would interface with the working group along the way; would review documents perhaps for the working group. The working group might want the consultants to take a look at a particular set of comments that have been received, or a particular of document under development for consideration for feedback and analysis. That consultant would perhaps meet with the

working group periodically to discuss progress; to provide technical assistance and so forth.

Public stakeholder meetings; multiple. The plan that we are currently developing calls for three opportunities for public comments. We would be soliciting public comments early in the process, obviously on the issues paper as I mentioned, as the proposed rule as being developed. There would be a second round of opportunity for public comment, and then obviously in between the proposed rule and the final rule there would be a third round opportunity for public comment.

The stakeholder meetings; there would be many of them as I said, and there would be a need to involve professional societies.

We envision for example, two or three public facilitated meetings in which professional organizations, such as the ACNP, the Society of Nuclear Medicine, Health Physics Society, ACR, ACNP, and so forth and so on; all the appropriate professional societies -- and I didn't mean to exclude any; those are just the ones that come to mind.

But we would want to have a facilitated meaning with those types of organizations, in which the working group would be interfacing with professional societies via a facilitated public meeting. So that the working group that ultimately is going to develop the proposed rule would get direct feedback and interface with professional societies.

I would envision at some point that this committee would actually interface with the working group. It might be for example that in the fall meeting that it would be a situation where the working group would be here. That would be the purpose of this meeting, where this committee would interface with that working group in a public scenario obviously.

As I said, much opportunity for solicitation of public comments. At least three rounds in the plan that we're working on right now. Ultimately then the working group would develop a proposed rule, and that proposed rule would be submitted to the Commission for its consideration. Then the rule would be published, and it would go through the normal process associated with the proposed rule. That would probably be May, June, July of next year, when we would have a proposed rule.

And then of course comments would be gathered on the proposed rule. Those comments would be dealt with, analyzed and so forth. Ultimately the working group would develop a final rule, and of course all the comments and so forth and so on that it will receive on the proposed rule will have to addressed within the statements and consideration for the final rule.

But in general terms that's what the program or plan, depending on your choice, is going to entail. And we're going to submit this to the Commission in June, along with the issues paper, and ask the Commission to bless that approach.

So the idea of course is to provide as much opportunity for input and all the players, the appropriate stakeholders and so forth along the way, as well as general public comment.

This committee is the first, and you're leading off. So that's what I wanted to cover. I wanted to just share with you what the SRM had to say, and generally what the program will involve that we're developing currently. And I think what we would like for you to do now, as I said earlier, is to provide your preliminary views about the direction from the Commission to the staff, thoughts as to how we might go about achieving those assignments which the Commission has given us; any issues which have not been addressed in the SRM that you think we should be addressing; and then of course using this as a basis to build a written report to us as well.

Any questions or comments at this point?

Dr. Nelp.

MEMBER NELP: Larry, if you go through the regulations as now written, there are seven subsections, or something like that.

MR. CAMPER: Right.

MEMBER NELP: Do you envision that they'll be changing the writing of the regulation in each of those subsections, or just one or two? What do you perceive will happen?

MR. CAMPER: That's an excellent opportunity to lead into something here.

In your briefing books you have this model, this modality driven model, and you have some background information, which by the way was prepared by the Office of General Counsel. It has some notes on organizing by modality, what terms should be defined, should there be an operational definition of adequate protection, and so forth and so on.

To answer your question, Part 35 is on the block. We have a clean piece of paper. We have the capacity and the opportunity to build a brand new Part 35 if in the final analysis that's what all the various ideas which are offered, comments which are provided, suggest that we should do. We have an open mind about it.

I think that there are things about Part 35 that are good. Personally, I don't think Part 35's all bad. I think there are parts of Part 35 that seriously need to be fix. And one of the things that would be very helpful to me is that, if there are things in Part 35 that make sense and that are good, the committee could help us with that.

What are those? By contrast that there are things that are ridiculous or overbearing, or not consistent with the risk involved; what are they.

But I think what you will end up with is something like a following. I think you will end up with a Part 35 that is organized by modality, probably not terribly unlike it is right now, in that 35.200 is a certain category of radiopharmaceutical use; 35.300 is therapeutic use; 35.400 is brachytherapy; 35.500 is seal sources and diagnosis; 35.600 is teletherapy.

You'll probably have a part like that, that deals with high dose rate remote afterloading; a part dealing with gamma stereotactic radiosurgery; a part dealing with radiopharmaceutical therapy; a part dealing with diagnostic uses.

What we need to do though is, is one looks at "A", you've got dose calibrators and various technical issues in the first half of Part 35. Then you get into 35.100, which is structured upon the -- if one goes back in time, it goes back to the days of Groups 1 through 6, and before that it was grouped by diagnostic and therapeutic. It's a historical evolution to get to where we are today.

I don't take 35.100, 200 and 300 are so flawed, particularly with the changes we made in radiopharmaceutical a couple years ago. What's bad is you've got, or what's problematic is, you've got all these various technical or administrative requirements that go across the board.

In other words, anything and everything that deals with diagnostic could perhaps be in a module, a Part 35; everything that deals with radiopharmaceutical therapy could be in a module. So that if we need to go back at some point and change only that which deals with radiopharmaceutical therapy, we could easily adjust the module, and not to have change the whole thing.

My guess is -- and again, I'm trying to be very cautious because we have an open mind about it; we're open to suggestions.

But I think you are going to end up ultimately end up organized by modality. And I think that modality and what is in the regulation for that modality should be a function of the risk associated with that modality.

For example, it is entirely reasonable to imagine that there could be reporting requirements of some type that are specific only to high dose rate remote after-loading but don't exist clearly, for diagnostic uses. Or may not exist for some other therapeutic use like iodine, for example.

So, certainly based on our discussions thus far, we envision that if it were modality, segregated by modality, risk driven, could allow change readily, accommodate new modalities, that makes sense.

But, in examining that, these are the kinds of things that we have looked at and said would need to be addressed in any modality.

Who needs to be licensed to use that particular thing?

What are the technical issues; surveys, access control and so forth?

What training and experience is appropriate for that particular modality?

What events misadministrations or reports pertain or should exist for that modality.

What about quality management as it relates to that modality?

What records, what organization, what QA and so forth.

There is a series of questions and answers that OGC developed which you can consider as you look at this potential model. I emphasize though that it is only a model. But I think that ultimately organizing Part 35 along those lines makes sense; but there may be other ways.

Does that help?

MEMBER NELP: I think that is the answer to my question. It sounds like you are really looking at a fairly complete re-write.

MR. CAMPER: Oh, yeah.

MEMBER NELP: Restructuring the whole thing.

MR. CAMPER: No question. This is not a band-aid.

MEMBER NELP: Which, if that's true I don't think you want to get the committee involved in that process. You want to get the committee involved in focused issues, so that we can say if this is high risk, low risk and you can do that.

A lot of that is just good hard work and organizational writing.

MR. CAMPER: Right. That is true. And we will be bringing to you along the way as this is being developed -- well the working group will actually develop it. And there will be opportunities along the way to examine and document on the approach as it is emerging in terms of actual specific language, organization and so forth.

But I do think though, picking up on your last point, one of the things -- and we ask you to do this later in this specific session. We do ask you to take at least a first cut at organizing by risk; modality and risk.

Now, I recognize that in the amount of time that we have for that topic, one hour, we can't make a lot of progress on risk. But at least some preliminary thoughts on how organize Part 35 with risk in mind, by modality.

CHAIRMAN STITT: Larry, let me ask this. From looking at the agenda, am I right, we can work from now until 11:45 to discuss what is currently on the floor? So, I want to encourage the committee to do that.

Dan?

MEMBER FLYNN: So, Larry, so I understand and am not misunderstanding, we have Reg Guide 10.8 in modular form. Would it be reasonable for a first attack at Part 35 to be to try to put that in modular form, parallel to Reg Guide 10.8? Not to strap it to Reg Guide 10.8.

But then, when you have a final Part 35 two years from now or three years from now, then you would go back and revisit and make adjustments to the modular Reg Guide 10.8 to make sure that it fits the new Part 35.

In other words are we working on these in parallel?

MR. CAMPER: Well, the guidance, well obviously the Reg Guide 10.8 will undergo major change; it needs to reflect the new regulation. We will be charged with creating the guidance along with the rule. In other words, when the rule is published in final, the guidance will have to be available. Okay? That is the way we do it now.

It is no longer a situation where the rule is there, and guidance comes along. We now have to do it together.

Obviously, we can't develop the guidance until we know what the rule is going to look like. And if we assume that Part 35 is going to undergo major change, then we sort of have to wait along the way.

I think that the most effective thing that you can do now is this idea of what is good about Part 35, what is bad about Part 35, how should Part 35 be organized with risk in mind, what are your preliminary thoughts about the idea of the modality with everything pertaining to that particular discipline being captured within that one section, that one modality if you will.

I think that, if I understand your question, the actual construct of the guidance, our capacity to literally structure it is going to have to wait a while until we start to see what Part 35 is going to look like.

MEMBER FLYNN: For example, if 99 per cent of your licensees don't have HDR, do they really need to have a lot of HDR mixed in with various parts of Part 35?

MR. CAMPER: No.

MEMBER FLYNN: Or could it be a modular system where if they should acquire HDR , of course they have to make sure that their program is in compliance with the HDR "module" of Part 35 and the Reg Guide for HDR.

MR. CAMPER: The Reg Guide 10.8 is not, I would argue, not designed particular well today, from a modular standpoint. We recently developed the modules that in fact the committee helped us work on, that would be added to Reg Guide 10.8. That was a big step in the right direction.

But the idea is that if someone picks up Reg Guide 10.8, they should be able to go, in short order, to look at any administrative issues that apply to all licensees, then thumb through to that particular appendix that deals with HDR. Because if I am a nuclear medicine person and don't use HDR I probably don't have any interest in it.

So, it needs to be organized in such a fashion that it tracks the rule and it accommodates that modular approach. Because, again, if we revise the rule, we want to be able to revise the guide the same way.

CHAIRMAN STITT: I want to encourage the committee to give feed back on the issue of risk. Risk has to be one of the hardest things to describe, to discuss and there are different versions of how to look at risk.

Trying to talk to a patient about what is the risk of this treatment versus that treatment, what is the risk of you developing breast cancer in the next five years, most people cannot understand.

So, there are certain concerns about developing regulations based on the topic, risk, that are very difficult to understand in the professional sense and then relate to the public sense.

There are a bunch of people who had questions or comments, on the left. Start with Jeffrey.

MEMBER WILLIAMSON: Yes, since the new approach is supposed to be risk-informed and performance-based, I was wondering if you could just give some working definitions. I think I understand a little bit what risk-informed means, but I must confess the concept of performance-based is a confusing one.

MR. CAMPER: Well, the first thing that I would do is I would draw your attention back to DSI 12.

CHAIRMAN STITT: Ooo, bad place to start.

MR. CAMPER: But DSI 12 actually defines what is meant by the Commission in terms of risk-informed, performance-based regulation. So, clearly I am going to first latch on to the definition of DSI 12.

Now, having said that, I think what it means is, in practical terms, let's apply common sense. Let's have that level of regulatory presence, first in terms of regulatory requirements, secondly in terms of licensing and inspection that are consistent with the risk involved.

Now, intuitively we all know that diagnostic pose minimal if any risk. We know that, okay? And therefore, we can intuitively decide that that level of regulatory requirements should have a commensurate low level of presence.

What I think you need to do is give us some rationale for the basis that it is low level risk other than the obvious intuitive, some conceptual basis of why it is low level risk, and then what is the appropriate level of regulatory presence?

You could make specific suggestions about what the regulation should contain for diagnostic and then go up the ladder for various pharmaceutical use, for brachytherapy, et cetera, et cetera.

Jeffrey, I read the DSI 12 and I actually thought that DSI 12 dealt with very difficult subject matter but I didn't think it was all that bad.

But I guess I kind of stepped back, one time removed, and said let's apply common sense. Let's apply a level of regulatory presence consistent with the risk involved from a common sense standpoint. But have a rationale and a basis for doing it,

MEMBER WILLIAMSON: Well, I can understand that. I think if I recall, DSI 12 contrasts performance-based with prescriptive rule. And I am wondering for the purposes of rewriting Part 35 since Commission has directed you to take this performance-based criterion into account, what exactly does that mean?

MEMBER NELP: Could I make one comment. I thought the Commissioner, himself, told us to totally disregard DSI 12. It is a terribly written document. But he stood up here and said, you guys ignore DSI 12.

MR. CAMPER: He did.

MEMBER NELP: And I would choose, on behalf of the committee, to emphasize that.

MR. CAMPER: That is why I say that in the final analysis I think what you will end up doing is you are going to apply common sense. I mean, you can spend an awful lot of time trying to be sure that you define the color and shape of the box as to

what is performance-based and what is risk-informed. You can spend a lot of time doing that and I don't think you will get anywhere.

Rather, by contrast, you can spend a lot of time trying to apply what I call common sense, risk in mind, with the appropriate level of regulatory presence.

MEMBER WILLIAMSON: Okay. I had a point for bringing it up; it wasn't to do nitpicking.

I think that one of the major concerns of the part of the regulated community that I represent is to some extent the enforcement activities of the regulations and how we get dragged into a whole lot of trouble and squabbling with the agency over what are effectively paper-work sorts of violations that have no clinical significance, whatsoever.

So, to me, maybe performance-based has something to do with the system of enforcement, evaluating licensee performance.

MR. CAMPER: Well, I understand and I have heard the complaints about the enforcement process along the way. But again, let's start in the beginning.

We are going to ultimately license, inspect and enforce a written regulation. Change the regulation now; start new. The enforcement process and the inspection process and the licensing process will follow and we will bring to you, once we have a regulation and we have guidance, we will bring to you the inspection process and the licensing process and any changes that fall out to the enforcement process, as well.

But first we have to start with the regulation.

CHAIRMAN STITT: I am going to jump in here. I had brought up the issue of risk which we are currently discussing with a member of the public who

wishes to present the views of the American College of Nuclear Physicians and Society of Nuclear Medicine.

MR. ROTMAN: For the record, my name is Mark Rotman. I am going to read this statement into the record.

If you haven't gotten a copy of the statement we will make an effort to get a copy for you.

The Society of Nuclear Medicine and American College of Nuclear Physicians are pleased to address the ACMUI as it considers the radiation risk posed by the use of byproduct material in medicine, and nuclear pharmacy as practiced by qualified professionals. We believe that the proper appreciation of the risk posed by nuclear medicine is critical to developing an appropriate regulatory framework for nuclear medicine.

What is risk? We believe risk is the consequence of an action multiplied by the probability or frequency of that consequence happening.

We believe that there has been ample scientific evidence published to support the view that low doses of radiation are not only harmful, but are occasionally beneficial. By "low dose", we mean doses not in excess of at least 5 rem ede, and subscribe to the position of the Health Physics Society that 5 rem ede per year or 10 rem ede once, has no associated risk.

In addition, we must point out that all risk from internal emitters constitutes chronic, rather than acute, radiation and the dose should be decreased by a factor of two to ten to be comparable to sources of acute radiation, such as x-ray and fluoroscopy machines.

In nuclear medicine and nuclear pharmacy, we know the exposure history for each and every worker. Therefore, we know the consequence and

probability for each and every worker; thus, we know the risk as well. Likewise, we know the rate and the consequence for misadministrations, so we know the risk there, too. The data show that the risk to workers is extremely low.

Therefore, we wish to make the critical point that in assessing potential radiation risk, one also needs to look at who is responsible for handling and managing unsealed sources of byproduct material. In the hands of qualified professionals, risk decreases substantially.

Diagnostic nuclear medicine is one of the safest medical procedures patients undergo. The absence of risk for diagnostic nuclear medicine was determined by the NCRP in Commentary number 7, published October 1, 1991.

The NCRP determined that the average diagnostic dose from nuclear medicine to be 440 mrem ede, a dose lower than yearly background in numerous mountainous areas of the United States. We believe this helped convince the NRC to delete diagnostic nuclear medicine from the Quality Management Rule.

We recommend that the NRC change its requirements for authorized user physicians, substituting instead a requirement that a user demonstrate substantial evidence of mastery of basic nuclear and radiation sciences, including laboratory experience.

This requirement should be equivalent to the radiation safety training covered by several medical boards already recognized by the NRC. No other regulation of diagnostic nuclear medicine would be needed.

The existing 10 Part 35 should be revised to impose no greater level of regulation than is necessary to oversee this low risk activity.

We believe that a further investigation by NRC will show that the same is true for therapeutic nuclear medicine, except that the absorbed dose to the

patient is purposefully higher. Doses to workers, to the non-patient public, and to the environment are known, and they are low.

If we look at more than a half century of thyroid therapy, about two million treated patients, we see no examples of morbidity or mortality except for a minuscule number of patients adversely affected by human error, a phenomenon that cannot be stopped, except by withholding treatment altogether.

Nuclear Medicine therapy, involving wide variation in administered activity also lacks the harmful side effects often seen with other forms of radiation therapy. Again, in the hands of qualified professionals, this is a low risk activity.

We also believe that nuclear pharmacy is a low risk activity for the same reasons that nuclear medicine is low risk. We know the exposure history of nuclear pharmacists; we know they operate within the dose limits of 10 CFR Part 20. Additionally, due to an economy of scale, nuclear pharmacy manages to prepare doses with an exposure rate per dose that is substantially lower than what would be found in a nuclear medicine service radiopharmacy laboratory.

Medical and pharmacy oversight is accomplished by State and local professional groups and by national professional organizations. The sale of manufactured radioactive drugs, including radiobiologics, is controlled by the U.S. Food and Drug Administration. The United States Pharmacopoeia writes radiopharmaceutical standards and information. There is no relevant radiation safety niche unfilled by qualified professionals except for the considerations of 10 CFR Part 20, and that is where a radiation regulatory, like the NRC, should concentrated its activities. In essence, this was the conclusion of the NAS/IOM and we agree.

We strongly recommend that the ACMUI vote in favor of a resolution that states that, "The ACMUI believes that, in the hands of qualified professionals,

diagnostic and therapeutic nuclear medicine and nuclear pharmacy are low risk activities".

Thank you for the opportunity to make this presentation.

CHAIRMAN STITT: Thank you very much, Mark.

Are there people who need copies of that?

Commentary on what you have just heard or on the topic that we are currently working on?

Jeffrey is making noises. Anybody else?

MR. GODWIN: I will go back to the general topic if you want to.

CHAIRMAN STITT: Go ahead.

MR. GODWIN: Looking at your plan, Larry, I didn't see one thing that I thought should be in there and that is a provision to take action on current regulation that you might determine to be unneeded.

For example, 35.20 ALARA, do you really need it there? Can't you take it on out and eliminate that? Shouldn't that be part of your program? To eliminate those kinds of things. Quarterly meetings of committees; a lot of places that is not appropriate either and you might want to consider that.

There are a bunch of them we can talk about later, but that is a real deficiency that I see in the plan right now.

It does not talk about some interim changes that could be taking place today and helping.

MR. CAMPER: Well, if I understand what you are saying, I have two comments.

First of all, I think that as we revise Part 35, there are going to be existing requirements that will be viewed as being unnecessary; I think that is probably

true. I don't want to comment on which ones but I do think there are ones in there and you cited a couple of good examples, that will probably be eliminated or modified.

With regards to the interim step, at this point the Commission hasn't given us any direction to do any quick surgical fixes to Part 35. Rather, they said revise the whole thing and give us a new rule in two years.

Obviously you can't expend energy trying to surgically adjust a particular part that is perhaps burdensome or distasteful while trying to fix the whole thing. I think what they have done instead is they have said to us is expend your energies revising the whole shooting match through a participatory process.

So, we have no plan at this point to take any type of interim surgical strike on Part 35 to take select parts out or to modify select parts.

CHAIRMAN STITT: Comments from the left side? Go ahead.

MEMBER WALKUP: I just have a question. When these rules are decided, will they be implemented in steps or is it just boom, all at once?

MR. CAMPER: Rules can be done either way. Typically, they have some lag time associated with them. They are published on a certain date and they require implementation by date x. The date ranges anywhere form six months to two years typically, depending on the nature of the change.

Then for agreement states, for those issues that are items of compatibility, if there are any, that is typically three years to implement those.

So, the answer to your question is that I would expect that there would be an effective date of the rule and an implementation date of the rule, although there might be more than one implementation date, depending on what it looked like.

CHAIRMAN STITT: I'm a little disappointed in Dr. Siegel who has his great opportunity to come and advise us. You are not part of the committee any more.

Your spirit remains on but for heaven's sake, speak up. Give us your comments about risk, give us your comments about Part 35.

DR. SIEGEL: Sure.

CHAIRMAN STITT: If we make him, he will.

DR. SIEGEL: Well, diagnostic nuclear medicine is low risk.

CHAIRMAN STITT: Do you want me to write that down? Is that all we need to know?

DR. SIEGEL: That is all you need to know.

CHAIRMAN STITT: Okay.

DR. SIEGEL: I am actually sort of hanging back a little bit because we are starting to get the cart a little bit before the horse, in my view.

I am also absorbing and enjoying the luxury of being able to listen to what is being said without having to worry about what my next comment is going to be as I know you are doing. It is a nice luxury to be able to do that.

I think the Medical Policy Statement is where we have to begin. I think the real starting place of this discussion is where you draw the line between Part 20 and the rest of Part 35. Where you draw the line, what determines who is a member of the general public, who is a worker, and where a patient fits into that.

One way to frame this whole argument is to say that the real starting place is to retrench on the Medical Policy Statement so that the physician-patient interface is no longer part of the purview of the NRC because it is not clear to me, this is my amateur legal opinion, that the Atomic Energy Act says that the NRC needs to jump into that arena. And the Tenth Amendment might say that they really don't need to at all because that was territory reserved for the states because it is the apractic of medicine and the practice of pharmacy.

Now, that is a big jump, but I was kind of waiting for the after lunch discussion by Cathy, of the Medical Policy Statement, to get that issue on the table.

Because how you redraft Part 35 has a lot to do with whether you are able to reach the conclusion within this building that you drastically wish to retrench from the physician/patient part of this and focus more of your efforts on the workers and the general public.

If you are willing to do that, then Part 35 changes a lot.

If you put your foot down and say we can't possibly do that because we continue to believe that byproduct material-associated radiation is uniquely different from all the rest of medicine that it therefore requires a federal regulatory presence whereas, the physician choice of what drug to use, the physician choice of what operation to perform, and what types of psychotherapy to administer, do not require a federal regulatory presence.

If we can make that decision,t hen the rest is downhill.

MR. CAMPER: Just a comment about that. I think that is a very intriguing thought. If one goes back and reads the register notice that accompanied the 1979 Medical Policy Statement, the argument is made in the FRN, not to steal too much of Cathy's thunder because she will go through this, but the argument is made that the legal authority under the Act is in fact in tact. Then it becomes a matter of policy.

The Commission's 1979 policy statement made three guiding principles, if you will. Out of those guiding principles, in turn, in theory, all regulations and all guidance, and all inspection and licensing and everything that involves implementation should in fact flow from the policy statement.

I think last time you had a very worthwhile discussion and you ultimately, at that point in time as I recall, passed a resolution that you thought you ought to re-examine the 1979 Medical Policy Statement and perhaps make some suggestions to it.

I think Dr. Siegel has an excellent point because I think the underlying principles should be espoused in the Medical Policy Statement; everything flows from that. In theory, that is how it is supposed to work.

CHAIRMAN STITT: Go ahead, John.

MEMBER GRAHAM: I think if I can shape part of the discussion and the concern that we have, Larry. Having participated in that fairly long debate at the last meeting where we ended up passing a motion but with some dissent, with three dissenting votes, that we would insert the word "high" or "risk" in that Medical Policy Statement.

Then, jumping forward to looking at the Commission's direction to staff that you would focus Part 35 on procedures that pose the highest risk.

MR. CAMPER: Okay.

MEMBER GRAHAM: But then clearly understanding that they go on to say in number two, that for diagnostic procedures, staff should consider regulatory oversight alternatives consistent with lower overall risk, et cetera.

And that changing the nomenclature for misadministration or medical event or comparable terminology force me to go back and look at I think it is Commissioner Dicus, who in her vote, comments that to enhance NRC's regulations to protect patient safety, Part 35 should enlarge its efforts to prevent misadministrations.

To this end, reporting requirements should be maintained but should focus on the causes of the events and not ont he events themselves.

Nomenclature should be changed from misadministration reporting to medical event reporting. It is a Commissioner's opinion.

Moving that forward into the staff memo that went to Commissioner McGaffigan, the staff under their memo, page two, states that under misadministration, definition and reporting.

Another situation is a case where a patient receives a very low dose or no dose, say as a result of an equipment failure. This is not now reportable now, but it is in the NRC's interest to know what happened.

My concern I think, is I would emphasize the Commission's direction to staff that we focus Part 35 on those procedures that pose the highest risk and that we discuss the Medical Policy Statement of 1979 and how it potentially would be modified to direct all of its other activity.

My concern would be for the staff consideration of oversight alternatives with low overall risk, capturing relevant safety significant events and including precursor events in this whole process of changing from misadministration to medical event, is an opportunity to develop a broad oversight of healthcare providers to identify process issues that will further prevent misadministration or quality improvement over medical events.

My analogy is to the Joint Commission for Accreditation of Healthcare Organizations.

The Joint Commission finally concluded that there is no way they can come in and dictate quality. They can't dictate quality improvement. It is too large so they backed up and said we want to come in and ask you, as a major provider organization, how did you improve the quality for the community you took care of.

What they are beginning to discover is that, as providers with all of the brainpower that we can organize in a location, we are moving it further, faster, than they ever could regulate or mandate.

That is my concern going back to Dr. Siegel's comments is that program recommendations need to be as broad in oversight as possible. Where you are going to come in to look at how we set up a system to improve but not prescriptively tell us what we report. Or that you become the repository of data at a national level to be able to identify process issues that we ought to look at.

I don't think it will work. I don't think you will ever have the resources, the computer power, the ability to sort out significant changes in process.

Back away from that and focus on the really high risk procedures, push down to the provider level how we control those lower risk levels and focus on the Medical Policy Statement which, I agree with Dr. Siegel, means that a great of discussion about high risk/low risk, falls away.

CHAIRMAN STITT: Dennis?

MEMBER SWANSON: At the last meeting I was one of the dissenters on simply inserting the word "high" before risk. I consider that to be overly simplistic because it comes back to Dr. Siegel's comments: the risk of what?

What are our regulations directed at? Are we talking about risk of occupational exposure, public exposure and how does that risk go into the patient realm?

I think we have to back up to the original mandate of the Atomic Energy Commission and ask what are we talking about here? Risk of what? What are you trying to regulate.

You start at that point. Otherwise, I don't have a definition of risk. I can't even start to define high risk and low risk unless I understand what you are trying to regulate to begin with.

So, we need to go back to the beginning and take a look. It is simply too simplistic to insert "high" without first defining what we are trying to regulate.

MR. CAMPER: I think that's fine and I think that is where it kind of gets back to Jeffrey's point and I alluded to DSI 12.

What I meant was in DSI 12, risk-informed, performance-based was defined. Now, it may be problematic but at least it was defined and it is a place from which you can at least launch a discussion.

But I think one of the things that we are asking this committee to do is to not only to rank things by risk, but we also ask you from your perspective, define, tell us what is the risk criteria. What constitutes the components of the risk matrix and how do things fit into that.

All of you know as well as I that when you establish a risk matrix you can bring certain kinds of technical parameters to bear. Regulators would also probably factor in certain political consequences or public perception consequences.

Risk matrices are to be defined and it is entirely appropriate and we are asking you, the committee to define the risk matrix and then rank the things accordingly, whatever you deem it to be.

I think what I am hearing you say is that in the process of doing it, this committee should decide where you think the risk focus is.

If your position is that it shouldn't be the patient, then state that, state why. And then ultimately in turn I would think then you would also have suggestions for

the Medical Policy Statement as it relates to patients. But that is your call; tat is what we are asking you to do.

CHAIRMAN STITT: One of the things that concerns me about such matrices is that if you look at risk to general public of airplane problems, nuclear reactors, strikes by lightning, you don't see isotope therapy on there anywhere. I mean the risk doesn't even show up on those graphs.

So, it depends on whose risk you are talking about. And I think that we as a committee have to be careful not to get involved in extraordinary --. We spent a whole lot of time on a word and I think the whole subject, as I look back at it was sort of a fruitless endeavor on our part. I think we missed the point in general.

We will run down this side and that side.

Go ahead, Dr. Flynn.

MEMBER FLYNN: I think I disagree with Dennis only in the sense that the Medical Policy Statement, by its very nature is vague. It is sort of like the Constitution and as we interpret the Constitution we can interpret the Medical Policy Statement.

If we leave the word risk in there that implies any risk. Anything that is non-zero. We only insert the word "high risk" and the reason that I think that we voted for that is so that we can define what we interpret what is high risk. In other words, one chance in 10 billion in a diagnostic event is considered no risk in terms of it not being a high risk.

We can interpret ourselves what is high risk based on our clinical judgement without having to be so specific. If you want to, divide it into low, intermediate and high and then focus on high and then focus on high.

It might be hard to categorize some as either high or low.

And I think that is what you need to start today, start looking at various modalities and putting them in a box. HDR is going to be high risk but diagnostic radiology is low risk; we know that.

But as we get on there may be some gray areas.

CHAIRMAN STITT: Go ahead, Larry.

MR. CAMPER: I was going to say that on the agenda what we did is there is a session where we talk about risk. We will share with you some effort that the staff has undertaken to define risk as it relates to byproduct material use in medicine. We will also ask you some questions. There is also a section that deals specifically with the Medical Policy Statement.

So, you will have an opportunity to explore each of those issues in that particular topic area.

I think the thing that I would ask you to do at this point, is relating to the SRM and the direction provided to the staff. Do you have preliminary views on those directions? Are there specific suggestions as to how the staff could achieve those directions provided to us by the Commission? Are there things that you find strikingly absent from the direction provided to the staff by the Commission? Those kinds of things. In this particular session, is what I am suggesting.

CHAIRMAN STITT: Let's continue along that line We have ben told that the Commission supports continuing the on-going program with improvements and decrease oversight of low risk activities with continued emphasis on high risk activities.

Could I hear commentary on those two statements?

Anybody over here? Are you guys sleeping right now?

Okay, Jeffrey.

MEMBER WILLIAMSON: Well, I guess I want to support Barry's view. I think a lot of this sort of tussling back and forth between the SRM discussion and the Medical Policy Statement is that it is the Medical Policy Statement dictates what the consequences would be and really is going to define what domain is encompassed by the new Part 35.

To a very great extent that will affect the high risk procedures that we classify as such. And it is going to determine where the boundary between regulatory domain leaves off and the clinician/patient relationship can proceed without regulatory oversight, to put it kindly.

So, I think maybe there is a sense in the committee that that issue should almost be discussed first.

CHAIRMAN STITT: The Medical Policy Statement you mean?

MEMBER WILLIAMSON: Yes.

CHAIRMAN STITT: Well, there is a comment from Commissioner McGaffigan as a foot note in his reply that says, "Revisions to the Medical Policy Statement must be carefully considered and ultimately reflect revised Part 35 and regulatory program."

That was in response to all the gnashing of teeth that we did in inserting "high" before risk in the Medical Policy Statement.

I think the two work back and forth and you can view Part 35 in light of the medical policy statement. And I suspect that this committee might view it differently than other groups would.

Dr. Siegel?

DR. SIEGEL: Another way of reframing this, and Larry, this potentially could be an addition to things the staff is currently doing in response to the

SRM, would be for an analysis to be prepared though I don't know who would do it, spelling our and analyzing the consequences of essentially dropping items two and three from the Medical Policy Statement and drawing the line at a different place.

Essentially saying that for purposes of the interpretation of the Act, the patient is not considered and that is left to the other bodies in the world that regulate the practice of medicine.

Would there be consequences of grave concern if that position was taken by the NRC?

You know, I believe that the NRC has the statutory authority to do what it does, but I also believe that it has the authority to regulatory discretion and not do what it does.

I don't think anything in the Atomic Energy Act compels the NRC to regulate the explicit practice of medicine the way it does in the patient\physician interface and I am not aware of a large body of case law that specifically addresses that particular problem.

So, the NRC could, as a matter of course, choose to say what would happen if we drew the line at an entirely different place, would there be such a compelling regulatory void that we would have to step in as we have for the last 40 years?

MEMBER NELP: I would like to comment. Could the committee proceed with the idea that we want to eliminate the consideration of the practice of medicine from the concept of safety and risk and work in that direction? What would happen if we said the committee wants to get the patient and the physician out of the domain, now we will tell you what risk is.

Would that be feasible?

CHAIRMAN STITT: Well, I think the committee can do what it wants. I think what Barry is asking for is some clue as to what would happen.

MEMBER NELP: I am sure that the committee, if we took a vote, would say that is agreeable.

DR. SIEGEL: I suspect, but Judy might not. I would say that if you were going to do that which is perfectly reasonable, then we should do parallel tracks. We should play the game both ways; speak out of both sides of our mouth and say that in the world where the Commission decided it had regulatory discretion, had discretion to withdraw from this arena, then here is what we recommend.

Then, in a world where the Commission sticks to its guns, here is what we recommend.

MEMBER NELP: And the Commission would have to react immediately.

CHAIRMAN STITT: And why do you suggest that?

DR. SIEGEL: Because I am a realist and i think that if we just advise don't involve yourself with patients, we will have created a set of advice that won't end up being useful if the Commission chooses to continue to play the game this way.

On the other hand, if we have put on the table the notion that maybe they should completely reconsider where they draw the line, then we can structure the components of Part 35 to allow for both conditions.

MEMBER NELP: Would that be an issue that they would be forced to resolve at the upcoming briefing?

DR. SIEGEL: Well, it certainly is something that if you felt you wanted to address it, it could certainly become part of the upcoming briefing, I would think.

CHAIRMAN STITT: Um, anybody else down this line while I have got their attention?

Dennis, you are thinking, contemplative. Should I just let you speak later?

MEMBER SWANSON: I mean I am just contemplating that if we get to defining high risk and low risk and if I try to read this probabilistic risk assessment thing and you take the probability of risk times the potential outcome, then if we look at the probability of risk for risky procedures or the probability when it gets to patients of a misadministration, I think we all come to the conclusion that that is a low probability which would make this whole assessment of risk, low risk. Okay?

So, that is my thoughts and it is coming back to saying why are we involved in looking at this anyway. So, it comes back to your initial thing of saying that maybe the NRC shouldn't be into looking at patient worry and risk. Okay?

Because I think you are going to come to the conclusion, if you go to your probabilistic methodology that all this stuff is low risk.

CHAIRMAN STITT: Well, depending on what framework you are looking at, you are exactly right. Most of what is going on in the field is all research-based, and to start regulating based on models that are clearly research oriented where there is very little information is frightening.

Jeffrey, we got your attention.

MEMBER WILLIAMSON: Well, I would suggest we do the following thing since this time period we are supposed to be talking about the relative risk of different things, let's talk about three different populations that can experience consequences and rank the modality separately.

We can talk about he public, the workers and the patients. Then, depending upon how the issue of the Medical Policy Statement is resolved in our minds, we can dropout the patient column or not.

CHAIRMAN STITT: That is a reasonable framework. Now, how are we going to do that? Lunch supposedly started 30 seconds ago.

MR. CAMPER: Let me just point out something. The discussion on criterion ranking of medical procedures involving byproduct risks is on from 2:45 to 3:30.

The Medical Policy Statement is on from 12:45 to 2;30.

Now, again, you can go where you want to go, but we have set aside specific times to try to cover this full spectrum of topics.

I do think that Dr. Siegel made a very intriguing comment though, and that is the idea that you really have both to think about. On one end the 1979 Medical Policy Statement is the basis from which policy is derived. It is the basis from which regulation are derived.

I think you need to focus upon whether or not you believe the patient should be captured by the Medical Policy Statement along the lines that Dr. Siegel was talking about.

You also need to talk about the idea of regulations. If you assume, for the sake of discussion, the patient continues to be considered by the Commission to be within their preference for protecting, then what is the level of regulatory presence that should be in place for the patient as it relates to risk within the regulation.

I do think you have to do both.

The only point that I would like to make in relation to this time frame was reacting to specific line items in the SRM.

CHAIRMAN STITT: Yes, it sounds like we are going to have time. And Jeffrey, that would be a good place to start our committee discussions as we hear the first and second reports.

A question to Larry back on the DSI 7. If the Commissioners are interested in option one which was including one or more higher risk activities, does that require Congressional involvement?

MR. CAMPER: Ultimately, the Commission would need to seek change in its authority.

CHAIRMAN STITT: Other comments.

MR. GODWIN: Just one point on Dr. Siegel's comment there.

I believe that a lot of that opinion came from the OGC relative to how the Commission should be involved in the medical practice thing. So we have an uphill battle with those guys.

DR. SIEGEL: I actually am aware of that.

CHAIRMAN STITT: Probably personally aware of that.

It is time to break for lunch. We will be back int he allotted time in the agenda and work hard this afternoon.

(Whereupon, the proceedings recessed at 11:57 a.m.).

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

(1:01 p.m.)

CHAIRMAN STITT: The next agenda item is Cathy Haney, is that correct, to discuss the Medical Policy Statement of 1979.

MS. HANEY: Good afternoon. I have just a very brief presentation or formal presentation. You have a copy of my slides I think that was handed out in the folder that you had in front of you this morning. What I want to do is just go through the three key statements in the Medical Policy Statement, and then to reiterate the recommendation that came out of the last ACMUI meeting, and then the pose some questions, and then we'll open it up to a general discussion on where we go from the policy statement.

We kind of started this presentation before lunch, so we're stepping back a little bit, but we'll just take a couple of minutes and do that.

The first statement out of the Medical Policy Statement is that NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public. The second statement is that NRC will regulate the radiation safety of patients, where justified by the risk to patients and where voluntary standards or compliance with these standards are inadequate.

I'll put this slide back up in a second, because I think the second statement is where we have most of our concerns.

The third statement is that NRC will minimize intrusion into the medical judgment affecting patients and into other areas traditionally considered to be part of the practice of medicine.

Those are the three items of the statement that we'd like to have ACMUI focus on today. And to that end, I have a copy of the recommendation from the

last meeting of the ACMUI. Now, there were two recommendations that were made regarding the policy statement.

The first one was that the ACMUI recommended that NRC revise its Medical Policy Statement to include in statement 2 the word "high" before risk. The six individuals were in favor of this, and three voted against this one.

There was further discussion, and following that further discussion the final recommendation is what you see on the screen right now, is that the ACMUI believes the 1979 Medical Policy Statement should be reconsidered, which is really what we're here doing today.

The scientific base of this statement needs to be reviewed with consideration of current research and studies, and the ACMUI is committed to working with staff and commissioners to provide guidelines for determination of procedures and activities that range from low risk to high risk to patients. Therefore, the ACMUI recommends that the 1979 Medical Policy Statement be revised.

So I'd like to spend some time today in working with the group on how that statement should be revised, and these were some questions that we came up with in determining what I would say today. I'm going to run through all of them quickly, and then just open them up. And if we answer each one individually, that's fine. If we deviate from these questions a little bit, that's fine also.

First, is the current structure of the statement appropriate? In view of the DSI 7 and 12, should a new policy statement be developed? And if the answer is yes, which I think the answer is yes, what changes should be made? And then, if we have time, if we can work with developing the suggested policy statement and the basis for that policy statement.

And I think at this point I'll just open it up for some comments.

CHAIRMAN STITT: This has been a hot topic over the lunch hour, and long before that. Everybody has got opinions.

Jeffrey, why don't you start?

MEMBER WILLIAMSON: Well, I agree with Barry's earlier suggestion that we simply recommend dropping the second point of the Medical Policy Statement.

DR. SIEGEL: And the third.

MS. HANEY: And the third.

MEMBER WILLIAMSON: And we could discuss the third, too, but certainly the second, possibly the third.

DR. SIEGEL: If you drop the second, the third is irrelevant.

MS. HANEY: Right.

MEMBER WILLIAMSON: Okay. Then the third, too.

CHAIRMAN STITT: Let's keep going with some discussion on that one.

MEMBER WILLIAMSON: That would make a, you know, clean sort of statement of consensus that we think that the primary mission of regulation in the medical arena should be safety of personnel and the public, and that from protection of patient quality of treatment and patient safety as well would be safeguarded by other mechanisms available to radiation mechanisms.

MEMBER NELP: I agree with that. But if you read the second point, it says, "Will regulate the radiation safety of patients, where justified." If you didn't change the policy, the committee could think that it was not necessary or justified. Even if you left it the same, you could get around it. So I could see how you could get into a tremendous extended process here of really revising this as well as the others. So that could be considered as a possible out anyway.

DR. SIEGEL: May I?

CHAIRMAN STITT: Yes.

DR. SIEGEL: I mean, as we've discussed many times before, it has to be presented to the Commission. The key issue in "we are justified by the risk to patients" is what your reference framework is. And if your reference framework is sort of this Atomic Energy Act tunnel vision, then all you can see is that, yes, there was a patient once, and maybe several patients sometime, who were hurt because of the application of byproduct material.

But if your reference framework is all of medicine, then your concept of justification changes substantially in terms of whether or not there's a need for this regulatory framework. And that I think is really the key issue and why I suggested earlier in the day that it is worth taking a fresh look at whether the NRC really believes that Congress compelled it to do this by the language in the Atomic Energy Act. I personally don't, obviously.

CHAIRMAN STITT: Another issue regarding 2 -- and this was developed in '79, correct?

MS. HANEY: Correct.

CHAIRMAN STITT: The second part of that, the second clause, "where voluntary standards or compliance with standards are inadequate," I mean, there are tremendous things that have happened in the practice of medicine. JCHO was referred to earlier today. The medical industry and its various subdivisions have extensive standards on patient management. They get very, very explicit. Some of us have been involved in developing those. We all work under them.

I think that at least in this day and age, '97, there are many standards, some of which are not particularly voluntary, if you wish to keep your hospital open,

keep your license, and see patients. I personally support the Medical Policy Statement should be composed of the first bullet only.

Lou Wagner?

MEMBER WAGNER: I'm going to go and support that issue. But I think that if the ACMUI has a consensus on this, that it is incumbent on us to offer a reason, and I think that I would take it further and say that the rationale for this is that -- I don't know how many years we have of experience, but regulation, radiation safety of patients is not justified by the risk as has been shown by the fact that even though there have been a few instances that can be pointed to, they are extremely rare.

And this morning it was pointed out that risk should be the product of probability versus severity. And with the probability of these things occurring being extremely low, there simply isn't any justification even if the once-in-a-while incident, the rare incident that does occur, has a high risk.

So on that basis, as long as individuals have the proper training to handle radiopharmaceuticals I think that it is quite clear that the risk is low. And on that basis, the last two bullets should be dropped from the Medical Policy Statement of 1979.

MR. CAMPER: I have a question for you. In your discussions, listening to your explanation, what I was intrigued by was the argument in my mind that what I really hear you saying is is that the policy statement number 2 itself is not flawed.

Rather, the agency hasn't actually done what it said it would do in its 1979 Medical Policy Statement, item number 2, because where risk is justified to the patient, you're saying, certainly for a large component of what is done in medicine that

the risk is minimal, if any, and there are, in fact, voluntary standards of compliance which are adequate.

So that, to me, sounds like an argument that we haven't actually implemented or carried out the Medical Policy Statement as developed and intended.

MEMBER WAGNER: I'd say you abused it.

(Laughter.)

MEMBER WILLIAMSON: Let me say something to that.

CHAIRMAN STITT: Yes. Go ahead.

MEMBER WILLIAMSON: Yes. I think there is a very tricky issue here with the word "justified" and also with the word "risk." And I think that perhaps behind a lot of our comments is the idea that, you know, there certainly isn't zero risk with these procedures. Many serious, for example, cancer therapies, including surgery, carry, very definitely, a known risk to the patient, even if they are carried out perfectly.

I think that, you know, behind a lot of the comments is the idea that the risk due to misadventure is not substantially different from that of other medical subspecialties practicing procedures of similar intensity and complexity. But this Medical Policy Statement allows you to impose upon this small discipline of radiation medicine an artificially low acceptance probability for misadventures, which is only with great difficulty.

And a lot of added expense can be achieved, and that's, you know, why I would support deleting the second two bullets, because it leaves it totally in your hands to sort of arbitrarily decide what is justified and what is risk. And it gives you, you know, sort of a basis for imposing I think an excessively rigid criteria of basically zero occurrence of error.

CHAIRMAN STITT: Let's go ahead and start with our guests from the states.

MR. GODWIN: Just to raise an issue you all need to address, how then would you assure that the physicians who are giving these rather large doses in the therapy range and all would be adequately trained? Because this seems to address that issue, too. And that seems to be of some concern to some people, that, in fact, you do have well-trained physicians and technologists involved in this operation.

DR. SIEGEL: The training construct could be in reference to the risks posed to members of the general public and occupational workers.

MR. GODWIN: If you drop this out.

DR. SIEGEL: No, no, no. You're not dropping policy statement number 1, if you're dropping number 2. You could still require training equivalent to radiation oncology training to do high dose rate brachytherapy because it poses a substantial risk to members of the general public and to workers if you're cavalier and you leave 10 curie sources lying around. You still have the opportunity for licensure and training without having any of the rules that deal directly with application of the radiation to the patient.

CHAIRMAN STITT: And I think that if we are looking at the modular approach, which has been brought up both in the past history of this committee as well as today's discussion, training requirements would be part of a, for example, high dose rate module and that relates directly to point number 1, safety of workers and general public. So I don't see that that doesn't appear at all.

MR. GODWIN: But it might not be if he was using a high dose rate and gave 20,000 rads as opposed to 5,000 rads.

DR. SIEGEL: What was the --

CHAIRMAN STITT: I don't understand the point.

MR. GODWIN: Due to his lack of training, if he was giving 20,000 rads as opposed to what normally would be a medical practice of 5,000. I realize he has the option always of going back in malpractice, but that is another issue.

DR. SIEGEL: Well, but that's the real issue, though, is where does it say that this is so different that this has to be dealt with differently. I mean, if you cut off the right leg instead of the left leg, there is a way for dealing with that problem. The contract between the physician and the patient says you are supposed to do the right thing.

If you do the wrong thing, you deal with that through various grievance procedures. Where does it say that this particular component of the practice of medicine needs this additional regulatory authority inserted in the process? It is an anomaly of the Atomic Energy Act.

CHAIRMAN STITT: Dan Flynn?

MEMBER FLYNN: I agree with Barry, and he has convinced me. But I disagree with Judith, because in terms of voluntary standards for JCHO, for example, in radiation oncology, looking at all of the different accrediting bodies, you have the American College of Radiology, which has the oldest program, and the American College of Radiation Oncology. They both do technical reviews. Then you have the JCHO and also the American Association of Ambulatory Health Care Facilities. They do non-technical reviews.

As a matter of fact, when the site visitor comes from JCHO, it is not a radiation oncologist, not a radiation physicist. And I say this because a facility that I looked at for the ACR a while ago had just gotten JCHO full accreditation, and within a month we were site visiting them and there were serious problems. And so the JCHO

does not do a technical review. They would not be able to uncover or even look at something that's so technical as is the dosage correct, are the treatment fields in the right place, and those kind of issues.

The reason why I agree with Barry is for a different reason, because items 2 and 3 are covered by your state license, which can be revoked by the state, and the patient is protected by the various malpractice laws. That is why I think 2 and 3 should be removed, not because I have full confidence that someone like the JCHO is going to uncover a technical problem when they do not uncover technical problems.

CHAIRMAN STITT: Larry?

MR. CAMPER: A thought. If in the final analysis you decide to recommend that items 2 and 3 be removed, then I think it is incumbent upon you, obviously, to try to clearly articulate your justification for removing that.

If you go back in history, for example, to 1979 when the Medical Policy Statement came to be, it came about primarily as a result of a number of events that occurred in the 1970s -- 1975, '76 -- in particular, Riverside Hospital, for example.

The Commission, at that time, obviously felt it important to articulate its policy about protecting patients. So what I think you're going to need to do, if you decide to suggest to remove those two items, then you need to state a clear articulation as to what other protection is there for the patient.

You've made your point about that, you know, radiation medicine, in terms that will be unique, because what ultimately the Commission would have to do if it were to seriously consider your recommendation, it would have to ask itself, how do we justify the removal of the patient protection component of our Medical Policy Statement that has been in place since 1979, and came to be as a result, at least to a large degree, of some serious events involving patient fatalities in the mid '70s.

DR. SIEGEL: Right. And if I may, Judith?

CHAIRMAN STITT: Absolutely.

DR. SIEGEL: My answer would be I thought about bringing my yo yo with me, but I didn't. But I wish I had, because Riverside was terrible. But in a way, Riverside was government by yo yo, reaction to the last bad event, because that's the way the political process unfortunately works, and because the lawyers convinced the Commission that the Atomic Energy Act says that they could do it.

Are you aware that Congress, any time in the last two weeks, has introduced a bill to create the potassium chloride regulatory agency? A patient died two weeks ago because it was injected with potassium chloride by mistake, but we don't -- there is no regulatory agency about to be created for that drug.

We have a problem with duck and cover. The Atomic Energy Commission was created, and hidden in it are a couple of words in that Act that have created this monster. And I'm suggesting that it is legitimate to consider retrenching from the monster to bring the medical regulation of radiation in line with the regulation of the rest of medicine.

There are legitimate worker and general public protection issues, and there are some patient protection opportunities, even if you retrench from a lot of Part 35, because radiation sources get shipped in interstate commerce, and there is lots of consumer protection things you all can do that regulate the quality of what gets out there, much the way the FDA does, that will allow you to still exert a lot of control without being in the patient/physician interface.

CHAIRMAN STITT: If we have to document evidence to remove these portions of the Medical Policy Statement, it is going to be a little lame to say we do things pretty well most of the time. I mean, that is not as dramatic as the bad series

of events at Riverside, so I think we come up short on the evidence balance of the scale.

Let me ask Judith to speak, and then Jeffrey.

MEMBER BROWN: Well, in response to Dr. Siegel, I guess since he is making his position -- reiterating his position to the committee, I ought to reiterate mine, because I haven't done that in a while. So when Barry says, "Well, Judy wouldn't agree with me," I'd like you all to know why.

Barry says that bringing nuclear medicine in line with the rest of medicine would be a good thing, and I just fundamentally think that would not be an improvement. I like nuclear medicine's attention to detail and accountability that I see lacking in the rest of medicine.

When you say, Barry, that it is reacting to the last bad event, I think of a situation just a little while ago where I was reading the paper and saw that a neurosurgeon in Wilmington, North Carolina, had gotten his license suspended because he left the brain of his patient exposed for 25 minutes while he went to get lunch.

This is important only because I happened to read the paper that day, and because I just was privy to that information. I like the fact that NRC has information on those kinds of events. I don't know any place that I could find out that information except to go to North Carolina and say, "By the way, has anyone left their brain exposed in your state recently?"

There is no overarching authority. There is no clearinghouse. There is no scientific -- well, that's the wrong choice of words. There is no body of knowledge like there is at NRC, and you can argue that it was -- you can argue that it's not in line with the rest of medicine, but I would just reiterate that I kind of like it that way.

CHAIRMAN STITT: You know, it's good to have the two of you back.

(Laughter.)

It's interesting that you're on opposite sides of the table.

Go ahead, Barry.

DR. SIEGEL: But then, as I've said before, rather than telling the NRC that, you should be on the Hill right now trying to get Congress to pass some new legislation so that DHHS has that level of authority over all of medicine, rather than just saying, "Hey, we've got this opportunity. We've got the foot in the door. Let's go for it. Let's beat those nuclear boys up."

MEMBER BROWN: In my other life, I did that.

DR. SIEGEL: And it didn't work, did it?

MEMBER BROWN: No. I just had a baby and kind of dropped out of my other life.

Jeffrey, I think you were getting some place.

CHAIRMAN STITT: You had comments, Jeff?

MEMBER WILLIAMSON: Yes. Going back to sort of the issue of rationale, let me -- I'm not going to speak directly to what Judith said, but I think there still, you know, are some issues you can cite to support the parity with other medical subspecialties. And I know this is not addressing your concern, nor is it my intent.

One is in the QMP review that we see appended to our briefing book there is the comment that after four years of the quality management program, which is NRC's best effort to use this Medical Policy Statement to try and improve the quality of patient care, there is not a statistically significant difference in the incidence of misadministration. They have included denominators in there, and you can look and

see that the ratios range from 10^{-4} to 10^{-3}, if you normalize the number of reported misadministrations for a procedure. So I think there is some evidence there.

Finally, I think 90 percent of radiation medicine is not regulated directly by the NRC. Some of it is regulated to one extent or another by agreement states, but a lot of it is not. It is not particularly regulated with any great scrutiny by the State of Missouri, for example. But I think that the resources and level of quality certainly, you know, in my professional experience, is at least up to the standards of radiation medicine using byproduct material. And it has happened that way without, you know, this regulatory -- this federal regulatory apparatus.

So, you know, I think that, yes, there are bad things that happen. There are a subset of institutions that are practicing radiation medicine, and probably other kinds of medicine, at a very substandard level. But by and large, I think there is no evidence to suggest that the 90 percent of radiation medicine based on non-byproduct material is any worse off or produces care of any lower quality than the regulated portion.

But I think it -- one more thing. It puts byproduct radiation medicine very much at a competitive disadvantage, I think, to compete against these other sources. So I think in the end, maybe it hurts patients that pulse dose rate got trashed.

CHAIRMAN STITT: Yes. That's an interesting point. And then, certainly, when you're making decisions about what equipment to buy, institutions make a decision to buy something that is not regulated, if you can use the same -- achieve the same clinical result.

Dennis?

MEMBER SWANSON: A concern and a different -- I guess a different viewpoint. I'm concerned that the NRC is not going to back away from their

Medical Policy Statement. You know, we've asked them to step away from the Medical Policy Statement before, and this Commission has not agreed to do that. What makes us think that they will do that now?

What I think I'm hearing from Larry is perhaps rather than worrying so much about this Medical Policy Statement and whether it's in or out, is to make sure that the actual regulations reflect that this Medical Policy Statement is truly applied as written.

CHAIRMAN STITT: Can you expand on that?

MEMBER SWANSON: Let me give you an example. You might have for diagnostic nuclear medicine training and experience requirements that only reflect Part 20. You might have for teletherapy training and experience requirements that reflect appropriate training in the delivery of teletherapy. I mean, certification in teletherapy. There you have made a decision, you have included in your regulations a consideration for the radiation safety of patients, where justified by the risk to the patient.

So all I'm saying is, you know, rather than trying to argue the Medical Policy Statement, which I'm not certain we're going to win, it may actually distract from arguments and put more emphasis on the actual regulations and the fact that the regulations reflect this Medical Policy Statement.

MR. GODWIN: Madam Chairman, I think that's a very good point. I don't know whether you all can win or lose the argument on 2 and 3, but I think it is important that if it stays in that the NRC staff and the commissioners are advised that there have been changes. There are some doses that are so small we really shouldn't have to worry about, you know, a lot of things in the way of patient injury.

And we could -- I suggest putting out a general license where any physician can do the prescribing and everything. It would only have to be taken at a nuclear medicine facility. The nuclear medicine facility is authorized to distribute it under a GL or, in some cases, maybe a pharmacy if the doses don't range above so much. And that way your physicians can do their referrals, or however they want to do it, with a lot less of this intrusion into their practice.

Number 2, for those areas where there is legitimate need for assuring training, then you could require a consultant type relationship to be established and require the physician to do the prescribing. I think that this would support sort of the concept you're looking at, and it would address this issue here.

Now, taking it out or leaving it in, you know, the main thing I think we're all interested in is making sure there's a safe practice overall, and that's what we're looking at. And I think that either way can go and accomplish that.

CHAIRMAN STITT: Other comments? This group has nothing else to say? It's post-cranial somnolence or something.

MEMBER NELP: Is it appropriate to make a motion at this time?

CHAIRMAN STITT: Oh, I think we -- I don't know. We spent all of our last meeting arguing over a motion that probably didn't get us anywhere.

I can't turn down a motion. I think that we're discussing so that we, as a committee, can get some sense of where we want to be going as we put something together for the March 8th meeting. Is there some further discussion you'd like to --

MEMBER NELP: No. I think this has been pretty fully discussed. I was just curious how you felt about a motion. I think I know how the committee would probably vote, but I'm not sure. I guess we could take a straw vote.

CHAIRMAN STITT: I think there are probably a lot of other things to continue discussing. Does anybody want to make a -- do you feel a motion is appropriate at this time? It's a discussion point. What did you say?

MEMBER WILLIAMSON: Well, I think we should have at least a vote in the minutes on this very important issue, whether or not it's in the -- do you want -- are you calling, Madam Chairman, for a formal motion?

CHAIRMAN STITT: I think I'm sitting on the fence. I think this is -- we can make a black and white statement, and then we're going to be back where we were in this discussion, and we have to come up with something in print.

As you recall Larry saying, at each of our meetings we need to work to a consensus, and the dissenting votes need to be recognized for the dissention that's there. That's where I want to be by May 8th, to the best of our ability, is this afternoon where we're ready to go.

Let's put a motion out there to see where the sense of the committee is, and that will help us over the next month. I mean, we'll have a vote on a motion and see where we end up.

Wil, you had one in mind.

MEMBER NELP: Well, I think I will make the motion that we advise the Commission regarding the Title X on rules and regulations that the statement of general policy, at paragraph numbered number 2 and paragraph numbered number 3, by omitted from the general policy statement.

CHAIRMAN STITT: Is there a second?

MEMBER WILLIAMSON: Second.

CHAIRMAN STITT: Okay. Discussion?

MEMBER WAGNER: I'm very confused. You're talking about -- which two paragraphs are you talking about here?

MEMBER NELP: The general policy statement comes under items 1, 2, and 3. And on page -- well, it's 82-42 where it's copied here. It's just like was up on the slide.

MEMBER WAGNER: Okay. I see it. I see it. Okay.

MEMBER NELP: 1, 2, and 3. And my motion was to take the last two bullets out.

MEMBER WAGNER: Oh, okay.

MR. CAMPER: He's referring to items 2 and 3 of the 1979 Medical Policy Statement.

MEMBER WAGNER: Yes. I thought you said general policy statement and I was confused.

MEMBER NELP: I think that's the discussion that has been held.

CHAIRMAN STITT: Okay. Everybody now with it?

All right. Discussion? We've got plenty of time, so -- go ahead -- use it to our advantage.

MEMBER SWANSON: Again, let me express my concern. The NRC answers to the public, and it is going to be difficult for the NRC to take out any statement that makes it appear that they are giving up regulatory authority over a risk issue. Okay?

And I think that fundamentally, I mean, if you listen to Judy's comments, she has clearly stated that. This is a public opinion. She represents the public. Okay?

The NRC is answerable to the public. I think us coming to them with this kind of statement, they're going to come right back to us and say, "We're not going to do that." I don't think they can do that. Okay? I don't think the public is going to allow them to do that.

CHAIRMAN STITT: Comment?

MEMBER NELP: I'd like to comment to Judy's remark, in the sense, Judy, that the practice of medicine is very highly available and the mistakes are very readily available to those who are interested. And if you wanted to see how many people lost their licenses because of malpractice in any state in the country, I'm sure you could even access it on the Internet immediately.

So your idea that just because you casually read the paper was information to you, but that information is widely available.

CHAIRMAN STITT: Andrew, do you have a comment?

MEMBER KANG: I'd just generally agree with Dr. Barry Siegel's position that NRC should not interfere too much into medical practice. However, I am really concerned that if you drop out the second option and the second bullet and the third bullet, I mean, the third bullet may be omitted. But the second bullet, although I agree that the second bullet should be revised because the sentence suggests very strong regulation, you can change it. But I am really concerned about the patient's radiation safety. Somewhere the NRC should be concerned about some safety to the patient.

DR. SIEGEL: I'm a physician.

MEMBER KANG: I am a physician, yes.

DR. SIEGEL: I know. And I'm concerned about patient radiation safety.

MEMBER KANG: I understand. Of course.

DR. SIEGEL: Why does the federal government have to be concerned, too? I'm concerned. The state licenses need to take care of my patients with the expectation that I will be concerned about my patients. The state has the authority to take my license away. The courts have the authority to take my assets away. Why does the federal government have to be concerned about my patients?

MEMBER KANG: I think we are --

DR. SIEGEL: I am already concerned about my patients. A lot.

MEMBER KANG: I agree with you.

DR. SIEGEL: Probably more than the federal government is.

MEMBER KANG: The point -- what I am trying to say is that NRC has a particular duty to ensure some reasonable assurance for the radiation safety for the public, as well as any citizen in this state. That means, including the patient -- we are talking about radiation safety, not general medical practice -- that, of course, NRC should not look into the medical practice-wise, but radiation safety-wise.

That's why I think we are heading in the right direction to revise the risk-based -- the modality. I think that is the right direction -- that high risk and low risk division is the proper way to assess the radiation safety risk-wise.

But totally dropping out the radiation safety for the patient is, to me, a little bit going too far to me.

DR. SIEGEL: Okay.

CHAIRMAN STITT: I have a comment, and then I'll call on you, Jeffrey.

I think that probably point number 2 is where the clinicians have the greatest head-butting with the NRC, because there is a lot of leeway, latitude, in point

number 2 as to what's regulated, what's not, tight numbers that have been designated about what you can do or can't do about a dose that happens to be with a radioactive source versus an external unit.

And I think that's where a lot of our practical bind comes out. I agree with you that to say we're going to drop out this item that says the regulation of patient safety. The converse would be presumed that the NRC is not interested about the safety of patients. I can just see that that is how that would be viewed.

But I think that where we find ourselves competing is how number 2, the second bullet, is interpreted.

Jeffrey?

MEMBER WILLIAMSON: Well, two comments. I guess the first comment is even with bullets 2 and 3 deleted, the patient still has all of the protections accorded a member of the general public. So, for example, I presume that would cover inadvertent delivery of a radiation treatment prescribed for some different patient, or patient, you know, who is in the hospital room and irradiated by the brachytherapy patient next door. The patient would receive safety.

But the sort of efficacy and quality of treatment delivery, how do you distinguish that from the safety of the treatment? This is the sort of slippery slope. Once you decide that this falls within the regulatory scope of this agency, it's a very difficult distinction to make. And NRC has decided to look at a very limited kind of tiny segment or bit of the treatment delivery or diagnostic process.

So, for example, to address Aubrey's example, I think if a physician prescribed 20,000 centigray when 5,000 was the standard of practice, and correctly filled out the written directive, I don't think there's a thing NRC could do.

So, you know, one could question whether this sort of excessive focus on this tiny part of the treatment delivery process, aspect of radiation medicine, how much good does it do relative to the sort of trouble it causes in resources it consumes. In the long run, we still rely on the quality of the training and experience of the professionals involved, really, to protect patient safety. And I would argue that's the force all along.

CHAIRMAN STITT: Dennis, you're looking at me. Does that mean you want to say something?

MEMBER SWANSON: Yes. Let me reemphasize, though, that the NRC is asking us to rewrite the regulations from scratch. Okay? We have the opportunity to take out all of those nit-picky things and rewriting the regulations. I mean, you can rewrite the regulations and still have this medical policy in here and get what you want. We have the opportunity to do that, okay? At least that's what I've heard.

CHAIRMAN STITT: You have to be recognized before you speak.

MEMBER NELP: Could I be recognized?

CHAIRMAN STITT: Well, I'm looking this way, so I'm going to let him have it this time.

DR. SIEGEL: The answer is this year, this Commission, yo yo. You change Part 35, the medical policies there, and the next bad event occurs and Part 35 gets ratcheted again. By the way, the more I listen to the discussion the less I am probably going to stick to my guns on dropping items 2 and 3.

But I think the problem is is that we keep riding up and down the waves here, and we keep ratcheting. Dropping items 2 and 3 and getting the NRC to admit that the Atomic Energy Act does not compel them to enter the patient/physician interface is one way to avoid the ratcheting in the future, because Part 35 can be

rewritten, and 10 years from now, or five years from now, it can be rewritten again, or it can get amended every year when the NRC reacts to congressional pressure to another bad event.

The trick is: does it need to be there? Does it need to be there at all? Does this patient part need to be there at all?

CHAIRMAN STITT: Comments down here? Go ahead, Wil, and then Aubrey.

MEMBER NELP: I'd like to get Dennis' attention, because this is directed to him. Dennis, I concur with your feeling and your thinking that, you know, we could take this to the Commission and they'd say, "So what? We don't want to change it." And we're left having to work through it and around it.

On the other hand, if we don't take it to them and say, "We really want a cleaner set of rules, and we'd like to eliminate this," if they do it, then we're much further ahead, you see. And if we don't try, it ain't going to happen. If we do try and we fail, we're no worse off than we were. We can go into your posture, and we probably all would adopt that as you suggested. But if we don't try, we'll never make a step forward.

CHAIRMAN STITT: Dan Flynn?

MEMBER FLYNN: I think if we vote on the motion about dropping numbers 2 and 3, which I would agree with, I still think we should address each of these modalities in terms of what's a high risk for the worker and the general public, and high risk for the worker, general public, and patient -- in other words, classify high risk for both scenarios.

That is, if sections 2 and 3 were maintained or sections 2 and 3 were dropped -- and see where we come out in terms of what is high risk or what is not high risk, whether or not the patient is included or not.

CHAIRMAN STITT: And you think that's not -- is that still compatible with the discussion that -- can you say that and still be supportive of dropping 2 and 3?

MEMBER FLYNN: No. I'm dropping 2 and 3 for the reason that Barry has brought up, but I still think we can -- no matter how we vote on this motion, I think we can define high risk with and without the patient in the loop, so to speak. If it's the worker and the general public versus the worker, the general public, and the patient, what is high risk and what is not high risk.

MEMBER NELP: The patient is intimately involved when it's -- the worker and the training really protect the patient. That's the whole issue, the way I see it, and that's totally available to us.

CHAIRMAN STITT: Aubrey?

MR. GODWIN: Just a minor little point. But, Dr. Williamson, Part 20 specifically excludes medical administration as far as being considered in the part of the public dose.

MEMBER WILLIAMSON: Right. Yes.

MR. GODWIN: So they would not be included anyway in that, as it is currently phrased.

CHAIRMAN STITT: Lou?

MEMBER WAGNER: I think for a different reason that the ACMUI should take a vote on this, because I think it's important that it be put on record whether or not the ACMUI reaches a consensus on the issue as to whether 2 and 3 should be dropped, whether or not the NRC decides to do it or not.

I think we should take our position, we should say what it is, and pass that along. If they don't do that, we will continue to operate along the lines that we are constrained by. But it's very important that we put this position forth to the Commission.

CHAIRMAN STITT: Jeffrey?

MEMBER WILLIAMSON: Yes. I would also suggest that, you know, taking this position and voting on it, I think we should still continue along the pathway laid out in front of us, which presumes that this position will not be accepted. We do both. We make our feelings known, but we, you know, proceed with sort of a contingency plan and march through the discussion of relative risks, even though parts of that may be incompatible with the position we hold. But I think just to be realistic and make full use of our influence, we should do both.

CHAIRMAN STITT: Other comments? Is there a member of the general public that would like to comment?

Barry, it looks like you're -- are you working on something for us?

DR. SIEGEL: You bet.

CHAIRMAN STITT: Okay. We'll leave you be for a minute.

Go ahead.

MR. ROTMAN: For the record, Mark Rotman. In listening to this discussion, something seems to me needs to be said. It's very clear that Part 20 addresses radiation safety for workers and for the general public. And Part 20, according to our state regulators, seems to specifically exclude radiation safety for the patient, yet the Medical Policy Statement and some of the actions of the NRC seem to contradict that Part 20 patient exemption.

Perhaps maybe the real issue needs to be a description and definitions of exactly how much radiation safety the NRC is going to provide for patients, and where it's going to allow physicians to provide radiation safety for patients.

DR. SIEGEL: The Part 20 is there because it's covered by Part 35. All that's saying is is that the patients are not covered by Part 20 because they are covered by something else.

MR. CAMPER: That's correct.

DR. SIEGEL: It's just establishing authority.

CHAIRMAN STITT: Are you ready yet, Barry?

DR. SIEGEL: Nope.

CHAIRMAN STITT: Okay. Quick. Somebody else needs to do some philosophizing while he is working up something for us.

Jeffrey?

MEMBER WILLIAMSON: I think I wasn't referring to the radiation patient, him or herself, but that there would still be a possible ground for some sort of regulation such as patient identification, because one has to be concerned about giving an inadvertent therapeutic dose to a patient who hasn't been prescribed such dose, because that patient clearly -- the non-radioactive patient who accidentally gets irradiated clearly would fall, I would assume, within the protections of Part 20.

MR. GODWIN: I would hate to run that in a legal case, because it is given by a doctor.

MEMBER WILLIAMSON: Well --

MR. GODWIN: And if their patient is in a hospital, it would be a little bit tricky.

MEMBER NELP: But that's covered in 35 now. We're going to revise 35, and we can keep those requirements in there for writing a prescription and ensuring that things are done properly.

CHAIRMAN GRIFFITH: Go ahead, Larry.

MR. CAMPER: You are. That's right. But bear in mind, if the Medical Policy Statement were to be changed as you are suggesting, and the Commission adopted it, then clearly Part 35 would look a lot different than it does today, because there would be nothing in there about patient protection at all.

MEMBER NELP: But we would still have training, and we would have requirements the trained person, whether a physician or whoever, has to meet before he does anything.

CHAIRMAN STITT: Aubrey?

MR. GODWIN: Since we're trying to kill a little time here, I can play devil's advocate a little bit longer.

Regarding training, without those statements there, I believe the only training the agency would be interested in would be radiation safety related training only. So essentially, any physician, regardless of their knowledge of nuclear medicine, would be qualified if they took a two-week training course to practice nuclear medicine. They could very easily end up in that, at the therapeutic level even.

MEMBER NELP: You're not taking away the license requirements. You still have license requirements.

MR. GODWIN: I agree. But the only thing you would be asking would not be related to anything of their clinical training experience at all. This would remove any question of that, as I see it. So the only thing left would be, what is his training

experience dealing with radioisotopes? In a couple of weeks of training, he could probably be prepared to deal with therapeutic levels.

CHAIRMAN STITT: No, your hospital privileges wouldn't allow that at all.

MEMBER NELP: I don't think that's our intent at all. Our intent is to maintain that.

MR. GODWIN: These may not be in hospital in all cases, although most of your therapy is, admittedly. But you do have your IPLAX and things of that nature.

CHAIRMAN STITT: It still sounds like hospital privileges to me. I mean, it's way beyond safety, before you would ever be accredited to use that by your local agencies.

Dennis?

MEMBER SWANSON: Let me ask a question, and I'll ask this of the nuclear medicine physicians. Do you feel that there should be more training and experience requirements for somebody doing strontium-89 therapy than for somebody doing diagnostic nuclear medicine?

MEMBER NELP: Well, you know, you got into this issue with the cardiologists who wanted to do imaging only. And it all, from the point of view of nuclear medicine training, you know, the real training, they all come together. That's part of the whole package.

For instance, I think the training requirements in here for I-131 therapy for cancer are extremely minimal. You need three experiences.

MEMBER SWANSON: So you would agree that there needs to be more training for people doing therapy than for diagnostic, in general?

MEMBER NELP: I think they have to be trained in therapy. They have to be trained in that specific area.

MEMBER SWANSON: Okay.

MEMBER NELP: Exactly.

MEMBER SWANSON: And if we were to put that at all in the regulations, how would we justify that if we took this section out? Because I would say that for strontium-89 --

MEMBER NELP: Well, we would look at high --

MEMBER SWANSON: Let me finish. For strontium-89, the risk to the general public and the worker are less, if not, you know, equal, than the risk of the technetium agent.

MEMBER NELP: Yes, I agree.

MEMBER SWANSON: Okay. So how are you going to address the increased --

MEMBER NELP: If I'm --

MEMBER SWANSON: -- training requirements for therapy?

MEMBER NELP: If you're giving me a license, if you're going to license me to use a therapeutic modality, then you must insist that I have the proper training, and I know how to administer the dose, and that I know the expected effect and of the toxicity, and that I have had that documented training.

MEMBER SWANSON: That's the point I'm trying to get at. If we put that in the regulations --

MEMBER NELP: We already have it in the regulations.

MEMBER SWANSON: Well, if were to put that in the new regulations, which is what I'm hearing you want, we would have no justification to do that if we took out statement number 2.

MEMBER NELP: No, that's incorrect. We've been asked to revise 35, and it's in 35 and we can keep it there. The Commission is asking us what would be our ideal world. Thoughtfully and intellectually, we're supposed to tell them. So we're not going to throw the baby out with the bath water.

We can keep those requirements in there for licensing and training just the way we are. What we're trying to do is get away from them trying to regulate my judgment or lack of judgment in a medical outcome.

MEMBER SWANSON: But the basis for the regulations need to come form the policy statement. What you're saying is that if our policy statement only says that they're going to regulate based upon radiation safety of the workers and the public, you've already agreed that strontium-89 and diagnostic agent -- let me finish -- have no difference from the standpoint of occupational and public safety. Okay?

MEMBER NELP: I am not. We have a whole series of requirements that you have to meet in order to be a licensed user. Those are all directed at safety for the whole process.

MEMBER SWANSON: But those requirements, as they appear in the current regulations, came because of statement number 2.

MEMBER NELP: No, no. No, they didn't. This came as an afterthought. They've had these requirements in there before this was written.

CHAIRMAN STITT: Let me summarize where we are. We have a motion that we're discussing.

MEMBER NELP: I think they can still be maintained. That's what I'm saying.

CHAIRMAN STITT: And several people want to make some comments, and then we need to be moving to a vote on the discussion. I'm going to take -- Graham, I thought you had your hand up.

MEMBER GRAHAM: I did. I put it down after --

CHAIRMAN STITT: Well, I was going to take you and --

MEMBER GRAHAM: I didn't want to have all of the blood flow out.

(Laughter.)

CHAIRMAN STITT: You're next, and then Jeffrey, and then Barry has a comment.

MR. CAMPER: I'm not Stonewall Jackson.

CHAIRMAN STITT: Are you ready?

MEMBER GRAHAM: I'm next?

CHAIRMAN STITT: Go ahead.

MEMBER GRAHAM: Thank you, Madam Chairman.

I've listened to Dr. Siegel during the early session and during lunch talk about, I think from a philosophical standpoint, the logic behind removing paragraph 2 and paragraph 3 from the general policy guide for regulation of medical use of radioisotopes. And I've listened to Judith in the past take a different philosophical approach to federal regulation and this need for a clearinghouse oversight that goes beyond what medicine may have done on its own, and what state regulation may have done, and what malpractice may not have accomplished.

If I were a commissioner -- and we had a very long debate last time about how to amend or whether to amend the Medical Policy Statement. If I were a

commissioner and this group sent up a recommendation that we just eliminate the two paragraphs that refer to patients, politically I'd have a real problem with that because, if I were in the press, I could interpret that fairly easily that somebody at the NRC doesn't care. And one of the commissioner's votes in the footnote clearly says, "I don't understand why you'd want to revise it to even insert the word 'high.'"

At the risk of belaboring an old discussion, a different approach which gets at the medical provider concerns, but still recognizes patient advocate concerns, would be that statement number 2 -- and I am not proposing an amendment to the motion at this point in time. This is purely discussion -- would be that the NRC will limit regulating the radiation safety of patients, where justified by the risk to patients.

It throws out this whole word of "high." It throws out all of the definitional discussion we had last time. But I think a frustration medical providers have is that this statement has been on the books, and we have regulations today that don't seem to make a lot of sense. That's a legitimate perspective that some people have.

So this policy statement, as it is written, didn't provide enough guidance to create rational, reasonable regulation, that would provide the protection that a patient advocate would be looking for. So at least if we recommend that they should limit their focus to those areas of radiation safety for patients, where there is clearly a risk, perhaps we've given them clarification of a policy statement that they can use in discussing with us revision of Part 35 so that we can test recommended changes in 35 to eliminate excessive, unusual regulation that doesn't provide any measurable benefit from retaining those regulations on training that clearly make sense for public safety.

CHAIRMAN STITT: I'm going to ask Barry to speak next, because I think you have some comments that relate to that.

DR. SIEGEL: Well, I have a substitute motion.

CHAIRMAN STITT: But you can't say that right now. Well, no, you can say that.

DR. SIEGEL: Sure I can.

CHAIRMAN STITT: But we do have a motion we have to vote on.

DR. SIEGEL: No. Actually, if a substitute motion is put on the floor, what you would do is vote first on the substitute motion, and then you vote on the original motion. I think that's the way parliamentary procedure calls for it.

MEMBER GRAHAM: But a point of order. As a guest, he is only discussing a possible substitute motion.

DR. SIEGEL: Right. Actually, that is probably correct. I mean, because I'm not sure I can make a motion.

CHAIRMAN STITT: You can't.

DR. SIEGEL: But I could put a motion on the table that if you all liked it, so --

CHAIRMAN STITT: Well, we want to hear what you have to say first.

DR. SIEGEL: Well, I would propose the following motion as a way of killing both birds with one stone here -- getting our viewpoint across while allowing us to continue to work in good faith on the revision of Part 35.

And the substitute motion would be: "Whereas, the ACMUI believes that the regulation of radiation safety of patients is not justified by the risk to patients or by inadequate compliance with voluntary standards. The ACMUI recommends that the NRC modify its Medical Policy Statement to delete the second and third components of the policy. If the NRC believes that the Atomic Energy Act compels it to continue to regulate radiation safety of patients, the ACMUI recommends that its assessment of the

risk justifying the regulations be made by reference to comparable risks and comparable modes of regulation for other components of medical practice."

MEMBER NELP: Bravo.

(Laughter.)

There's a word that you used in terms of voluntary. Would you read the sentence that says "voluntary."

DR. SIEGEL: "Whereas, the ACMUI believes that the regulation of radiation safety of patients is not justified by the risk to patients or by inadequate compliance with voluntary standards." I am simply --

MEMBER NELP: Inadequate compliance with required and voluntary standards. There really are some required standards.

DR. SIEGEL: No. But the current policy statement refers specifically to voluntary standards.

MEMBER NELP: Yes. But that was before there were -- as Judith pointed out, that was back in the dark ages before you had much in the way of requirement.

DR. SIEGEL: Well, I understand your point, although you could argue that an office practitioner is not subjected at the moment to JCHO requirements, which, by the way, even a hospital is not subjected to. JCHO is voluntary accreditation in lieu of being inspected directly by the Health Care Financing Administration.

MR. GODWIN: That varies a little bit from state to state.

MEMBER NELP: But isn't he required -- he cannot purchase any radioactive material for any purpose in medicine, unless he meets the requirement to purchase to be a user.

DR. SIEGEL: Yes. But the requirements are currently Part 35.

MEMBER NELP: Yes. That's fine.

DR. SIEGEL: That's the whole point. So we don't want to -- that's circular reasoning. The reason for Part 35 to have required standards, required regulations, is because voluntary standards of practice don't seem to be doing the job. That's what the second component of the Medical Policy Statement says. So I'm going after that part of the component by way of the wording here.

MEMBER NELP: I just wondered if you wanted to keep "voluntary" in there.

DR. SIEGEL: Oh, okay.

MEMBER NELP: It sounds like it's not the real world.

DR. SIEGEL: I'm not sure. I'm not sure whether "required" fits there.

CHAIRMAN STITT: Jeffrey, go ahead.

MEMBER WILLIAMSON: Could you read it again, please, in its entirety?

DR. SIEGEL: Sure. I suppose we should xerox it and pass it around.

CHAIRMAN STITT: Well, that was what Cathy asked me. Should we --

DR. SIEGEL: It's pretty hard to read. Want to try?

CHAIRMAN STITT: Well, it's going to be easier to read it than try to remember it.

DR. SIEGEL: Okay.

CHAIRMAN STITT: And we'll have some more discussion.

Dan?

MEMBER FLYNN: I'll make a brief point. I think for training and experience you could play word games and actually incorporate training and

experience. And, number 1, by saying that as opposed to the safety of an individual patient, as a physician when you license you're taking care of, in your career, many thousands of patients. Basically, you're taking care of many members of the general public.

In other words, the training standard is not because of a problem with one patient, a problem that you had with one patient because of some error that you committed that might be malpractice. As opposed to, if you are taking care of thousands of patients, you should have the appropriate level of training to take care of members of the general public.

DR. SIEGEL: I don't get it.

MEMBER SWANSON: Part 20 says that patients aren't members of the general public.

MEMBER FLYNN: Yes. But we're not going to use the word "patients" any more if we did this. We would drop it altogether and say that we have to have the appropriate level of training to administer radiation while caring for members of the general public, not individual patients, just the training to take care of all of our patients. But not interfere with one so-called misadministration between the physician and a specific patient on a specific incident, as opposed to having the training, the basis, the framework, by which to take care of members of the general public.

CHAIRMAN STITT: Go ahead, Lou.

MEMBER WAGNER: I think that's a very good point, and I think that the justification is quite clear that in regard to practicing with these radionuclides, there is a very good rationale to say that if you're going to be practicing for a long time using radionuclides, you should be trained for the specific use of those because your misuse

of those could affect other members of the general public, not necessarily even that patient, but the other members of the general public.

But you should be well trained in that according to the standards of the profession, and that makes a heck of a lot of sense, just to have people out there who are trained to use the thing in terms of the standards of the practice. And it doesn't have to get into a lot of prescriptive regulation.

That's a very nice way, I think, of putting that forth. And I believe it does get rid of parts 2 and 3, which we have recognized now, since this whole process began, as being the focus of the head-butting. And it has given -- and we have seen how you can write some words on a page. But once you get those words down on a page, we have seen how you can use those words to do things that now we -- many of us recognize are not in line with the original words as they're written, because they are open to a wide range of interpretation.

CHAIRMAN STITT: Go ahead, John.

MEMBER NELP: I would just want to add, though, if --

CHAIRMAN STITT: He's got the floor.

MEMBER NELP: Oh, I'm sorry.

MEMBER GRAHAM: Well, I guess my concern is that I'm hearing the Advisory Committee talk through ways that they could propose standards for training, because it would cover the general public. I just think we're getting caught up on a semantics word game here that -- fine, okay, as a commissioner, fine, we're going to eliminate 2 and 3.

But you, the Advisory Committee, have clarified to me that if I leave in number 1, which they'll continue to regulate the medical use of radioisotopes as necessary to provide for the radiation safety of workers and the general public, and

therefore we're going to give you some training criteria, I'll continue to regulate things that happen to patients because they're part of the general public.

I don't know how you can -- well, if you're going to eliminate any reference to this physician/patient relationship by eliminating any reference to the patient, then you either have no regulatory input beyond the general safety for the general public, or where do I draw that line as a commissioner on when the patient has become part of the general public versus being this sacrosanct relationship that you're saying is off the table. I don't know that you can have it both ways.

DR. SIEGEL: I'm not saying that.

MEMBER NELP: I'm not saying that.

MEMBER GRAHAM: Well, I'm hearing people say that there would still be very rigid training requirements that would be promulgated.

MEMBER NELP: Of course.

MEMBER GRAHAM: Well, I'm hearing that it might be related to this organization, and I don't know how you're explaining the need for training regulations on physicians if we're eliminating any reference to the patients.

MEMBER NELP: This amendment isn't going up there naked. I mean, we're going to I guess explain to them why we would prefer to have this position. And I reiterate, in 35, the licensing requirements aren't going to disappear for any kind of user. And if you're going to give me therapeutic materials, you're going to have to be sure that I am a licensee who is qualified to use those by training and experience.

MEMBER GRAHAM: Only within the broad general policy that is --

MEMBER NELP: No. Anything we want to say. We're revising it to make sense for protection of me and the fact that I do the right thing when I do come in contact with a patient.

MEMBER GRAHAM: We're not throwing it all away.

CHAIRMAN STITT: Larry, did you want to make a comment, or are you still thinking?

MR. CAMPER: No. Go ahead. Go to Aubrey. I want to come back and say something.

CHAIRMAN STITT: Okay. Aubrey?

MR. GODWIN: I'm afraid that if this was the guiding principle that was adopted, the only basis I could judge any person using any amount of material, regardless of purpose, would be the general requirements in the NRC equivalent to 30 and 31, 32, somewhere along in there.

If you start coming in with other criteria that relate specifically to patient relationship, with the modified statements you're adopting, I think that many states would have a difficult time doing that through their radiation regulatory programs, because basically what you've done is cleaned all of 35 out.

There is no 35 there whenever you do that, and you start over again. And when you start putting these in, you have to relate it to specific radiation safety requirements, because that's what number 1 says. There will be some states that can pick it up, so you have a very mixed bag from a state point of view.

MR. CAMPER: The thing that I was going to say about -- what is very unique about the patient is -- and clearly, the patient was called out as a distinct and unique member of the general public in the 1969 Medical Policy Statement. The thing that is very interesting about the physician training and experience is that we avoid competency of physicians in terms of their capacity or ability to practice medicine.

But if you look at the training and experience that's required minimally, it involves clinical experience. It involves experience of types and quantities of materials. And, of course, it involves the basic sciences that apply.

But one of the fundamental tenants of the physician training and experience requirements is that they are going to be involved in administering materials to patients, and they're going to supervise individuals who administer radioactive materials to patients.

And what I'm saying is that if you were to remove from the policy statement, and, in turn, the regulations, the protection of the patient, I think you would in turn, then, be required to throttle back dramatically the level of training and experience that you would expect for a physician authorized user, because you would not have the patient consideration any longer on the table.

CHAIRMAN STITT: One of the comments that -- John, let me say what I thought I heard you say, and then I'll let you speak.

MEMBER GRAHAM: Okay.

CHAIRMAN STITT: You were referring to point number 2. Did I get this correct, that you might say that the NRC will limit the regulation of the safety of patients, where justified?

MEMBER GRAHAM: Correct. As an alternative. I'm trying to create a general framework in which we, and staff, and the commissioners, would have a guide to refer back to as you go through 35 and try to make it more rational that, okay, we're trying to accomplish this general policy. Does the change that we're proposing accomplish that general policy or not?

If we just take out 2 and 3 -- let me clarify, Barry, because I don't understand. The FDA, having approved a drug, doesn't set any training criteria for

whether you, as a physician, can administer -- pick something -- an IV push that could kill a patient within seconds versus some more innocuous drug that has such a low LD50 that, you know, you could misprescribe it for years and it won't have much effect on the patient.

DR. SIEGEL: That's correct.

MEMBER GRAHAM: So if you take 2 and 3 out of here, I'm struggling with why this group or the NRC ought to say anything about the training of physicians, or others that are going to use these materials, beyond having clarified that they are not going to violate the safety of the general public.

MEMBER NELP: It's because Part 35 is titled "The Medical Use of Byproduct Material." In it, it has a whole series of things, what you have to do in order to use byproduct material in --

MEMBER GRAHAM: Okay. Maybe what I'm confused about is we opened the discussion this morning that we should treat Part 35 as a blank sheet of paper. And now we're discussing a general medical policy. And if you create a general medical policy which doesn't talk about a patient, I'm comfortable with the concept of ending up there. But then I'm going to turn to you and say that, fine, Part 35 shouldn't even talk about that stuff.

Most of what is in Part 35 today will go away, from my perspective, if this group says that we ought to only show number 1. And I just want to make sure everybody understands the implication of taking away 2 and 3.

Is that true, or is that --

MR. CAMPER: No, I think that is true. I think that is true.

Now, you know, obviously -- I mean, again, bear in mind, and Marjorie Rothschild had given me a nudge here a while ago, and I have to be very careful about

how to say this. But I think regulations take precedence over policy statements. Okay? And regulations can be developed despite what policy statements say, and I think that there's a fair argument that can be made that the regulations today reflect -- despite what the policy statement says. All right?

So you may end up with a set of regulations in place anyway, you know, no matter how you change the policy. But in theory, if one subscribes to the belief that a policy statement should set the stage from which regulations are developed, then you come back to the definition in Part 35, which says, "Medical use means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user."

If you take patients out of the Medical Policy Statement, I would argue, in turn, that Part 35 would be --

MEMBER NELP: You don't have to take it out. You just told us we didn't.

MR. CAMPER: I'm trying to draw you back to the idea of the policy statement and the fact that regulations should flow from the policy statement.

CHAIRMAN STITT: But I think that's why we're focusing on the policy statement before we start grinding around on 35 and find that the two, in our minds, aren't relating well.

John, finish your comments, and then Jeff.

MEMBER GRAHAM: Okay. Just to clarify your question, so what I was suggesting, instead of the motion on the floor to eliminate 2 and 3, was that we could consider amending or recommending amendment of that general policy statement to reflect under number 2 that the NRC will limit regulating the radiation

safety of patients, where justified by the risk to patients, and where voluntary standards or compliance with these standards are inadequate.

CHAIRMAN STITT: Jeff's been patient, and then you can make your ad hoc comment.

MEMBER WILLIAMSON: Well, two things. One is a question for Larry. If I'm not incorrect, I believe the training and experience requirements requiring board certification in the various different areas predate the 1979 medical statement. So clearly, an independent basis could be generated.

Secondly, I wonder maybe if we should consider amending one of these motions, dropping 2 and changing 3. The NRC will not intrude into the patient/physician interface with the exception of requiring the, you know ... training and experience requirements for the following types of personnel, which you may want to include others than physicians.

So that would solve -- because it sounds like the central concern that many people are arguing from for not supporting this motion is that a rationale for training and experience requirements might disappear.

CHAIRMAN STITT: Is the group thoroughly confused? Thoroughly? Do you want to rehash your comments that you were just -- somebody made a trip to the xerox machine, so now that everybody has it, would you restate what you wrote?

MR. CAMPER: Should I answer his question?

CHAIRMAN STITT: Oh. He did ask you a question.

MR. CAMPER: I think I should answer your question. I think there was a question in there, wasn't there?

MEMBER WILLIAMSON: Yes, there was a question. My question is --

MR. CAMPER: I understand the question. The physician training and experience requirements do pre-date the 1979 Medical Policy Statement. That is correct. There have been changes, obviously, to them since the 1979 Medical Policy Statement.

I would argue, though, that what happened was is all along, in the course of developing physician training and experience, I think if you went back and you researched the history of those, the development of those criteria, you would find, either in the regulatory history itself or in discussions with this committee for that matter, concerns about protection of the patient and that 1979 was merely a codification by the Commission of its concerns about the patient, and that it encompassed an already existing concern about patients as it relates to training and experience for a physician user.

CHAIRMAN STITT: John, are you in the mood to make a comment? Do you want to think about it? Barry is writing madly again.

DR. SIEGEL: Well, I'll talk.

CHAIRMAN STITT: All right. You have the floor.

DR. SIEGEL: The more I've listened, the more I realize it is really quite impractical to throw out 2 and 3. You definitely can't throw out 3. Three is protection from 2.

CHAIRMAN STITT: Right. Yes, it is.

DR. SIEGEL: Three is protection from 2. You've got to keep 3.

CHAIRMAN STITT: That's right.

(Laughter.)

DR. SIEGEL: You can't do them one at a time. And you will recall that I once told Chairman Selin that 3 was obvious because the NRC otherwise would be practicing medicine without a license if they intruded into the practice of medicine.

It sounds to me like what John is suggesting is a slightly stronger way of saying what this already says -- limit its regulation when justified. But then I would go a step further, and I'm struggling with the words here, and suggest that the Medical Policy Statement, item 2, should contain the second component of the second part of what I wrote here, which is that in its assessment of the risks to patients, the NRC will evaluate those risks by reference to comparable risks and comparable modes of regulation for other components of medical practice.

So that would be the NRC telling itself, "These are what the rules are. Don't assess risks in an Atomic Energy Act vacuum. Assess risks in a medical universe and regulate accordingly."

CHAIRMAN STITT: Well, I think as people have been in general talking about 35, and certainly what we're hearing from the commissioners, the idea of risk keeps coming up. As we look at the components of 35, that's in our minds. That is also what we're told to do. What you are now framing in your statement relates to that and gives us a --

DR. SIEGEL: I think that would get what we're being asked to do explicitly by the SRM, and what the staff is being asked to do. That would get it into the Medical Policy Statement.

MEMBER NELP: Could you read that again?

DR. SIEGEL: Well, I didn't write it down.

CHAIRMAN STITT: He is still thinking.

Now, let me also go back to where we are. We have a motion we're discussing. There are no other motions. We can discuss subsequent motions if we wish.

MEMBER NELP: I guess I could withdraw my -- what is that word? You withdraw your second?

CHAIRMAN STITT: We do this every time we get together. We need --

MR. GODWIN: You can discuss this one as long as you allow it, Madam Chairman --

CHAIRMAN STITT: Well, that's why I'm trying to pull us back here, because we are starting to see some light.

MR. GODWIN: -- and then you get a vote on it.

MEMBER NELP: I believe I can --

CHAIRMAN STITT: Do you want to?

MEMBER NELP: -- withdraw my motion, and he can withdraw his second. And then the slate is clean. And I would like, Madam Chairman, to withdraw my motion.

CHAIRMAN STITT: Do we have to second withdrawals?

MEMBER WILLIAMSON: I'll withdraw my second.

CHAIRMAN STITT: All right. The slate is clean. The white paper we keep hearing about, we're back there again, folks.

MEMBER GRAHAM: Well, I'd like to pursue a comment Jeff made. I'd like some reaction to the suggestion that number 3 -- potentially, that paragraph number 3 would be modified to read that the NRC will not intrude into medical

judgments affecting patients. Clearly, if they do intrude, they are getting involved in the practice of medicine.

So to say that they're going to minimize intrusion to me is a difficult concept. If you get in there at all, you're practicing medicine. And as a corporate management person, you know, I spend a lot of time trying to make sure what we do as a corporation doesn't get into medical practice. I don't know how you can -- I don't know how I could minimize my intrusion.

CHAIRMAN STITT: Lou?

MEMBER WAGNER: John, and I think that the biggest problem is that the regulations that are the most onerous are those that specifically address the patient/physician interface, the misadministration rules, those things.

So that the only regulations that, really, the NRC ought to be making is not those that they should not make any regulations that even touch the physician/patient interface specifically, but they can by requiring certain specific training of physicians, that physicians be well trained. This will protect the patients in general. It doesn't interfere with the interface, but it requires specific training, and that's the best thing you can do for a patient to get the biggest bang for your buck is require physicians be trained.

To me, that is how we can modify it in order to make sure that 3 specifically spells out that no regulation would be made to effect specific physician/patient interface. That would still leave open the ability to write regulations regarding training.

CHAIRMAN STITT: All right. So let's have more discussion on point 3, and we'll get back to 2. Are we seeing similar things about -- you brought this up, is that right, Jeffrey?

MEMBER WILLIAMSON: Yes. The original suggestion was to -- I think I said was eliminate 2 but keep 3, with the exception of a provision encouraging them to have requirements that address license or certification and equivalent training and experience for critical professionals involved in radiation medicine.

CHAIRMAN STITT: Well, I don't think that's what number 3 says, and I don't think that's what you were saying.

MEMBER GRAHAM: It's not what I think I heard. I think what I was suggesting is just, again, looking ahead, blank sheet of paper, Section 35. In an ideal world, if this statement could be revised, no change in number 1. Number 2 would be that the NRC will limit regulation to the radiation safety of patients, where justified by the risk to the patients, etcetera. And that number 3 would be modified to read that the NRC will not intrude into medical judgments.

Then, I think we've got a rational general policy statement that gives a great deal of guidance to potential changes from what is in 35 today, but that is trying to retain as much of the safeguard of the public as possible. And that's not in the form of a formal motion. Actually, I'd like to hear reaction.

CHAIRMAN STITT: You called it a suggestion for discussion. Let's leave it at that point, because we can spend a lot of time in our Roberts' that we get stuck with.

You want to discuss the suggestion, Barry?

DR. SIEGEL: I'd suggest slightly different language to do the same thing.

CHAIRMAN STITT: Well, speak into the microphone, then.

DR. SIEGEL: You probably could get rid of -- you could drop the limit word and add two other words instead.

CHAIRMAN STITT: Which point are you on?

DR. SIEGEL: Bullet 1 stays intact. Bullet 2 is, "NRC will regulate the radiation safety of patients only where justified by the risk to patients, and only where voluntary standards or compliance with these standards are inadequate." That's the same as limit. Okay?

CHAIRMAN STITT: Yes.

DR. SIEGEL: Then, add another sentence to policy statement 2, which is, "Assessment of the risks justifying the regulations will reference comparable risks and comparable modes of regulation for other components of medical practice."

CHAIRMAN STITT: Say it again.

DR. SIEGEL: "Assessment of" --

CHAIRMAN STITT: I'm sorry. It is on your -- okay.

DR. SIEGEL: "Assessment of the risks justifying the regulations" -- this is not what I wrote before. This is slightly different. "Assessment of the risks justifying the regulations will reference comparable risks and comparable modes of regulation for other components of medical practice." What that does is it defines what the universe is, what your reference framework needs to be.

CHAIRMAN STITT: Right. Do you also have a comment on bullet 3?

DR. SIEGEL: I mean, I think the suggestion on 3 that "minimize intrusion" should be changed to "not intrude" is clearer and stronger.

CHAIRMAN STITT: I think we're on a roll here. Let's keep going with some talk, okay?

MEMBER NELP: I'd like -- well, as long as you're hitting bullet number 2, why don't you take out -- or, you know, you say "where voluntary standards,"

why don't you say "where required or voluntary standards for training" or something like that.

DR. SIEGEL: I think you're missing the point of policy statement number 2.

MEMBER NELP: I am.

DR. SIEGEL: What policy statement 2 says is that where it perceives a controlled point vacuum, it is going to step in. And in the absence of regulations, the only thing that controls the behavior of practitioners is voluntary standards.

If it perceives that people are not -- where the standards either are no good, or where people just say, "The hell with those standards. I'll do whatever I want," then it says, "We're going to step up to the plate, and we'll get you guys in line." So "voluntary" needs to stay in the policy statement.

MEMBER NELP: I really believe that.

DR. SIEGEL: "Voluntary" is what the community did on its own, not what government did.

CHAIRMAN STITT: I agree with you. I think that's very important. And I think if you look at changes in time, that there is a lot that is voluntary standard now that just simply wasn't available in '79 and subsequent years.

Let's keep talking about 2 and 3. If there are some comments from over on this side? John?

MEMBER GRAHAM: Well, I guess my -- I'm struggling with your last statement. Now, that's the assessment of the risks, justifying the regulations?

DR. SIEGEL: Will reference.

MEMBER WILLIAMSON: Patient safety regulations.

MEMBER GRAHAM: Will reference --

DR. SIEGEL: Comparable risks --

MEMBER GRAHAM: -- comparable risks --

DR. SIEGEL: -- and comparable modes of regulation --

MEMBER GRAHAM: -- for other components of medical practice.

DR. SIEGEL: -- for other types of medical practice.

CHAIRMAN STITT: Would you like to give us some examples of what you might mean? Elaborate.

MEMBER GRAHAM: I assume that the FDA does not regulate how you use a drug once they've approved a drug. Is that what you mean?

DR. SIEGEL: No. Like the NRC says, "Ooh, radiation can hurt patients." But so can surgery. And this is not regulated. Therefore, this is really -- and there is no justification for regulating the radiation, because it is no different than all of these other things that are going on in medicine, which is the point we've been making for six years and which has been being gently ignored for six years, because the answer has been we have the opportunity to regulate it because of the Atomic Energy Act.

This would just mean that the NRC has some additional responsibility in the process of creating regulations, to make sure that it has a broader medical perspective and not just Atomic Energy Act perspective.

CHAIRMAN STITT: I view the clause that is being suggested -- discussed right now as relating to the assignment we got from the commissioners in the DSI 7, and that we discussed this morning, and also being a link to the changes that we have yet to discuss for 35.

MEMBER GRAHAM: I guess that's what -- I was asking the question/clarification because the alternative opportunity would be that we would recommend -- and I agree with your changes on number 2 -- that we would recommend changes in the Medical Policy Statement to only include the word, you know, "only where justified and only where voluntary standards or compliance are inadequate."

And modifying number 3 with a very slight change to just be "the NRC will not intrude." So we made significant changes in focus but very little change in the actual policy statement, and that this -- what would become a fourth point should be the introduction to the discussion we're going to have in the next hour.

CHAIRMAN STITT: Go ahead, Barry.

DR. SIEGEL: I feel that it really is part of 2, because it provides the framework in which 2 operates.

MEMBER GRAHAM: Well, you're including the how in the statement of the why.

CHAIRMAN STITT: Is there something wrong with that?

MEMBER GRAHAM: We could hire a consultant for a couple of weeks, have a mission and goal statement writing and all of that stuff.

MEMBER NELP: So your suggestion was pretty simple for 3. You just said "will not intrude."

MEMBER GRAHAM: Correct.

MEMBER NELP: And leave the rest of it the same, because it says "affecting patients and into other areas traditionally considered to be part of the practice of medicine," which is another way of saying, I think, what Barry has just said.

CHAIRMAN STITT: Well, Barry's getting a lot more specific. He is bringing in the risk, and he is trying to include the concept that you would also look at other areas of medicine.

DR. SIEGEL: And I'm responding precisely to what Larry said earlier, and what we're implying is that there was nothing necessarily wrong with the policy statement. It's just that they chose not to follow it a lot of the time. And by adding this to the policy statement, it gives them a little more internal guidance about what their reference framework ought to be.

CHAIRMAN STITT: Jeff?

MEMBER WILLIAMSON: Well, I think it's a reasonable compromise. I think another way of looking at it, what it says, is is that the process of risk-based rulemaking, you know, should be driven by the baseline error rate that characterizes comparable medical subspecialties and not by something orders of magnitude below other medical subspecialties --

CHAIRMAN STITT: Well, those are points that this committee has tried to make --

MEMBER WILLIAMSON: -- saying, you know, don't play this game of being driven by single random events.

CHAIRMAN STITT: We'll refer to it as the Siegel yo yo principle, right, instead of the Medical Policy Statement. I think that's a comment that this committee has tried to make over time.

Dan?

MEMBER FLYNN: The only -- in part 2, the section where it says "where voluntary standards or compliance were inadequate," can you -- I was wondering, can you give me an example where the NRC currently does not regulate

because it believes that voluntary standards are currently adequate? Because one of the problems with all of the professional societies is compliance is voluntary.

And as a matter of fact, the people who are really practicing substandard radiation oncology will not seek accreditation because they don't care to. They'll keep on going along, doing the wrong thing, because they're not -- but the vast majority may comply with voluntary standards so they can -- I don't know where voluntary standards would be adequate.

DR. SIEGEL: If the NRC believed that the American Board of Radiology was doing an inadequate job of certifying diagnostic radiologists and radiation oncologists, it would step in and it would change that part of Subpart J overnight.

MEMBER FLYNN: Well, it would take three years, but overnight.

DR. SIEGEL: Okay. It is a voluntary choice on my part to be certified by a board, and setting forth that as sort of theme status credentials, the NRC has chosen to accept that. The NRC could choose to accept certain aspects of JCHO accreditation as fulfilling its requirements.

The NRC could choose to allow for practice accreditation to be a way, and we'll maybe talk more about that later this afternoon, to be a way to meet certain requirements.

MEMBER FLYNN: So you're talking about the future, not the present. You're giving them that option.

DR. SIEGEL: Well, the present is --

MEMBER FLYNN: Because even if you're not board certified, you're still going to meet the minimum number of hours of practical experience to be able to be licensed for the isotope. You don't have to be board certified now to use the isotope.

DR. SIEGEL: I understand. But if NRC believed that the voluntary performance of the American Board of Radiology was inadequate, then it would change the regulations such that certification by the ABR would no longer be good enough to be licensed by the NRC. It believes it's adequate. Therefore, it is in the regulations. But it's voluntary.

CHAIRMAN STITT: Are we getting to the point where we want to try to make a motion?

MEMBER GRAHAM: Sure.

CHAIRMAN STITT: John, what was that?

MEMBER GRAHAM: Sure.

CHAIRMAN STITT: Sure. Do you want to make it? Do you want me to read what I've got here? We have it written.

MEMBER GRAHAM: Yes.

CHAIRMAN STITT: Go ahead.

MEMBER GRAHAM: I would move that we recommend to the commissioners a revision of the Medical Policy Statement to reflect revision under statement number 2 that the NRC will regulate the radiation safety of patients, inserting the word "only" where justified by the risk to the patients, and inserting the word "only" where voluntary standards or compliance with these standards are inadequate.

We would revise number 2 to further add the statement, "Assessment of the risks justifying the regulations will reference comparable risks and comparable modes of regulation for other types of medical practice."

That statement number 3 will be modified to read, "The NRC will" -- strike the word "minimize" -- "intrusion," insert the words "not intrude" into medical

judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

CHAIRMAN STITT: We need a second.

Jeff?

All right, we have it seconded. Time for discussion.

MEMBER NELP: I'd like it reread if you could.

CHAIRMAN STITT: I think that makes a lot of sense.

You did it well the first time. Would you like to --

MEMBER GRAHAM: So there's no change in number one.

Statement number two: The NRC will regulate the radiation safety of patients only -- so we're inserting the word only -- only where justified by the risk to patients and only -- again, we're inserting the word only -- where voluntary standards, or compliance with these standards are inadequate.

The second sentence, paragraph two: Assessment of the risks justifying the regulations will reference comparable risks and comparable modes of regulation for other types of medical practice.

Also recommending revision of statement number to read: The NRC will not intrude -- so deleting the words minimize intrusion, substituting not intrude -- into medical judgements affecting patients and into other areas traditionally considered to be part of the practice of medicine.

CHAIRMAN STITT: All right, further discussion?

Larry.

MR. CAMPER: I have a question I'd like for you to help us with as you discuss this issue.

If I go back and I look at the FRN that's in your book, look on page 8243 of the FRN, and I read the third component of the policy statement which says, you know, will minimize its intrusion into medical judgements affecting the patient and into other areas traditionally considered to be part of the practice of medicine -- if I read on to the third column, about halfway down, I find what to me reads like an attempt by the Commission at that point in time to define what it considered to be the practice of medicine.

For example, it says "The Commission believes that the diagnostic use of radioactive drugs is, in most cases, clearly an area of low radiation risk to patients. Therefore, NRC will not control physicians' prerogatives on patient selection, instrument selection, procedure selection, drug selection, and dose level for most diagnostic uses of radioisotopes.

"For all therapeutic uses of radioactive drugs and in certain diagnostic uses -- for example, the use of phosphorous-32 for localization of eye tumors -- the risk to patients is not low. The risk of tissue or organ damage (or even death) is inherent in the use of therapeutic levels of radioactive drugs.

"NRC will continue to restrict the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that have been approved by the FDA."

Well, obviously we've moved away from that since then.

"The NRC will not control the physicians' prerogatives on patient selection and instrument selection for therapy procedures because these procedures are so specialized and patient specific."

And I think one of the things that would be helpful to the Commission to look at as it considers your recommendation is, what do you include within the scope

of the practice of medicine -- or excuse me, medical judgement and those things traditionally considered to be part of the practice of medicine that are either the same or different than those addressed in the 1979 medical policy statement that I just read?

Help them understand what you mean by medical judgement and traditional practice of medicine so they know what not to intrude in given that they seem to have defined what they thought it was in 1979. At least that's how I interpret that.

DR. SEIGEL: And in 1979, it was clear they were still intruding because they were telling you that you could only use drugs for certain indications.

MEMBER FLYNN: If anything, I would recommend we create that bridge as part of the discussion this afternoon of the next section, not as part of this closure on recommendations regarding medical policy.

CHAIRMAN STITT: Commentary on the motion that's on the table?

MEMBER WAGNER: John, would you -- one of the issues that I see here as being raised is the interpretation of the phrase "where justified by the risk to patients."

You can have an extremely rare event with a very high risk and can justify it because one in ten million patients might have this severe confluence. And so I would wonder if you would entertain revision to state that it's where justified by the risk to the population of patients --

MEMBER GRAHAM: Well, thank you.

MEMBER WAGNER: -- to make it clear.

MEMBER GRAHAM: I thought you were going to suggest we put high in there again.

MEMBER WAGNER: No.

(Laughter.)

MEMBER GRAHAM: I was going to leave.

MEMBER WAGNER: No, to the population of patients. Because there it's clear that they should assess the risk based upon the administration to thousands of individuals, not to what might happen on a rare event to one individual.

Those things are terribly unfortunate, but I don't believe any regulatory agency's going to prevent them. They're so rare that they really don't justify the burden it places on the rest of the medical practice in trying to enforce those regulations.

MEMBER GRAHAM: I guess my reaction would be that we're not going to get what might be an ideal clarifying statement. I'm bowing to political reality and consciously embracing a desire to reaffirm responsibility for patient safety in the statement of policy that we've put on the floor as a motion.

Okay, what you're describing will be the siren song of this committee for the next six years. It will -- even if this passed, even if we revised 35, we will still have to come and continue a debate of where the risk is significant enough to justify federal regulation and where it is not.

I don't see it as being a panacea that's going to solve all that problem. I'm concerned if we start to introduce that concept, we'll lose the whole thing. I thought about it. That's why I left the word high out.

CHAIRMAN STITT: Barry, we're mumbling and then --

DR. SEIGEL: I agree with Jeff.

CHAIRMAN STITT: All right, Jeff.

MEMBER WILLIAMSON: Well, I think that the additional sentence that Barry made up to put under point two is supposed to address that. It recognizes that the serious event incidence in other fields of medicine is not zero and that there should not be an artificially imposed ultra low level in this field of medicine either.

So I think it's covered.

CHAIRMAN STITT: John?

MEMBER GRAHAM: We could probably have an Institute of Medicine study to discuss the other modes of medical practice.

CHAIRMAN STITT: Well, that's a good idea.

Go ahead.

MEMBER SWANSON: It's perhaps somewhat nit-picky, but I would like to make just a small change in your second sentence under two to say an assessment of the risk justifying such regulation which then ties it directly back to the first statement.

CHAIRMAN STITT: I like that. I was contemplating it myself. Now does that make it something we have to do something wicked with?

MEMBER SWANSON: Second sentence under point number two I think would better read assessment of the risk justifying such regulation rather than the regulation.

MEMBER GRAHAM: Is that a recommended amendment?

MEMBER SWANSON: Yes.

MEMBER GRAHAM: I would accept that amendment.

CHAIRMAN STITT: Do we have to vote on it?

MEMBER NELP: Is this on the floor?

CHAIRMAN STITT: Yes.

Not if he accepts it? Okay.

MEMBER NELP: Call for question.

CHAIRMAN STITT: All right, are we ready to vote on this?

Does it need to be read again? Looks like people are feeling okay about it. Then those --

MR. CAMPER: Just an administrative point.

CHAIRMAN STITT: All right, administrative point.

MR. CAMPER: The three invited guests cannot vote.

CHAIRMAN STITT: Right.

MR. CAMPER: Okay.

CHAIRMAN STITT: One, two, three. Okay.

Those of us who are privileged to be committee members get to vote on this.

(Laughter.)

And all you wanna-be's just hold still.

Those in favor of the medical policy statement revisions as we have read them on several occasions, raise their hands. And is somebody counting?

Okay, and those opposed?

And as I recall from our last meeting, we need to allow the dissenting votes the opportunity to speak.

MEMBER BROWN: Okay, well I guess I have the rare pleasure of quoting Dr. Nelp here who said that the Commission is asking us what would be our ideal world, and the current medical policy statement surely reflects my ideal world much more than any alternative language I've heard.

CHAIRMAN STITT: Okay, I'm going to call for a break. And we will let the invited guests take the break with us.

(Whereupon, the foregoing matter went off the record at 2:46 p.m. and went back on the record at 3:06 p.m.)

CHAIRMAN STITT: I think we're ready to get going again, team; is this true?

MS. HANEY: I'm Pat Rathbun. I've changed names.

CHAIRMAN STITT: We're going to resume with discussing the criteria and ranking of medical procedures involving byproduct materials by risk.

MS. HANEY: Pat Rathbun from our office was going to make this presentation; but unfortunately, she found out late today that she was called away to another meeting, so I am happy to stand in for her at last minute notice. So you're not going to get a long introduction to this topic.

In our preliminary discussions on this section, what was going to happen, we came up with a couple of key points and questions and things that we wanted to get out of this session. So I'm just going to kind of jump right to the end and tell you what we're interested in learning about.

Basically, from the DSI and the direction from the Commission, we're supposed to be looking at things by risk. And we pretty much, you know, in talking to people, HDR's typically go into a high risk and diagnostic nuclear medicine go into a low risk.

But now what we're looking for is some type of idea of where does everything else fit in, and then what is your criteria so that when a new modality comes about or when we're justifying why a modality has been placed into a high risk or a low risk category, we'll be able to justify it by using this criteria.

I think in this case, maybe it would do good if you're agreeable to stepping through this question by question rather than just opening this all up. These questions are in your book under the section in risk. It's grouped in there with a small introductory paragraph and a larger one.

So we can leave this up on the screen and we can go through these one by one, or -- and just follow along in your book.

The first one is looking at identifying the key modalities and then their relative risk. I guess I threw out two already from nuclear diagnostic and HDR, but I would open it up to this point as far as what should be the other, you know, grouping of modalities.

MEMBER SWANSON: I guess before I can answer any of these questions I need to know what you mean by the definition of risk. If the definition of risk is a standard definition of risk of the probability of the event times the consequence of the event -- is that what you mean by risk?

MS. HANEY: I'm comfortable in using that. I guess really we're open to a discussion even on what you would want the definition to be.

MR. CAMPER: We would like you to tell us.

MEMBER NELP: This is risk to patients?

MR. CAMPER: I mean, it is both. It is risk to patients and risk to --

MEMBER NELP: Do you want to say risk to all three?

MR. CAMPER: Sure.

MEMBER NELP: Okay.

MEMBER WILLIAMSON: I would suggest we consider somewhat separately the different categories, as I noted before, the public workers, patients.

MS. HANEY: That's fine.

MEMBER SWANSON: Actually, that's very important because even if you look -- if you say that it's the probability of the risk times the consequence, then you've got to say from a probability standpoint are you looking at a risk over time; or in the case of patients, are you looking at a risk for number of administrations.

So it's very important, I think, that we consider the risk differently. Okay, risk over time would be important to the public and occupational worker. Risk per administration would be important for the patient basis.

CHAIRMAN STITT: John Graham?

MEMBER GRAHAM: I just have a question/clarification. I've heard several references to a potential definition of risk, and I think it was part of the public statement earlier. Do we have copies of that? Do I have anything in writing that refers to it?

CHAIRMAN STITT: Yes, that was circulated.

MR. CAMPER: I'm sorry?

MEMBER GRAHAM: Well, I assume that this definition I keep hearing is in the -- I've heard it referred to in the public statement this morning, so should I have it? Should I have read that and somehow I missed it?

CHAIRMAN STITT: Did you get anything like this?

MR. CAMPER: Did you get your APSNM?

CHAIRMAN STITT: The statement in the -- under what is risk, we believe risk is a consequence of an action multiplied by the probability or frequency of that consequence happening.

But then there's still all these issues that other members have brought up, and who does this pertain to, what's the time frame? So it's multifactorial.

MR. CAMPER: Let me make a couple of things to help you with this topic which is kind of tough.

We gave you a couple of pieces of information. We gave you a NUREG/CR-6323 entitled Relative Risk Analysis In Regulating The Use of Radiation Emitting Medical Devices. We also gave you another NUREG, NUREG/CP-0144,

which is a Workshop on Development -- Developing Risk Assessment Methods for Medical Use of Radioactive Material.

And if you read those, you'll find they talk about doing things such as fault trees, HRA, PRA, GEMS, those kinds of things in terms of, you know, academic risk assessment. And they talk about how, you know, we ought to do pilots and there's difficulty in plotting the materials uses and so forth and so on.

In addition to that, you'll find a Commission paper entitled Frequency and Consequences of Misadministrations. And if you read that, what you're going -- and it references the NCRP Commentary Number 7 which was referenced earlier today.

But what you're going to find if you read about misadministrations, for example, you're going to find with the staff in its Commission paper said that there really hasn't been a very strong application of quantitative risk analysis in determining misadministration assigned thresholds because it's very difficult to know what the consequence is; and that the consequence may be variable in patients and variable is a function of dose, and dose and patients, and dose and patients and disease state, and so forth and so on.

So I don't know to what degree you've had a chance to look at that, but there are two pieces of information here. The one tells you how the staff has viewed this question of consequence assigning misadministration thresholds and some of the work we've done thus far.

Now, it may be, when it's all said and done, that classical, you know, risk assessment following known academic models should be applied to materials uses to the extent possible. It's problematic. It's not like I have a static scenario and

I'm going to rank probability if something happened and I know what the consequence is once it happens, and therefore I can assign a risk coefficient.

It's a little more complicated than that in materials world, and particularly in medicine. But it may be that your suggestions will be that some of these models should be applied. But what we need from you when we ask you this question, identify the key modalities and the relative risk, we need from -- what is the ACMUI's perception of what the risk is or what criteria or models or guidelines should we follow in assigning risk.

I mean, we want your perspective on that.

CHAIRMAN STITT: Okay, go ahead.

MEMBER WAGNER: I would recommend that we limit our discussion to patients. The risks as regards to public or workers are dealt with in a different part, not Part 35, and so we shouldn't even address them. We're not thinking about changing that stuff, so we should limit our discussion only to risks to patients.

CHAIRMAN STITT: Well, that's a good place to start.

Any other commentary on that?

MR. GODWIN: With regard to that, are you talking about possible exposure from the patient as being part of that inclusive, or part of the procedure; or are you talking about strictly the dose to the patient and the dose to the worker that may be associated with it or the dose to the public associated with the patient not be included?

MEMBER WAGNER: The dose to the public from the patient is dealt with by the regulations in Part 20 because it says the public can't be exposed to radiation exceeding certain amounts. And we've dealt with that in regard to other regulations.

So I think that that number is set. That number is set in regard to risk. We can't do anything that is going to expose patients to -- no, I'm sorry, expose members of the public to levels above those existing in Part 20. That's a fact.

MR. GODWIN: Madame Chairman, if I may respond just a little bit to that.

It appears that we're trying to assign risk. We're not trying to set, in this case, a number of exposure. And what I thought we'd be looking at is -- or I missed the whole, which I may have -- that a given procedure has with it a certain potential exposure to the patient and a certain potential exposure to the public and a certain potential exposure to the workers.

Granted, there are limits on the worker's exposure, there are limits on the public exposure, and there's none on the patient. But it would appear that if we're assigning risk, we're really not worried so much about limits; but what we're trying to say is that if you reach this exposure limit to say 100 rem to the patient, we're going to call that a high risk procedure.

On the other hand, it may only be a half rem to the public. It doesn't make any difference. If a -- you know, the point is that you really have on a given patient procedure a potential risk to each one of these groups. In some cases, -- well, I guess in all cases, something would be controlling about whether you make it a high risk or a low risk, and you have to sort of look at all three of them, I think.

Maybe I've missed the point.

CHAIRMAN STITT: Barry, what's your point?

DR. SEIGEL: No, I agree completely.

I think that we have to consider the risk to all three groups as part of the risk equation. But what the question that's being asked is, if unregulated, what is the probability that members in each of those three groups could potentially be hurt?

If regulated, can you reduce the risk? And so you can't leave workers and members of the general public out of the equation. The probability is often going to be very low, but you still have to consider it in terms of the risk assignment.

CHAIRMAN STITT: Jeffrey?

MEMBER WILLIAMSON: I think we should include the public and staff because there are dozens of little regulations in current Part 35 that pertain to safety such as the detailed requirements for inventory and brachytherapy sources have nothing to do specifically with the quality of any given patient treatment, but they are perhaps, in some sense, philosophically consequences of Part 20 that NRC has decided to make these very detailed requirements.

So in order to address the necessity for such sort of detailed regulatory guidance above and beyond Part 20, I think we have to comment on it modality by modality.

CHAIRMAN STITT: Well, it is a number one bullet up there. Is that how you want to -- the committee wants to try to proceed, looking at modalities?

Go ahead, Dan and then John.

MEMBER FLYNN: I hope that can -- can we identify what we think is risk in clinical terms rather than get stuck with trying to define certain dose levels to the -- either the patient -- I mean, I hope we can stay away from defining 100 rem here or 400 rem there as opposed to some modality whereby the improper use or some kind of an error occurs where it results in some permanent, symptomatic injury in the patient or death of the patient.

Some permanent injury to the patient would be something that would be significant. As opposed to technetium-99 at a diagnostic level, no matter what you do with it, it's -- there's no significant risk to that patient.

CHAIRMAN STITT: Well, that's certainly my personal opinion is to try to avoid statements that just don't relate to the clinical world, *ie.* certain dose levels.

John, I think you were next.

MEMBER GRAHAM: Well, I guess what I'm struggling with in trying to understand, we passed a recommendation on a policy revision that says that assessment of the risk justifying the regulations will reference comparable risks and comparable modes of regulation for other types of medical practice.

Now, if you give enough drug to kill a patient, that's a risk; but it doesn't mean we're going to regulate the use of that drug anymore because risk exists. So I thought we were going to get into a discussion of these modalities with the relative risk to the general public and the workers, and I guess what I'm struggling with what's missing is how you're going to tag the potential benefit to the patient against each of these relative risks so that in a high dose radiation setting, the risk is -- the risk of it's not handled appropriately is high to the general public, it's high to a worker.

The risk to a patient's high, but the potential benefit outweighs that risk. So I'm still struggling with what we're trying to develop here.

CHAIRMAN STITT: Well, you're not the only one that's struggling. And I think that the NRC is going to regulate stuff, and that's something that's there. And we can try to direct which stuff is regulated and to what degree and how, so to try to start assigning all sorts of interesting .02 of relative risk compared to having your hernia repaired is not going to get us anywhere because they're going to regulate stuff.

So how we can to go about that is up to our recommendations. How we want to go about developing recommendations is up to the committee.

Jeff?

MEMBER WILLIAMSON: Well, why don't we start at what we would maybe consider to be the bottom or lower end of the spectrum of risk and say diagnostic radiopharmaceuticals, do we consider the risk low, medium, or high with respect to the public, the staff, and the patient?

CHAIRMAN STITT: All right, is the group ready to take on something like that?

I think it's reasonable. We do have to understand that there's -- things will be regulated.

That's a good one to start with, right, Dr. Seigel?

DR. SEIGEL: Yes.

MEMBER NELP: Would a term like insignificant be a better term than low? Could there be a category for insignificant, or would that -- that would express, I think, more strongly some of the --

CHAIRMAN STITT: Shake your heads, acknowledge you're still with us.

MEMBER WILLIAMSON: It seems reasonable to me that we don't have to have some rigid scale. We could just sort of make a comment and kind of maybe indicate the relative ranking of some of these things might be the best we could do.

MS. HANEY: What we would ultimately need though is, at the end point, is where one ends and one picks up. But that's probably, you know, down --

CHAIRMAN STITT: And that's very rigid. Very rigid, and I think --

MS. HANEY: No -- yeah, we don't want it to the point of rigid, but what we'd be looking for is a new modality came into the where -- what criteria should we use for putting it into one of these bins.

CHAIRMAN STITT: Let's go back to diagnostic materials. Let's look at the framework of public workers and patient.

Let's start with this side. You guys have more lights on you. I can see you better. I think this side's going to go to sleep pretty quick.

MS. HANEY: If you don't need this, I can turn this light off. You do have it in your book.

MEMBER NELP: We can see even with the lights out.

CHAIRMAN STITT: Yeah, I think it's fine. Leave it up there. It helps me focus on what we're doing.

Jeff, you are the one that has brought up some of this framework idea. Give me your comments regarding those three worlds regarding diagnostic.

MEMBER WILLIAMSON: I will try. I'm not an expert in diagnostic. But starting with the patient, as I understand, the incidence of errors under the system as currently practiced is pretty small. Maybe it's smaller now that it used to be, but I gather it was always pretty small.

So there's a low probability, for example, of a patient getting too much stuff, the wrong stuff, too little stuff. But as I understand also from -- and nuclear medicine colleagues here can say whether this is true -- the consequences in terms of an acute -- a non-stochastic effect is practically nil for a patient.

So one would say maybe, given the numbers of patients involved, that perhaps approaches the level of insignificance both by virtue of low probably of it happening in the first place and low consequences.

MEMBER NELP: Undetectable consequence. No evidence of consequence.

MEMBER WILLIAMSON: Maybe the level of epidemiological if a huge population got exposed. Perhaps in 30 years there might be some -- but for individual patients, it wouldn't be much of a risk.

MEMBER NELP: I concur.

I think the whole diagnostic category, regardless of what diagnostic procedure --

MEMBER WILLIAMSON: Why would it be that way? Well, it's because the dose levels versus volume treated is so small that it's below the threshold to produce a -- you know, which is perhaps on the order of several hundred centigray in an acute exposure to a limited volume to produce an effect.

MR. GODWIN: I believe there might be one exception you need to look at, and that's at 30 microcuries of iodine or greater.

MEMBER NELP: I consider that to be insignificant in individual patients.

MR. GODWIN: Occasionally you have a diagnostic dose of one millicurie also.

Would you consider that insignificant?

MEMBER NELP: Pardon me?

MR. GODWIN: Occasionally you have a one millicurie diagnostic dose of iodine-131.

MEMBER NELP: Those ordinarily are to patients who have thyroid cancer who are about to be exposed to I-131 therapy in rather high concentrations. So

they typically get five to ten millicuries, and that's nothing to what they will be treated with. So in that individual patient, the risk is very small.

DR. SEIGEL: But that's not the issue.

MEMBER NELP: What is the issue?

DR. SEIGEL: The issue isn't if you correctly gave the five millicuries to the patient who's supposed to get five millicuries. The issue is if you incorrectly give the five millicuries to someone who was supposed to get a bone scan or someone who just walked in off the street, which is what the quality management program focuses on.

And the way you would stratify it, I mean, I think, is that you say that in the case of diagnostic studies done with technetium radiopharmaceuticals, that there really is no special procedures that need to be in place to ensure that the standard of care is being met to the federal government's satisfaction.

Whereas in the case of administration of I-131, some set of rules might need to be in place like identifying the patient, giving the correct dose, and following the instructions of the authorized user, which is the quality management program stripped down to its prescriptive minimum without the audit and the self flagellation components that are part of the existing quality management program.

MEMBER NELP: I concur.

I was looking at the question a little differently, but I agree with you 100%.

DR. SEIGEL: So that diagnostic becomes relevant when you start talking about I-131.

MEMBER NELP: Saying it properly, there's no --

DR. SEIGEL: It's also relevant to workers too. I-131 is relevant to workers, and I-131, even diagnostic, can be relevant to members of the general public.

MEMBER GRAHAM: For the layperson in the audience, what are we classifying -- that that's no longer being called a diagnostic radiopharmaceutical?

What's I-131 in this case?

DR. SEIGEL: Diagnostic.

MEMBER GRAHAM: What nomenclature are you going to put on it? Because I'm hearing it's no longer low, it's --

DR. SEIGEL: Medium risk diagnostic --

MEMBER GRAHAM: It's medium risk. What are you calling it? Or are we subcategorizing diagnostic radiopharmaceuticals at this point? We started with a fairly general discussion, which I followed; but diagnostic radiopharmaceuticals, are we simply now breaking that into two subsets, part of which is low and the other which is medium?

MEMBER NELP: There is an infrequently used group, the group that we're talking about now. What do you mean by risk?

Are you going to go back to your definition of risk in terms of frequency and probability versus numbers? In that event, the risk is insignificant.

MEMBER GRAHAM: I'll just make --

MEMBER NELP: The actual risk of injuring someone is totally insignificant.

MEMBER GRAHAM: I would recommend we avoid the word insignificant. It is just so value laden that politically I would have a field day with it. I mean, I can get onto my -- you know, my panicked public podium and say that there is no insignificant radiation risk.

DR. SEIGEL: It's like the word de minimis.

MEMBER NELP: It's low.

CHAIRMAN STITT: I just want to point out that we -- I think we sort of selected this as an easy place to start, and obviously it's not an easy place to start. I go back to point number two from the Commission where they support a combination of the two options, the ongoing program; and option three, decreased oversight of low risk activities.

And we're stuck on that, although we've just gotten started; and then they want us to discuss continued emphasis with high risk activity. So this is not going to be simple.

MR. GODWIN: May I make a couple other comments?

Regardless of how we feel about doses, that may be a way to tag things so that we have something to look toward to the future. I would like to see us get away from naming specific isotopes, if at all possible, so that when new developments come along, we don't have to play the game again.

It would be nice that if we had some comparable dose and said okay, diagnostic procedures below this much patient dose and doesn't involved something to the public is low; above that, it's medium, high, whatever we decide to call it. I think it would be a lot easier in the future because when something new comes along, you merely calculate the dose and you see where you are.

You know which group it falls in.

CHAIRMAN STITT: That may work for the pharmaceuticals. I don't -- I think it falls down dreadfully in therapeutic radiology and isotopes.

MR. GODWIN: Therapeutic would be a different issue.

MEMBER WILLIAMSON: What would be the whole body and bone marrow doses from ten millicuries of I-131 given to a normal patient in that group?

DR. SEIGEL: Unfortunately, the effective dose is irrelevant there. What's relevant is the thyroid dose.

MEMBER WILLIAMSON: The thyroid dose?

DR. SEIGEL: Yes.

MEMBER NELP: That's the only -- in terms of frequency versus if you define risk like the SNM does, it's low risk. And I think if we stick to a definition of that sort, the probability of that happening is very low. The reality of checking the dose and giving it to the right patient is very proper.

But there's -- you know, I don't know how you deal with that particular part of it. By regulation, you always check the dose. You always have a prescription. You wouldn't do anything different for those dose. The probability of that creating a problem in terms of an observable effect is very low.

DR. SEIGEL: You just said by regulation.

MEMBER NELP: Right. I can't give a drug to a patient without a prescription. I personally, as a physician, prescribe that medication to that physician under my state licensure, etc., etc.

MEMBER GRAHAM: But I guess what I'm struggling with Wil, is that --

MEMBER NELP: And I can't purchase that without a prescription the way the pharmacy laws are set up.

MEMBER GRAHAM: But rewriting 35, technetium may fall out of that requirement, and I-131 may continue to have that requirement.

DR. SEIGEL: Actually, technetium will never fall out of the requirement for a prescription because it's a prescription drug.

However, prescriptions in nuclear medicine are implicit prescriptions 95% of the time. They're not real prescriptions. You don't write a prescription for a patient to have a bone scan. You follow a procedure.

MEMBER NELP: It has my name on the slip for Dr. Nelp for patient X, as a matter of fact; and I have evidence that -- you know, there is a written pad. It's probably not that way in a lot of places. But in --

DR. SEIGEL: I mean, in most places, it's done in accordance with a procedure manual --

MEMBER NELP: Yes.

DR. SEIGEL: -- which was created by the authorized user effectively to create an implicit prescription.

CHAIRMAN STITT: I'd like to hear some discussion regarding the specific isotopes. I think it was brought up -- or a question was raised gee, don't set this up based on an isotope.

Could somebody -- I'd like to hear more discussion about that comment.

Dennis is rubbing his eyes and shaking his head. What do you mean?

MEMBER SWANSON: Not out of disagreement, just total confusion I think.

CHAIRMAN STITT: Okay.

MEMBER SWANSON: Yeah, I don't think you want to break -- I mean, you don't want to break it out by isotopes, okay. I do understand the concern

about I-131, but I just wonder if I-131 comes under -- even at the diagnostic doses, comes under therapy because it's really part of therapy planning.

There might be a way to get by that, okay. Whereas, you know, the other ones are -- I can't think of any other ones that we administer as part of therapy planning per se. I mean radionuclide therapy planning.

MEMBER NELP: Yes, it could be therapy and therapy planning.

MEMBER SWANSON: Yes.

CHAIRMAN STITT: Jeff?

MEMBER WILLIAMSON: Well, I think that maybe there would be no argument that even if there is maybe a significant probability of some incident if at the normal doses that are practiced the likelihood of an observable injury is extremely low, one would want to put it in the low category because the severity is so low.

And so perhaps, you know, that forms the basis of a general criterion that any radiopharmaceutical will be low risk based on severity considerations if no organ dose, you know, comes close to the level if you do give it to the wrong patient of producing, you know, a clinically detectable side effect of some kind.

So that would -- you know, presumably there would be some cut off where the thyroid could tolerate, you know, a given dose of radiation without experiencing clinical disfunction. Perhaps that level would be for I-131 somewhere significantly below ten millicuries.

CHAIRMAN STITT: So then are you -- I don't want to put words in your mouth, but one way of looking at this would be for diagnostic isotopes, yet incorporating some sort of an organ dose?

MEMBER WILLIAMSON: Yes; basically, if you want to be radionuclide independent, which sounds like a reasonable thing, one way to think about

it would be, you know, a general criterion that, you know, no organ system receive an absorbed dose of radiation in gray that is likely to produce a functional injury of that organ system.

CHAIRMAN STITT: I can see lots of --

MEMBER WILLIAMSON: And we only have radionuclides that are capable of producing, you know, if given to large numbers, large population by mistake, you know, stochastic effects.

CHAIRMAN STITT: Dan?

MEMBER FLYNN: Information's going to change in the future as to what an organ can tolerate, whether it's the liver or the kidney. Instead of saying the dose in gray, just saying when you're judging a new isotope, an isotope, whether it's a low risk or not, has to meet the test that either the effect on the whole body or the effect on any organ is not sufficient enough to cause any side effect or -- side effect or injury to that organ, and don't get into what the dose would be.

MEMBER WILLIAMSON: I accept that.

I didn't mean to suggest that --

MEMBER FLYNN: Instead of saying dose in gray, then next year we have to modify -- you know, every year we're going to be modifying it based on new information as to what the liver and kidney can tolerate as a single organ dose, whether it's protracted or a single shot. It could be a nightmare, all these tables.

CHAIRMAN STITT: All right, so -- just restate the comment you just made and let's have more discussion on that.

Again, I think we're in the context of diagnostic isotopes currently.

MEMBER FLYNN: Diagnostic isotope is a low risk procedure providing -- don't want to use the word misadministration, but the medical event --

subsequent medical event that may occur does not produce a clinical detectable effect on the whole body or a clinical detectable event on any organ system resulting in a side effect or injury.

CHAIRMAN STITT: More comments on --

MEMBER FLYNN: Covering whole body and individual organs.

DR. SEIGEL: This sounds like the abnormal occurrence for reporting criteria all over again, but actually that dividing line is not bad.

MEMBER FLYNN: Without the dose.

DR. SEIGEL: I mean, it's basically dividing -- I mean, you really have to be excessively negligent to hurt a patient with technetium, to hurt workers with technetium, and to hurt members of the general public with technetium.

You've really got to be a bad apple to do that.

MEMBER NELP: I don't think you can hardly be that bad.

DR. SEIGEL: You can, you can, you can.

Well, maybe --

MEMBER NELP: Yes, you could.

DR. SEIGEL: Less with the technetium and more with the molybdenum that came before, but it's pretty hard. You don't have to be all that bad an apple to hurt people with I-131.

MEMBER NELP: So I like Dennis' suggestion putting I-131 therapy and therapy planning into another box because then there's nothing in the diagnostic category that has anything with extremely low risk.

DR. SEIGEL: Well, I think Dan's suggestion is capturing much the same thing, is that we're -- one way is to stratify the -- both diagnostic drugs in terms of

whether there's a low -- a very low probability or a moderate probability that members of the general public will get above the 100 millirem limit -- below or above.

Occupational workers will get doses in excess of the occupational limits; and that patients, as a result of misapplication, will get doses that are capable of causing clinically detectable or important organ injury. That's a good dividing line. And I-131 meets the criteria across the board.

If you don't behave properly with I-131, you can hurt everyone in the chain, right?

MEMBER NELP: I agree.

MEMBER GRAHAM: I assume if Dan repeated his definition that I-131 would fall out of it, correct?

DR. SEIGEL: No, it would fall in that second category because it can hurt all three groups.

MEMBER NELP: Now the SNM didn't come to that conclusion. I believe they said the probability of that happening versus the number of times that that probability exists, the number of applications -- still, even though you killed someone, one out a billion times, it's still low risk.

DR. SEIGEL: But frame the question this way and think in terms of if the use of the material were totally random, completely irresponsible, the potential for harm is there to all three groups. The level of -- the regulatory posture should now be conditioned both by the fact that indeed, there's some risk; and the level of regulation needs to be conditioned also by what's the probability that this kind of behavior will occur.

MEMBER NELP: I accept that.

MR. CAMPER: Just as a function of operational history and --

DR. SEIGEL: You bet, you bet.

So that you don't have to have people doing this stuff in a tight block, in a tight box. You can give them some wiggle room based on the fact that you've got a long history that shows that people get it right 99% of the time -- 99.99% of the time.

But some minimal level of regulation to sort of set the standard of care is not unreasonable.

CHAIRMAN STITT: Let me just interject something here.

It's 3:30, and according to the agenda, it's time we move on to our next agenda item. We didn't have --

DR. SEIGEL: We didn't do the important stuff.

CHAIRMAN STITT: Well, I think we made a step, haven't we? Haven't we made a major step here? I didn't have the idea that this was going to be solved. And I want to respond to the committee's opinions here, but it looks like we're getting somewhere.

MR. CAMPER: Let me just suggest, if you can -- I mean, at least summarize your preliminary views and you'll have the opportunity in your written to, you know, further articulate --

CHAIRMAN STITT: Right, that's where I thought we'd be able to take this as we're working frantically in the next month. If we can make some sort of a statement that we'd like to be thinking about for diagnostic isotopes, maybe that will help us to determine where we're moving as we look at -- we will be seeing these again.

I think we have to be looking at these as a committee as we move from here to May. But I also think we made some steps here.

Dan, do you have a comment?

MEMBER FLYNN: Well, the only thing -- I've been thinking about it before this meeting, but in radiation oncology -- and I ask if you would agree, that brachytherapy in general can be a high risk to all three groups; but teletherapy could be a high risk to the patient and the worker, but not the general public.

No one walks away with a cobalt source out of a teletherapy machine. There's no way to get it out of that machine and get it out into the general public. And I think that that risk would be low to the general public, but potentially to the worker or to the patient.

CHAIRMAN STITT: Right. Except for transportation of that source issue, but I believe that's already --

MR. GODWIN: Yeah, that's not addressed in this.

CHAIRMAN STITT: That's taken care of in other mechanisms.

DR. SEIGEL: Unless you leave your source out and the room open.

MEMBER GRAHAM: Well, yes; see that's where I disagree on the general public use to the extent that if you don't have some control over the room. And I'm not saying you necessarily need regulations to get that control.

CHAIRMAN STITT: But we have looked at a stratification of patients, workers, and the public; and we have talked about diagnostic and therapeutic. Also stratifying in that sense.

You're shaking your head. What does that mean?

DR. SEIGEL: No, no; I agree.

CHAIRMAN STITT: Oh, you're shaking it the other way?

DR. SEIGEL: I was just -- the interlocks of design in teletherapy rooms are not just to protect the workers from going in while the machine's on. It's

designed also to protect random visitors to the radiation therapy department from walking into the room while the machine is on.

CHAIRMAN STITT: Would somebody like to summarize the comments?

MEMBER FLYNN: The machine can't go on with the door open. And that may be a --

DR. SEIGEL: According -- because the regulations --

MEMBER GRAHAM: Exactly.

DR. SEIGEL: -- made it be designed that way.

MEMBER GRAHAM: You might not have built it that way otherwise.

CHAIRMAN STITT: Does somebody want to summarize where we are with the low -- with diagnostic isotopes?

MEMBER NELP: I think we've said diagnostic isotopes in all categories of medical diagnosis are of very low risk and would have no measurable effect on any body organ in any patient at any time.

CHAIRMAN STITT: I think Dan had a little fluffier version of that.

MEMBER FLYNN: I'd have to spend some time writing it, but a diagnostic isotope is a low risk procedure provided in a medical event the whole body effect or the effect on any organ is such there will be no clinically detectable adverse effect.

I've got to, you know, work that out, but the effect on the whole body or the effect on any individual organ will not result in any clinical detectable adverse effect. Clinically detectable adverse effect.

CHAIRMAN STITT: Are we looking for motions here or shall we let that sit and keep working on that as a basis?

Everybody say let it sit?

MEMBER NELP: Probably a concurrence at least.

CHAIRMAN STITT: Jeff?

DR. SEIGEL: Well, yes; I think that's a reasonable statement. And I think on the basis of that, diagnostic radiopharmaceuticals excluding I-131 for the moment, we could say, are very low risk in all three patient categories to summarize.

CHAIRMAN STITT: Okay, so we've at least, in our stratification, looked at the three -- patient, workers, and public and made a statement about diagnostic isotopes. Maybe we should just view that as success for the moment and move on with the 3:30 talk.

MS. WOODS: Since I've not had the opportunity to address this group before, I'd like to take a moment to introduce myself.

My name is Susanne Woods. I'm the staff member for the medical academic staff in the Division of Industrial Medical Nuclear Safety.

I'm fighting a bit of laryngitis. Please bear with me.

Well, as you're aware from this presentation this morning, the SRM has directed us to go forward with the program to revise Part 35. And item seven of that SRM addresses industry medical standards. Specifically, it states the staff should consider the viability of using or referencing available industry guidance and standards within Part 35 and related guidance to the extent that they may meet NRC's needs.

With that then, we plan to review professional medical standards and guidance, as well as the guidance of other organizations, to address specific medical uses, especially those that we regulate in the areas of byproduct regulation.

Today then, I would like to examine within the context of Part 35 regulatory framework as it may exist to include these standards and guidance. I would

like to look at how we might bring that into the regulatory framework. Once it's in the framework, how can we maintain it.

And then more specifically, which organizations should we turn to for this information; and what standards and guidance, more specifically, can we begin to look to as applicable to the types of regulation that we have in Part 35.

With that then, I'll turn to the overall question of what is the role of industry standards within regulatory framework? More specifically, what are ACMUI recommendations for incorporating these standards and the guidelines?

Two possibilities, the direct reference within the regulations or including the reference in regulatory guidance to support compliance with the regulatory requirement.

What is your recommendation?

MEMBER NELP: Could you us a specific example of an industry standard that is, say, dominant or prominent in your thinking so we can have a little better perception?

MR. CAMPER: Let me give you two things to think about.

We have an example in our regulations that deal with industrial radiography, Part 34, in which we specifically cite ANSI Standard N-432. And we require our licensees to -- who use industrial radiography cameras to meet that standard and then some other requirements that we imposed in 34.20.

Well, it's very interesting; if we go forward in time to 1997, we find that that poses a number of intriguing problems for us. First is that since that ANSI standard was created in 1980, it's subsequently been changed again. It was 1985 it was modified again.

But yet I've got a regulation that cites a 1980 ANSI standard. And so one of the problems you run into when you try to bring to bare an industry standard -- in this case, an ANSI standard; but it might well be a double AAPM standard or an SNM standard or an ACR standard -- you know, these standards get changed, and then your regulation isn't necessarily consistent with the current standards.

That poses a problem. Another problem I have with regards to that particular standard is that I have substantial differences of opinion even from individuals who were on the ANSI standard committee as to what it meant.

Now in that particular case, it deals with something known as an industrial radiography system. And this system consists of several components in that case. Of course, it includes the shielding, housing for the source, the source itself, the guide to N stop devise and so forth.

Now so there's an example of where we tried to incorporate an industry standard into the regulations by reference and I find that it's problematic. I can certainly see how that problem could be repeated if we incorporated, let's say, for example -- I don't know, AAPM Monograph 5 or whatever, or NCRP Commentary Number 7, whatever -- how one keeps it up to date, how one makes the regulations consistent with the standard over time and so forth.

But it does -- what it does is raises a larger question. The Commission has said to us bring industry standards to bare. And so what we're trying to get a handle on from you is what is the role that these industry standards might play.

I mean, for example, should they be incorporated in the regulation? There are problems. There are questions about enforceability when you bring a referenced standard into the regulations. There are questions about inspectability that come to mind.

So as Susanne has pointed out in her bullets here, a couple of possibilities is direct reference in the regulations; another is inclusion in the guidance themselves. And then when those documents are changed or modified over time, they can be updated in the guidance as well.

So those are just some problems in the one case where we've actually cited it in the regulations. But just the question, what is the role?

DR. SEIGEL: Judith, is a partial answer to that in the medical policy statement already that you will make a regulation where voluntary standards or compliance with voluntary standards is inadequate -- are inadequate?

And looking for the existence of standards doesn't mean that you have to reference standards in your regulations, but rather have to look to see if the standard of care is being defined by the existence of those voluntary standards; then have to decide whether or not there's general compliance with those voluntary standard, and then decide not to make a regulation.

That, in some ways, is preferable unless you go to deemed status for accreditation, which is another voluntary approach. I mean, that's preferable than getting linked in federal documentation in the Code of Federal Regulations to a standard that can be changed without the federal government having anything to say about it.

MR. CAMPER: Yes, so your point is that the role for the industry standard is not to be included in the regulation, but to be considered and evaluated during the development of --

DR. SEIGEL: And in deciding whether there's a need for the regulation.

CHAIRMAN STITT: Jeffrey?

MEMBER WILLIAMSON: Another example of a standard is -- industry standard that's included in current regs are the cobalt-60 teletherapy requirements where every two years, I believe, the ion chamber use for said purposes is supposed to be calibrated according -- at an AAPM accredited dosimetry and calibration lab.

There are many AAPM standards, if you want to call them that. We call them task group reports, and they're very detailed sets of recommendations. Some ones that are relevant maybe to this committee that are about to come out or in various stages of approval would be the Task Group 56 which is brachytherapy physics code of practice.

Task Group 59 is high dose rate brachytherapy safety to give you an example of what's in high dose rate brachytherapy. There's quite a sort of a detailed description of various sorts of procedures and how to design forms, some suggestions what should be in what we call the written prescription, what are the various activities that should occur during applicator insertion, treatment planning, preparation of the patient for treatment, delivery, and so on to avoid errors.

What should be the required elements in verifying the dose computation inherent in any graphic treatment plans. But it's a very detailed set of suggestions. It's not meant to be a prescriptive document followed to the letter. It's meant to be a kind of a very highly detailed model protocol that every institution adapts to their own environment.

Because -- so in that sense, I think to just say thou shalt follow Task Group 59 in doing high dose rate brachytherapy I think would be very difficult. It was not designed for that purpose. It was designed to be used with a lot of professional

judgement as to exactly what elements are to be implemented, how they're to be implemented, and what the documentation standards are for each of those elements.

CHAIRMAN STITT: Other comments?

MEMBER GRAHAM: To answer the questions you have there, both actually -- it's to really answer it. Because I think each standard has a potential to be handled differently. For example, the potential ANSI classification of sealed source that might be used in brachytherapy, you may well wish to put that in the regulations as a minimum standard for the type of sealed source so the physician can expect that source to hold together when he's using it.

On the other hand, your AAPM guidance documents ought to be putting guidance saying so that they can be modified as appropriate for that institution. So I think -- no, looking at these things, I can see several going both ways. So you really are going to have to look at them as they come out and see which fits where.

And I don't know that we can do anything without some specific examples you want us to look at because there are lots of things out there. Basic good practice standards -- physicians may come out with some particular things that might need to be incorporated in the guides.

Here again, you've just got to look at them as they come out. The problem you will always have is, as updates come out, you have to reevaluate that update, put it in the Federal Register, and give people a chance to comment on it before it really gets adopted.

So you will be lagging the industry practice some, and the societies that are adopting these standards have a problem in that they goof up on coming out with a new one that really doesn't cover all the things that the previous one did, they may not get accepted.

And so they may have a standard out that's no longer the one that's accepted by the agency. And those are just risks of the game.

CHAIRMAN STITT: Dennis?

MEMBER SWANSON: Just a quick comment bringing it back to the medical policy statement that we just looked at.

Is inclusion in the regulatory guidance, is that officially regulations?

MR. GODWIN: No.

MEMBER SWANSON: Well, your medical policy statement says NRC will regulate were compliance and standards are inadequate. So I think by definition of the medical policy statement, you're going to have to put them in the regulations in answer to your question.

MR. CAMPER: Well, -- I'm sorry, go ahead.

MR. GODWIN: If they were voluntary and were adequate, you could put them in your guides, you see, and let that be something to help people fill out the forms.

MEMBER SWANSON: I assume we're talking about what we're going to put in the Part 35 regulation?

MR. CAMPER: Yes. I mean, for example, you might -- in guidance space, you might have a requirement -- again, we've talked in the past about dose calibrator, for example. You might have a requirement that a licensee would have a quality assurance program for a dose calibrator.

You might, in guidance space, have an appendix which would contain those minimal things which were deemed to be appropriate like, you know, linearity inaccuracy and geometry and so forth. Or you might identify an ANSI standard or

AAPM document or something and the licensee would be expected to have a program equivalent to one of those.

It would be a pure guidance function.

MEMBER WILLIAMSON: I just think with some of the guidance documents, especially those that the AAPM has created for clinical practitioners, a certain level of flexibility would have to be built into the guidance. If you make it sort of like your QMP guidance document, 8.33 -- as I recall, the Lawrence Livermore evaluation of the QMP's was sort of less than flexible.

It basically took that guide as if it were engraved in stone. And if you didn't, you know, use the -- almost the exact language, you got cited as having -- or criticized for having a weak or inadequate QMP. So, you know, if you're going to take attitude for -- to an industry standard that's designed to be more like a paradigm or example that you can modify to fit the needs of your particular institution --

You know, to give you an example, in the Task Group 59 report there's a extensive discussion of staffing with some minimum recommendations, but a lot of discussion about how you might adapt a good HDR quality assurance program to institutions with different levels of staffing.

Well, you know, in terms of do there need to be two physicists there, one to check the other and so on, and things are sort of put into hierarchy and it would be really a burden, impossible, to just say everyone must follow every detail in that guide. It was not meant for that.

CHAIRMAN STITT: I second that. I was one of the authors on that one.

MEMBER WILLIAMSON: 56.

CHAIRMAN STITT: 56, right.

And I was very impressed because the individuals who were part of 56 were primarily physicists, but also physicians, and they were from all across the country. They were from academic, they were from private practice communities. And what seemed intuitive or obvious to one part was done quite differently from someone in a different location.

And so you can still come up with standards that are viable and are good references; but if you start then regulating down to the commas, it becomes unmanageable.

Are there other responses to the questions in front of us? Do we have what we're going to give them?

Jeffrey?

MEMBER WILLIAMSON: Oh, I'm sorry.

Well, I think that to include -- make reference to some of these documents in the guidance documents is a good idea. And I think the idea of saying in the regulations develop an adequate quality assurance program for your dose calibrator that we suggest you adapt, you know, maybe the guideline specified by some professional society and allow institutions to develop a plan that meets perhaps some minimum standards but allows for a lot of flexibility would be a good thing sort of like, as I understand, the quality management plan was supposed to be.

It was supposed to allow users a wide level of latitude how one would achieve the five aims of that program.

CHAIRMAN STITT: Dan?

MEMBER FLYNN: One point I was just thinking of.

Instead of direct reference within the regulations, as AAPM and others come up with updated documents, more refined documents, electron beam dosimetry

or whatever it's going to be, it could be direct reference within the regulatory guides that apply to the regulations.

But don't put all these citations in the regulations which then have to be updated every year and then we've got all these -- stuff in the mail. And it gets confusing. The reg. guide can be updated annually as opposed to the regulations. Wouldn't that be a simpler approach, put the reference in the regulatory guides?

MEMBER NELP: One question.

Do you have a shopping list or some perception of how many items would be included as "an industry standard?" Do you have any feeling for you're going to have 20 items or ten items --

MS. HANEY: That's where we're going next.

MEMBER NELP: -- or five items.

MS. HANEY: That's what we're moving to next shortly.

MEMBER NELP: Okay.

MS. HANEY: And I've provided a handout of things that we've been able to collect so far listing some various organizations.

MEMBER NELP: Okay, I guess I haven't seen that.

MS. HANEY: So we are moving towards that.

MEMBER NELP: Oh, you're way ahead of me.

CHAIRMAN STITT: Larry?

MR. CAMPER: Let me ask a question getting back to Barry's point. This idea of within the medical policy statement where voluntary standards are compliant with these standards is inadequate. Imagine a scenario where we have an issue -- well, let's take something that's happened.

We had the event that occurred in Indiana, Pennsylvania. And so we have a heightened regulatory concern as a result of that, obviously. And so now we're looking at what should we do in our regulations to address that, and there's a feeling that perhaps we need to do more.

How might we go about determining what voluntary standards -- or more specifically, the level of compliance with those voluntary standards that are in place? Because I think what I'm hearing you say is okay, we have this heightened concern as a regulatory agency. We want to do something. And as regulators, we'll do -- we're inclined to impose requirements because of a very tragic event.

We're being yo-yo, if you will. Okay, so we're in that frame of mind. And now we're saying okay, we've got to go tell the Commission if we're not going to impose more -- make suggestions for more regulations, what these industry standards are that are in place or how they're being complied with as to whether it's adequate.

How might we do that?

DR. SEIGEL: You pose a tough one because HDR was unfortunately sort of relatively early in its evolution at the time when that event occurred. It would be a little bit easier where there were mature technologies and there was an unusual event from a mature technology that you hadn't encountered before where standards were already clearly in place.

Now, I don't know at the time that Indiana, Pennsylvania occurred whether the radiation oncology groups and the physics groups had already written the standards for HDR, or were they still in evolution?

CHAIRMAN STITT: No, they were in the process at the time.

DR. SEIGEL: They were in the process?

CHAIRMAN STITT: Basically everything that physics --

MEMBER FLYNN: But there was the ACR standard radiation oncology around 1990, 1991 which involved for brachytherapy to have a -- perform a survey on a patient following the procedure. It was also part of the Part 35. So neither one of those was followed in terms of this incident.

That was the major probably deviation.

CHAIRMAN STITT: Right, that is true. So in that sense where the event caused the death of a patient, that standard that had been in existence for some time was ignored. But there are a lot more elaborate high dose rate -- so this still doesn't answer his question.

DR. SEIGEL: See, Larry, I'm not sure as I reflect back on -- and as we've discussed Indiana, Pennsylvania, whether that event necessitated new regulations. I mean, I think we as much as said that if that practitioner had followed what we generally believed was the standard of care and if that practitioner had followed NRC regulations, the event wouldn't have occurred.

Existing NRC regulation.

MEMBER FLYNN: But there were other things. You know, at the time I was there in Indiana, Pennsylvania, I was urging that we say something. And then about four or five days later, another source broke off in Pittsburgh. And because the Omnitron users were alerted, the physicist immediately retrieved the source from that patient so it never made headlines.

So now you're requiring -- now you had a temporary notice which is requiring people to be physically present at the console which was not part of --

DR. SEIGEL: But now we're getting into a different issue which is a truly legitimate role for government which is to gather data and let the world know what's going on. And we haven't gotten into the issue of reporting for purposes of

serving as a data clearing house which is part of the quality management discussion, which unfortunately I won't be here for all of.

CHAIRMAN STITT: Jeffrey, go ahead; you're next.

MEMBER WILLIAMSON: Okay, I guess there -- let's go to that incident. It's a very good example and a good question and it gets to the heart of the -- are the regulations the problem, or the enforcement strategy. So I think there are two things. If a serious incident like that happened, I think it should be of concern to everybody in the field.

And one question to ask is, are there adequate standards in the field to cover that? In 1991, they were emerging, but it was probably -- it's probably fair to say the standard of practice would be to do a survey of the patient after doing a high dose rate brachytherapy standard.

Certainly in the Task Group 59 guidance, you know, we used the should and shall and must kind of terminology characteristic of NCRP reports. The issue of the area monitor, that it works, and using a survey meter is, you know, definitely of the highest imperative.

So you had asked the question is there an appropriate standard or not. Okay, let's say there is in this case. Certainly in 1997, if this were repeated, it would be fair to say there is an adequate standard around. Then the next question is, did the individual institution adhere reasonably well to the standard or not?

If they didn't, then you sort of go and cite them and punish them and do bad things -- so on to them. But you don't necessarily have to spin off a new regulation just because that happened. You can ask whether the current standard of practice is adequate to handle that incident.

MR. CAMPER: Well, let me be clear.

I'm not implying that more regulations were in order. What I'm really getting at is trying to bring to bare the industry standards in terms of their appropriateness, which is a judgement call; or their compliance on the front end, you know, in keeping with the medical policy statement.

But with regards to voluntary standards, we would not be able to pursue an enforcement scenario relative to voluntary standards. We can only enforce regulations. I mean, if someone -- I mean, the best standard in the world could be in place for HDR and let's say a terrible event like that occurred again, and everyone would look at it and say gosh, I mean, they didn't do this, this, this, this and this.

They did not conduct themselves in keeping with the practiced standard. We would not be able to pursue that in enforcement space absent the regulation and a clear violation.

MEMBER WILLIAMSON: Well, in that particular case, even if there weren't regulations that impacted on the execution of treatment itself, there were plenty of regulations in Part 20 and perhaps in other parts of Part 35 that require you to maintain control of sources, so you could have --

MR. CAMPER: Well, there violations.

MEMBER WILLIAMSON: I think maybe the suggestion is, is if you're going to try and do an effective job of regulating the technical execution of radiotherapy, you better get used to making judgement calls; because if you try to define every little thing by a rigid regulation -- that's why everyone's complaining.

MR. CAMPER: No, I understand.

MEMBER WILLIAMSON: If you comply -- create a system where you could use, as you said, good common sense judgement, I think there wouldn't be so many problems.

MR. CAMPER: Well, I understand that. And what I'm really saying is that if one looks at the medical policy statement as it exists or as you have suggested it be modified, it seems to imply a burden upon the NRC to look to see before you or as you develop regulations what existing voluntary standards there are, and their adequacy, and the degree to which they're being complied with and the adequacy of that compliance.

And I'm searching for a way as to how we might make those judgement calls on the front end, which might then in turn lead to either no further regulatory development, some modification of the regulatory development which you had in mind, or perhaps it might result in a substantial regulatory development depending what you found.

CHAIRMAN STITT: Lou Wagner?

MEMBER WAGNER: I still have trouble with that discussion because, first of all, what you're addressing, Larry, I think is the patient. But the facts are in that case members of the public and other individuals were also exposed. You had the regulatory authority with regard to all those things.

The only thing you're trying to address is the regulatory authority with regard to the patient. See, and that's where we have to get back -- you're still thinking let's regulate the medical care of that patient. The medical care of that patient was indeed violated.

It's a terrible incident. But it violates all kinds of things besides NRC regulation. It violates other practice issues with regard to medicine. And if you think the Nuclear Regulatory Commission is going to be able to prevent isolated, rare instances of this sort by clamping down on regulation, that's just not going to occur.

MR. CAMPER: No, but again, I'm not suggesting that. Now, I mean, statement number two does talk about the safety of patients, okay; so the context of my question is in keeping with patients clearly, and that's in keeping with element two of the policy statement.

But what I'm really getting at is I'm not suggesting that more regulations are in order. I'm really trying to get at this idea of what -- you know, how can the agency going about -- go about evaluating the presence of industry standards, the adequacy of industry standards, the level of compliance with those industry standard, which in turn would have a substantial gauging effect, in theory, on the degree in which you do pursue regulation.

And I'm really getting at this point that Barry made, and what he's really saying is the place for industry standards is as you go about carrying out your medical policy statement, item two.

DR. SEIGEL: There actually is another problem which is hopelessly intertwined with this, which is that industry standard, in large part, or in substantial part, were predicated on existing NRC requirements.

MR. CAMPER: That's right.

DR. SEIGEL: And so you've got all kinds of circular reasoning going on here.

MR. CAMPER: That's right.

DR. SEIGEL: Would similar industry standards have evolved without NRC regulations? You know, I propose that as a randomized controlled study. You know, deregulate half the operation and see whether they go on about doing a good job.

MR. CAMPER: Right.

DR. SEIGEL: And I think -- my guess is that the standards would still evolve because professional organizations are increasingly being proactive in developing standards of care to keep all kinds of government interference out of their face.

And so I actually think that looking at the -- what the standards of care of and what is written down as standards, not just the legal standard of care, is a useful starting place in evaluating the regulations. Then the question is, can you find evidence from what is known about the practice that there's widespread violation of the standards or ignoring of the standards; and if so, step in.

CHAIRMAN STITT: Jeffrey?

MEMBER WILLIAMSON: Yes, I certainly concur from the -- just looking at the AAPM radiation oncology standards, what Barry says is really true. I think the bulk of the effort in the last ten years has probably been directed towards the development of standards for Lin Acc based radiotherapy, and that really hasn't been influenced by anything, you know, the agency has done.

Calibration practices were standard for linear accelerators and cobalt-60 well before they were required in Part 35. And there's been a natural evolution and increasing concern with formalizing quality assurance programs.

One more comment I will make is the more recent standards we're making in brachytherapy, we intentionally have taken the attitude that we're not going to reiterate, you know, Part 35 regulations. We made a conscious decision we will, at the same time we proposed what we think is a good standard for quality assurance program, point out where we disagree in footnotes with the current Part 35.

So there are, you know, numerous examples of where we disagree in both Task Groups 56 and 59.

CHAIRMAN STITT: Yes, I second that. That was specifically laid out in that fashion.

Are there other questions you want us to address before the segment's up?

MS. WOODS: Yes.

Once the standards are in place, how might we maintain the regulatory framework to include both the guidance and the regulations? Now examining this overall issue, there are three questions that have come to mind.

How can both NRC and the medical community ensure that continued public health and safety will occur?

How can the regulatory framework be maintained with standards and guidance that are both updated and remain widely acceptable to the community?

And what relationship should NRC have with these organizations?

CHAIRMAN STITT: John Graham?

MEMBER GRAHAM: I think part of why I've been struggling with the discussion of this whole section is that in light of the discussion we had on the general medical policy statement, you have to turn this paradigm around. We're saying that the NRC will regulate the radiation safety of patients only where justified by the risk to the patients and only where voluntary standards or compliance with these standards are inadequate.

So okay, in a training standard, taking a real simplified version, we rewrite 35 and it says that if you're going to do brachytherapy, you have to be board certified by the appropriate group. Now, that's an industry standard, if I'm not mistaken.

That's what we're saying that is.

DR. SEIGEL: It's a restraint of trade.

MEMBER GRAHAM: Well, I was saying here would be other alternative forces of that training. There might be other appropriate industry standards that avoid restraint of trade. Having done that, that applies. And you wouldn't write additional regulations unless there is evidence that that's breaking down, that it's failing to protect.

CHAIRMAN STITT: You're saying that the answer is found in point number two of the medical policy statement?

MEMBER GRAHAM: Yes, and that you wouldn't -- you know, it's not -- the regulatory framework doesn't have to maintain monitor of those standards. Those standards -- a reasonable and prudent person would expect that those standards will be evaluated, they will be upgraded, they will be modernized.

And it would only be if you could identify a risk to the patient that where the voluntary standard or the compliance with the standard is inadequate that you would then step in.

CHAIRMAN STITT: Dan?

MEMBER FLYNN: I think the regulation could refer to something that is accepted -- accepted standards by the professional societies in that area. For example, which societies would you deal with, which organizations? Well, it would have to be those that are recognized by the regulated community as being the major professional societies which represent that practice.

And there could be some debate, but there may be two or three professional societies for each category, radiation oncology; there may be two or three or four. And you could refer to the reg. guide which would be, let's say, updated every January 1st to include the latest set of documents as to how you should do electron beam calibration or however that might be rather than have to constantly be changing

the regulations because you have cited documents which are no longer applicable for that area.

So I think you could do that in the reg. guide in terms of continually updating the standard and the guidance.

CHAIRMAN STITT: Go ahead, Jeff.

MEMBER WILLIAMSON: Yes, I guess this is quite complicated to do all of this. The simple answer is choose your battles wisely, stay out of it as much as you can. Look at the second sentence that was appended to paragraph two of the revised medical policy statement.

And you know, you can save a whole lot of headaches by leaving it to the professional community how to, you know, develop their own standards and promulgate them for many, you know, small details of the quality assurance program.

But the more detail you go into, the more complexity and expense and trouble you're going to have.

CHAIRMAN STITT: We will be reminded, as Commissioner Jackson pointedly told Dr. Seigel, that's like the fox guarding the hen house.

MR. CAMPER: Well, also I think that from a practical standpoint in terms of the Commission trying to -- you know, the Commission has told the staff to bring industry standards to bare in this process. So, you know, I mean, I think it's fair to say for years, the industry has been developing standards. Many of them are very good.

Levels of participation vary. The AAPM has done its thing, the ACR has done its thing, and the NRC has done its thing. But what the Commission is clearly saying to the staff now is bring industry standards to bare in the process. And

so we don't -- we can no longer just stand by and, you know, say that ACR will do its thing.

What we've got to try to do is find some way to bring that into our regulatory world. Now as we pointed out a few minutes ago, direct citation in regulation is problematic, and I hear you saying the same thing. It's not a good idea.

I hear you saying okay, incorporating them into guidance may have value and you should consider that further. But what I think the staff is hearing the Commission say is bring industry standards to bare; and if we're going to do that, we need to have some mechanism for keeping that timely and meaningful over time.

MEMBER FLYNN: Now just to -- another point that Barry brought up I don't agree with is that there are a lot of regulation in terms of getting accreditation in radiation oncology that have nothing to do with the NRC. Some of it's paperwork like you must have a documented history and physical, you must have a pathology report of the cancer; but others are very important.

For example, periodic checks of patients under treatment, weekly checks of the port films to make sure the right site's being treated. That's not an NRC regulation. That's a professional society regulation. Periodic chart reviews, peer review of patients under treatment, all these are -- and also weekly checks of the dosimetry by physics.

These are required to get accreditation, and these have nothing to do with any NRC requirements. So I think there are standards that are far beyond what NRC requires by the professional societies in terms of being accredited by either the American College of Radiology or American College of Radiation Oncology even today that you must meet that are outside of NRC requirements.

DR. SEIGEL: You have to meet those to be accredited.

MEMBER FLYNN: By those professional societies --

DR. SEIGEL: Correct.

MEMBER FLYNN: -- to have your cancer center accredited, yes.

DR. SEIGEL: But accreditation is voluntary.

CHAIRMAN STITT: Right.

MEMBER FLYNN: Yes.

DR. SEIGEL: Then there are other things that are written down by professional societies that are standards, and those take on, as they are generally accepted, the force of standards of care such that in a trial for malpractice, those standards are often cited by the expert witnesses as representing the standard of care.

MEMBER FLYNN: Yes. If you're not -- if you have missed the target and you're not treating where you're supposed to be treating and you haven't taken port films to document the fact that you are hitting the target on a weekly basis, check films, then you could be -- you could find yourself in trouble if you're not checking the dosimetry that -- maybe the first physicist made an error, someone else is checking that calculation or rechecking the calculation every week, then you could find yourself in trouble if there's a malpractice issue brought up.

MEMBER WILLIAMSON: Well, you know, there are many areas I think especially with staff and public safety where the standard of practice and what AAPM and perhaps the Health Physics Society and many others would say are very closely intertwined and maybe disagree with one another on small details, but probably there's an awful lot of common ground.

Where most of the dispute seems to be coming is when you propose to make a regulatory interface for patient care, which is what we're talking about. And

Dan is absolutely right. There's many, many details and recommended procedures which perhaps you don't need to make a ruling on.

So to just simply say these standards of practice will be the licensing guide for implementing a given regulation might not be appropriate. It might be better to go through these various reports one by one and isolate out the recommendations pertaining to the issue for which you have direct concern.

So, for example, if you're not concerned about the details of treatment planning and high dose rate but you are concerned about the recommendations pertaining to surveying a patient, it might be better to make a -- limit your comment in the guidance documentation to that particular section and only hit those elements that are -- you've decided are relevant for inclusion in the regulatory program.

Because these documents are very broad scope and they're intended to cover the whole spectrum of activities involved in delivering what we consider technically adequate radiation therapy.

MEMBER FLYNN: That's why it should be in the reg. guide and not in the regulation. You have to meet the regulation. The reg. guide's referring to a document, but it's only referring to, by inference, that part of the document which covers the regulation.

MEMBER WILLIAMSON: Right.

MEMBER FLYNN: The reg. guide is -- you don't have to comply with the reg. guide, but you do have to comply with the regulation.

MEMBER WILLIAMSON: But I think sort of a de facto standard against which licensees are judged is do you follow the reg. guide unless you make some very specific arguments why you shouldn't follow X, Y, or Z. And I guess what I'm saying is it's too blanket a statement to say you should follow, in place a detailed

NRC reg. guide, Task Group 59 for high dose rate brachytherapy because there's a lot of things in there that might not even need to be addressed by NRC.

If they limit their focus of interest to one or two or three things, they could just sort of pick those out and say follow the TG59 guidance on those points.

MEMBER FLYNN: Yes, but that would be automatic. If the regulation said you had to do a double check of the dosimetry before the HDR treatment and then the reg. guide referred to some document, then the only part of that document which is applicable is the fact that you double checked the dose before the treatment as long as it's in there.

CHAIRMAN STITT: Barry, something to say before you go?

DR. SEIGEL: Well, just a comment on the whole discussion. I have to leave in a couple of minutes, so I just wanted to lay this out for the group.

I think what you're trying to do here is very hard. You're trying to have a philosophical discussion about regulations. And I actually think the group will get further and the NRC will get further at such time as you start sitting down and looking what's there and thinking about what's missing and actually starting to put regulations to paper or scratching regulations.

Because you can start with existing regs and sit down and say okay, what has this accomplished, this particular regulation? Is there an existing standard of a professional organization or of several professional organizations that already covers this? And do we have evidence that this is a regulation that is often violated, often abused?

And if this regulation weren't there and people behaved randomly, what would the consequences be? I actually think that, you know, this philosophical discussion about kind of general principles is going to just give everybody a headache.

And that there is a point where you need to sit down and just start plugging through Part 35 and seeing what's good and seeing what's not and thinking about what's missing.

CHAIRMAN STITT: But I support your comment and also think that it relates back to point two of the medical policy statement with the suggestions that we made, that as you're looking at what's there or what's not there -- we've made those comments. Where does this potential risk sit in regard to other parts of medicine?

So it does come together here.

One more comment, and then I think we need to move on to get our last agenda item.

MR. GODWIN: Well, I don't know that we've really addressed the issues that's on the slide. When you look at the questions, how can the NRC be assured, etc., it looks to me like we're talking about communications with each other and evaluations. And I think periodic outreach type communications from both side would help tremendously -- periodic review.

And I think that would be -- look at the same thing in B. Not only reaching out to the medical community, but to the -- you know, the general public and let them now what the standards are, how they're being applied, and what's going on, and why they can have confidence in them.

I think those are issues that really need to be looked at seriously and taken to heart. Obviously C, I think, is -- you know, you have to maintain your typical arm's length type relationship with the groups as you deal with them and try to balance everybody's comment.

But I think that's the answers you're looking for in those questions, or something like that.

CHAIRMAN STITT: Thank you.

MS. WOODS: I didn't have an opportunity to get to the listing that I referred to, Dr. Nelp; but anyone who has read that information is welcome to look it over and give me a call. I'd appreciate it.

MR. CAMPER: The compilation that Susanne has provided for you contains a number of standards we've identified thus far. There is -- the AAPM is in there, ANSI, ACR, NCRP, and some others. And we're still compiling.

MEMBER SWANSON: Do you want input on that?

MR. CAMPER: The main this is if you can identify, you know, certain organizations or categories of standards that we might not have captured thus far, that would be helpful to us.

MS. WOODS: Additionally, in your slides, there's a listing of organizations that we've come up with as possibilities. If there's anyone missing, please let us know.

MEMBER SWANSON: Certainly a couple I'd like to emphasize now, the USP medication errors reporting program which may solve a lot of your problems, okay. USP drug problem reporting program.

CHAIRMAN STITT: And my question would be how do we keep those things updated? We don't have a direct mechanism for that. Some of it could come from the members of the committee who are aware of new publications coming in.

CHAIRMAN STITT: Time to move on.

(Slide)

MS. MERCHANT: All right. I'm Sally Merchant, and I am going to talk to you a little bit about the quality management program and mostly misadministration.

(Slide)

MS. MERCHANT: In order to provide historical information on misadministration and risk, we have provided you a 1993 Commission paper entitled "Frequency and Consequences (Risk) of Misadministrations" dated 3-10-93 and, as promised at the last meeting, the "Assessment of the Implementation of the Quality Management and Misadministrations Rule, 10 CFR 35.32 and 33" dated 2-12-97.

Both of these documents were provided as background only and should be considered in that context. Obviously the Commission paper is a little old. And the "Assessment of the Quality Management and Misadministrations Rule" is a little thick.

During this segment of the meeting, I'll be walking through those items in the SRM related to misadministration and to a small extent quality management.

(Slide)

MS. MERCHANT: In the SRM, the Commission directed the staff to address how best to capture not only relevant safety-significant events but also precursor events. Therefore, we should identify those events that have safety significance. In your opinion, what incidents, events, occurrences should be reported to NRC?

CHAIRMAN STITT: That's a question. Go ahead.

MEMBER SWANSON: Personally I'd like to see all medical events reported, not necessarily to the NRC. Okay? I think one of the things you're hitting at is the issue of precursor events.

One of the problems with the quality management rule -- and I've said this before -- is that you place a level of reporting where you only got safety-significant events.

If you're truly interested in trying to solve problems or look at what causes misadministration, you need to capture also the diagnostic events for several reasons. Alvei got to have more data. Okay? Not only that. The people who have sloppy diagnostic practices are probably also going to have sloppy therapeutic practices.

So I think it's important if you want to capture precursors -- I think that's what you mean, is what is a lower level that indicates this -- that you need to go after all types of medication errors or medical events. Okay?

Now, we've also stated this before. I think that this has to be done in a non-punitive type of environment. I think it has to be, the people have to feel that they can report these events and they're reporting them for the purpose of truly trying to find out what leads to these events, what causes these events. And I think that has, in fact, led to all of the controversy to begin with about what level of reporting was required and so forth.

So I would encourage, as I just mentioned, something that the NRC needs to take a look at is again what standards are out there, what industry standards are out there.

There is the USP medication errors-reporting program, which basically is a voluntary reporting program where people report medication errors with the idea of looking at the problems. And this can be reported to and it's actually done in cooperation with the FDA right now. And people can specify whether they want their name reported to the FDA or whether they want this event to be looked at by the FDA anonymously.

Now, here's a situation where I don't think I speak for the nuclear medicine community. Here's a standard that I don't think the nuclear medicine

community is following all that well. I don't think the nuclear medicine community right now is reporting medical events to the USP medication errors-reporting program.

But here is something where you're back to your medical policy statements where compliance with these standards is inadequate. So you could have a regulation or a regulatory guide statement that says that you must comply with the USP medication errors-reporting program or you must participate in the USP medication errors-reporting program.

And that data would be collected. You would have a mechanism of collecting all types of misadministration data. You could have that looked at by a peer group of people.

I think one issue there is: What if you got several events occurring at one site? How does the NRC become aware of that? Maybe that peer group of people would say, "Hey, these are too many events at this one site. This needs to be taken a look at." Okay?

I think there's a program in place where you could get reporting of all types of medical events. I think people would participate in it more freely because it's an anonymous reporting program.

I think that you can mandate participation in that program. When you go out for inspections, you can say, "Are you participating in that program? If so, show me some of your submissions or just show me that you submitted to it." Okay? And I think you could tie that back together again with your whole misadministration-reporting system.

CHAIRMAN STITT: Jeff?

MEMBER WILLIAMSON: Well, I think for many of the applications in radiation oncology, which you've listed mostly here, might not be completely

appropriate. Very few of our -- how could I say? -- misadventures probably would be caused by machine failure.

Occasionally that's happened, usually, though, because of the complex team-oriented nature of the delivery process. It's usually an error on the part of some individual. So we're into this.

I would concur completely with Dennis. If you would really like to see a full spectrum of problems, including what I assume you mean by precursors, kind of near misses, irregularities where something bad might have happened and we had to take some corrective action to fix the system. So you want to know about things like that; right?

You have to develop something other than the misadministration-reporting requirement because that's a punishment-laden activity.

MS. MERCHANT: Keep in mind that we have a blank slip. So don't think of these as: What misadministrations do we want to report? The question really is: Of this list, what kinds of things do you think should be reported?

And it doesn't really have to be related to the old list. The old list is off the plate.

MEMBER SWANSON: Well, I think that's what we're saying. I think if you really want to go after precursor events, if you really want to look at problems, you would encourage the reporting of all of them. Okay?

Why would you want to limit it if you truly -- and I think you do want to look at precursor events. Okay? I think it's important, but it needs to be done in a different environment, a different setting than what is done now.

MS. MERCHANT: Some of the reason some of these things are on the list, such as machine failure, these are things that we might want to get out to the

community and say such and such "happened to this machine. It's a no-fault accident, but you might need to know about it."

CHAIRMAN STITT: Let's go down this side.

MEMBER NELP: I'd like to comment that Dennis' comment about diagnostic misadministrations, number one, Dennis, the incidence of those as we perceive them is very, very low.

So you're not going to collect a tremendous amount of data. It is sort of punitive in concept. And we have determined that there is no risk. So to me I think the NRC has plenty of things to do except beyond that particular area.

I would discourage going on to say, "Every time you stub your toe, we'd like to know about it" because there are so many other things to creatively do.

CHAIRMAN STITT: Other comments? Go ahead, right down the line.

MEMBER KANG: My comment is that currently the FDA, the Center for the Device Evaluation, is receiving all these machine failure reports. So unless that's a really radiation safety incident which we consider that's a high-risk incident, I don't see why the NRC has to collect those small machine failures.

Again, this issue has to be discussed, but I'm just reporting that FDA is currently collecting all of these machine failure incidents.

MS. MERCHANT: Are you notifying the other members of the community when it happens?

MEMBER KANG: Community?

MS. MERCHANT: Medical community. Are you sending out a bulletin or --

MEMBER FLYNN: We get a list. We get a list of all machine failures from the -- what's the agency? It's through the FDA.

MS. MERCHANT: Yes.

MEMBER FLYNN: We get that.

CHAIRMAN STITT: John, you're next in line.

MEMBER GRAHAM: We've gotten into discussions of moving towards a clearinghouse as a collection of any precursor activity, any activity that may not have caused harm but that might have some implication on system redesign or process change.

I'm not hearing where we're going to get down to explicitly defining at a national level what the goal of collecting all of this information is so that you could apply some rudimentary form of cost-benefit analysis to it.

Somebody is going to have to pay to input all of this stuff into some system. Somebody is going to have to pay for all the computers there to crunch all of this stuff. More importantly, somebody is going to have to pay for the people who can look at the output from those databases and try to detect some sort of pattern or trend that makes sense.

When you start pulling that up to a national level, I'm struggling. Now, within a system, I would completely demand all of this occur inside the health care system that I work with.

It's big enough so that they're going to collect a lot of data. It's small enough so I can bring enough players in the room that they're going to take a look at that data and probably change the way we deliver care.

But as we get bigger as a system, that gets harder. And if I try to apply that approach nationally, I don't know what it is you're going to try to accomplish.

And it's gone to cost a ton of money if it's going to be truly effective. I'm not sure who's going to pay the money.

MR. CAMPER: I think part of what you're seeing here, too, is clearly we would need to try to avoid any duplication in terms of what FDA gets at. But what you're seeing hidden here also is that if you go back and look at some of the misadministrations, sometimes misadministrations, what we call misadministrations today, have some of these causes. Unfortunately, the only way we become aware of them is through the offensive term of misadministration.

And so what you're seeing is the staff is saying, "Look, there are certain kinds of things that go on that seem to be reasonable for the regulator to be aware of." They may be precursor events. They may or may not be significant in their consequence by a given event. But things like leaking sources or software failures seem to be reasonable for us to be aware of other than in the context of a misadministration.

By contrast, if you go down to the last bullet, maybe there are events that are driven purely through dose consequence to a patient. It might be a wrong patient who gets a dose that they weren't intended to get or it might be the wrong treatment site. Perhaps, for example, a threshold needs to be assigned to a wrong treatment site which it doesn't have right now.

So what you're really seeing is an attempt by the staff to capture significant events, to capture precursor events, but to do it in some logical fashion other than a misadministration.

CHAIRMAN STITT: Dan?

MEMBER FLYNN: We've been addressing this at one of the small community hospitals around the radiation safety officer now. When I was looking through what requirements the radiation safety officer has, the safety committee -- and one of the things we do in the minutes of our meetings, which lasts an hour and a half

every quarter, is only a page or two long, but we report like Part 35 right now. Let me read this section, "Review quarterly"; that is, at the radiation safety committee. "Review quarterly all incidents involving byproduct material."

So when we have incidents -- and every meeting we have there's a couple of small, minor incidents. We put them in the minutes of our meeting. When the NRC inspectors come around, they're smart. So they want to see our safety minutes.

And they can either through looking at the safety minutes, copying them, and taking with them, -- I don't know -- or interviewing the key people, including the RSO, during the past year, any unusual incidents, not a reporting requirement, not a misadministration, but any unusual incidents. And they can start documenting these that already exist as part of what's required in keeping the minutes of a radiation safety committee meeting.

The information is right there already. And when you start seeing, when you go around to 2,000 hospitals and you start seeing, some little problem popping up too frequently, you can start your Office of Research or whoever will start to look at that specific problem to see if that small problem which is occurring frequently throughout the system could potentially lead to a bigger problem or could be associated with potentially a bigger problem.

So I think the information is there already because we put all of out incidents in our minutes. And there is no black stigma associated with a small incident that was handled.

And then also we're required to make a comment, a sentence or clause as to what action was taken to try to address that little incident. And there was

no reporting requirement involved. It's just required that we discuss it at our quarterly meeting, which we do, and put it in the minutes of our meeting and how we handled it.

So I think you need to look at the minutes of all the radiation safety committee meetings of all your licensees.

CHAIRMAN STITT: That will keep them busy.

MS. MERCHANT: Actually, we do do that.

MEMBER FLYNN: That's where you're going to find the incidents, then. That's where you're going to find the precursor events.

MR. GODWIN: Looking at this list, the first comment about the FDA, they do a list. It gets out late. If you try to read it, your eyes glaze over because it's just strictly a database printout, the one that I get. And it's not organized. You have to hunt for everything you find in it.

And it shows no indication that there's been an analysis of it to see if it's generic failure, single event failure, whether it's really an alert to all the community, or whether it's just, hey, this happened.

I appreciate FDA trying to do it, but timeliness and organization are a critical problem. They really need to look at that. I hope you can take that back to them.

Secondly, the one thing that I don't see on here that I sort of expected to see was: What about where the wrong pharmaceutical was provided by the pharmacy? I don't see that little item up there anywhere.

Thirdly, is any of this going to be fed into Part 21 requirements on supplying things into these kinds of events? That's another little thing you might want to think about.

And if you're really interested in looking at precursor events and really getting industry wide to get the true information, you really need to go to a concept that

FAA uses, which is the pilot-reporting system, where you can report you screwed up without getting banged for it. That's really something you might want to look at if that's what you're trying to do.

CHAIRMAN STITT: And we've discussed that here before.

MEMBER SWANSON: A response to two issues: number one, Dr. Flynn's to review RSO minutes. You're only capturing data from institutions. You're not capturing data from private practices. And I would state that I think you have a different set of problems or perhaps have a different set of problems leading to errors in private practices than you do in institutions.

Secondly, in response to Mr. Graham's issue about a central clearinghouse, the point I'm trying to make is that already exists. The USP has a medication errors-reporting program that is a central clearinghouse to report medication errors. They do that. Okay? It's already there. They have a telephone setup, and they have the rationale and the justification to do that to take a look at what is causing these errors on a national basis.

I gave a copy of those materials to the previous speaker. And you might want to take a look at them because it's a pretty good program.

Let me also point out that here's a situation where we have a standard that is being done by the rest of the medical community that we involving the use of ionizing radiation have to comply with or should be complying with also and getting back to our medical policy statement again.

MEMBER NELP: But it appears, like in my community as an agreement state, when we give the wrong radioactive nuclide to the wrong patient by error, which occasionally happens, we immediately inform our radiation safety people.

And that's a done deal, and it's a matter of record. And it's harmless, as we've previously discussed. And the information is truly available.

MEMBER SWANSON: The issue comes down to why you would want to do a national clearinghouse of data, rather than just reporting at your institutional level.

MEMBER NELP: The issue is: Why would the NRC want to do that if I don't perceive there's a problem? It's not going to identify a problem that we don't --

MEMBER SWANSON: I will tell you as a professional practitioner, I think that there is extreme value in a national clearinghouse to look at national data as to why problems occur.

It's not an NRC issue. It's a professional practice issue.

MEMBER NELP: Exactly. And that's exactly what I meant.

CHAIRMAN STITT: Dennis, you're talking about a system that's similar to the pilot-reporting system, isn't it?

MEMBER SWANSON: It's exactly similar. You report it, and you can report it anonymously. They have a mechanism to report it anonymously or you can report it with your name. You can report it with your name and specify that that information is given anonymously to the NRC in this case. Okay?

The USP has a cooperation in place with the FDA as far as this is concerned with traditional drugs. And I'm sure the USP would be happy to do a cooperative agreement with the NRC.

CHAIRMAN STITT: Jeff? Sally, I wanted to ask you: Do you have other things you're going to throw up as slides.

MS. MERCHANT: Just a little bit more.

CHAIRMAN STITT: Okay.

MS. MERCHANT: The next one had to do with capturing precursor events. And I'll just skip it in the time.

CHAIRMAN STITT: Yes. Okay.

MS. MERCHANT: I just have two more, just quickly.

(Slide)

MS. MERCHANT: This one I don't think there's going to be any controversy over. What do you think about the option of changing the nomenclature from "misadministration" to "medical event" or some comparable terminology?

If there's a better word than "medical event" -- "medical event" was used because we have reactor events. But if there is a better word --

CHAIRMAN STITT: So we have all of the questions in front of us, and we can use our time --

MS. MERCHANT: Almost.

CHAIRMAN STITT: Go ahead and put them all up. And that way we will consider them all fair game.

MS. MERCHANT: I won't put what the Commission said about QM. I just have two questions about QM.

MR. CAMPER: Do you have the question, Sally, on what is the appropriate threshold for reporting medical events as a result of exposure to patients?

MS. MERCHANT: No.

MR. CAMPER: That was in here. What's the basis for the threshold? We can come back. That's fine.

MS. MERCHANT: These would be all the questions that I have at this point: the "misadministration" nomenclature and what provisions of the QM rule should

be retained and why and what provisions of the QM program should be eliminated and why.

(Slide)

MS. MERCHANT: That's based on the Commission in the SRM, which said QM "should be reevaluated and revised to focus on those requirements that are essential for patient safety," such as "conforming patient identity, requiring written prescriptions and verifying dose. To the maximum extent possible, the requirements should be revised to be risk-informed." And "given this objective, a mixed approach of performance-based rules and otherwise prescriptive regulations should be pursued." That's right out of the SRM.

CHAIRMAN STITT: I suspect the group has comments on all of the remaining questions. Jeff, you have been waving your hand. Go ahead.

MEMBER WILLIAMSON: Well, if all you do is change the name from "misadministration" to "medical event" and don't revise the underlying definition and requirements, it sort of seems like you haven't done anything. I wouldn't think it's much of an improvement.

So I really think what's more pertinent to answer your question is helpful. We would have to discuss proposed revisions of what the criteria are and what the reporting sequence is in the proposed Part 35.

MS. MERCHANT: Actually, my assumption would be that, again, we start with a blank piece of paper. And "misadministration" would not at any point ever go on that paper, whatever nomenclature is decided upon and then what gets reported.

MEMBER WILLIAMSON: I would suggest, if I could just follow up on this, that if you're going to use the term "medical event," it might be appropriate to reserve it for events which really have a high probability of resulting in some adverse

medical effect on the patient and distinguish that kind of error from a strictly bookkeeping error, distinguish that from sort of a technical kind of treatment delivery error that doesn't have medical consequences and distinguish that, furthermore, from what you've been calling precursor events of more what we call in our institution notable event in our internal reporting system.

CHAIRMAN STITT: I have a comment, then Larry.

MR. CAMPER: Okay. I just want to point out to get at Jeffrey's point --

MEMBER GRAHAM: I think the Chairwoman said she had a comment and then you. Just to clarify for the Chair, --

CHAIRMAN STITT: I said that.

MEMBER GRAHAM: -- she gets to go first.

MR. CAMPER: Oh, I'm sorry. Go ahead.

CHAIRMAN STITT: I just want to follow up on what Jeff said because I think several of us who do consultations for the NRC have coined our own term when we refer to a technical misadministration.

And when I saw "medical event," I guess being a clinician, I view that as something that's patient-related. Particularly as the technology has a lot more gizmos involved; i.e., high-dose rate, some of the gamma knife, et cetera, et cetera, "medical event" may not be the right thing because it to me has more of an implication of health care patient-related. And a lot of this is technologic software/hardware, et cetera, et cetera.

I suspect that the Committee will have a lot of comment as we have in our very limited time between now and the 8th to at least start making some comments on Part 35.

All right, Larry. Wake up and go ahead.

MR. CAMPER: Can I?

CHAIRMAN STITT: Yes, you may. Do you want written permission?

MR. CAMPER: All right. The point I wanted to address was the issue that Jeffrey raised. And that is the purpose of this question is the singular direction from the Commission.

I mean, obviously they have heard the plea that the term "misadministration" is an offensive term, and they want to change it. They're suggesting "medical event." We have talked about "medically reportable event."

But whether we call it "pink events" or "red events" or "chartreuse events," whatever we call it, that is not to say that the definition for misadministrations or chartreuse events, for that matter, will not be changed.

I mean, I can tell you you will spend in this process a lot of time revisiting the definitions for "misadministration." There's no question about that. We will reexamine them again probably not unlike we did when we created the quality management rule. There will be discussion in the public meetings and so forth.

The other point that I wanted to make was there is a question in your book that you don't have a slide for, but it's important to get some perspective from you on it. And that is: What is the appropriate threshold for reporting medical events as a result of exposure to patients? What is the basis for that threshold?

In other words, by now we have the situation where we have this reporting of errors at 20 percent. As you know, most of those have no consequence to the patient. And, consequently, the plea that we hear from the community is: Why do we have to report these things when there's no consequence to the patient?

So what we're saying to you is, on the one hand, there might be ways to get events that occur, like software failures and machine failures and leaking sources and so forth without calling them misadministrations.

On the other hand, there may be events that occur, whether you call it a medically reportable event or a misadministration or whatever, that results from exposure to the patient. We're asking you: What is that level?

The answer is it's probably somewhere below abnormal occurrence that we have today but well above misadministrations as currently defined.

MEMBER NELP: Can I answer that?

MR. CAMPER: Sure. Please.

CHAIRMAN STITT: Go ahead.

MEMBER NELP: Well, it seems to me when we started into risk, which we haven't completed, we thought things that were risky were things that would have some notable effect on the patient that can be measured as a relatively acute effect of the administration or the misadministration. It seemed to me that those would be the events that you would like to know about.

And, for instance, 30 microcuries of I-131 plus or minus 20 percent is rather ridiculous, but if you get up -- and I'm not sure plus or minus 20 percent is where you want to be anywhere. It should be I think thoughtfully established that when you do something that is an event which is a mistake, is likely to produce harm to the patient, you want to know about it. And that's going to raise that threshold pretty high.

I don't think you want to deal with other lower thresholds. That would be my saying. And that's what would make the medical community I think happy when you get into the real world, instead of a theoretical world.

MR. CAMPER: We agree. And somewhere along the line, what we're asking for is an articulation of what that threshold is.

MEMBER NELP: And I think in terms of nuclear medicine therapy, I could probably come up with some pretty reasonable comments or thoughts on that.

CHAIRMAN STITT: While it's true that some of these things that are reported as misadministrations have a particular dose there, they don't have any particular effect on the patient.

But what's a lot more interesting is what was the event that led to that alteration in dose. And it may well be a lot more significant than the dose. Depending on how it's already set up or any future changes we might make, I think that's the data that's of greater importance and potential consequence.

Dan, then Jeff, then Dennis.

MEMBER FLYNN: I think the problem with radiation oncology is that you're going to have people who don't want to report. And they're going to say, "Well, I didn't think that this would result in harm to the patient." And they just don't want to report.

MEMBER NELP: You could set what you think would do harm and I could set in nuclear medicine what I think would be the lower limit of harm so that you would be happy and I would be happy. And they would have to comply. And that's what I think the regulation suggests.

CHAIRMAN STITT: Jeff?

MEMBER WILLIAMSON: Well, I guess there are different ways to look at this. To amplify on something Judy said for one point, you could just set, I suppose, as a reportable criterion some level of organizational concern, where if you had such a discrepancy between the dose delivered and the dose prescribed, you

would want to perhaps reengineer some component of the treatment delivery system. That would have nothing to do with patient harm. In principle, you could review it to see whether an appropriate corrective action would be made.

My point is because it's decoupled from patient reporting, a sort of a sense of being punished for being a good citizen isn't there. If you wanted to isolated out of that set of events a subset of patients who had some significant risk of really being harmed by these experiences, it would seem to me you would almost have to do a case by case review as an appropriate physicians, then isolate out of that set of patients the subset where you think additional reporting requirements should be invoked. That's one approach.

And I think Judy and I once submitted a proposal. I don't know if it ever reached here. We developed a new definition of misadministration. I think we called it something else. And we sent it on through the ASTRO physics and onto ACR. I don't know what happened to it.

It basically said that the threshold for reporting would be an overdose of more than 20 percent when the entire prescribed course of therapy -- this is for radiation oncology -- is included, including external beam and any other planned radioisotope procedures that are part of that course of therapy.

And the lower limit for the wrong treatment of the wrong site I think was the dose. Threshold dose had to be at least two gray to some site that wasn't planned to be in the treatment field or ten percent more than the dose that would have been delivered there anyway had the treatment been correctively executed, whichever was greater, I guess.

So we did attempt to make a criterion that we thought was closer but still not really good. But the two major points where there was a lower threshold for the

wrong site -- because right now you could deliver a microsievert to the wrong site and that would be a misadministration. That's not even of epidemiological concern.

And, secondly, it would have to include the whole proposed course of therapy, recognizing that brachytherapy, for example, is most often used in combination with external beam. And you couldn't draw any inferences from a 20 percent overdose for the brachytherapy component as to what would be the probability of patient harm without taking into account the other planned components of the treatment.

CHAIRMAN STITT: Thank you, Jeff.

And Dennis?

MEMBER SWANSON: One of the problems now with the definition of misadministration is it's far too complex. I would venture to guess that many of the violations of the misadministration rule are simply because it's too complex to remember, when I have to report this, when I don't have to report this. Is this is recordable event that's for 10 percent over and a misadministration event that's 20 percent over? I mean, it's very confusing.

And put on top of that that we have state agencies that regulate the accelerator-produced products that have a whole different set of misadministration reporting requirements, and what you've got is a very confused practitioner group as to what needs to be reported.

Again, let me reemphasize I think what we need to do is to move to a very, very simple misadministration reporting requirement, put it into a voluntary format, non-punitive reporting, and collect data. We need to do that.

I mean, let's take this out of the NRC realm, folks. This is a professional -- and I'll emphasize that. This is a professional responsibility. We are

guilty as professionals of not doing this in the past throughout medicine. Okay? We need to do this because we need to look at why these things happen.

We've got a 14 percent misadministration rate in our hospital with traditional drugs right now. Okay?

CHAIRMAN STITT: Gee, where does that go on our risk schema that we're setting up?

MEMBER SWANSON: You know, again, as I'm saying, this is a professional responsibility. It's something that we need to be doing as professionals and taking a look at why these things happen. Okay?

CHAIRMAN STITT: And I suspect that as the Committee and the staff work together as we get ready for the 8th of May, that portion of 35 will have a lot of strong comments from the group.

I happen to endorse your general opinion. And we'll see where we get to as far as the specifics. I think we have a lot of evolving to do yet.

We're getting to 5:00. And so I want to ask for us to close on this session. And the agenda for tomorrow will start at 8:00 versus 9:00 depending on where you look, but this leg of the table says 8:00 o'clock.

MR. CAMPER: The Federal Register notice says 8:00 o'clock is the problem.

MEMBER GRAHAM: There seems to have been two camps in this discussion. One is that we ought to set up a non-threatening system that collects as much data as possible so that professionals can identify system or process issues or patterns that could be corrected. And the other is that we should strip it down to only reporting those things that clearly represent probable damage to the patient.

Did we reach consensus on one or the other or are we recommending some combination of both or --

CHAIRMAN STITT: We're not going to recommend anything. It's way too late in the day.

MEMBER GRAHAM: Okay.

CHAIRMAN STITT: And this is much too difficult a topic. But I think you summarized the different issues. And it depends on what you're trying to get. If you're trying to punish somebody, then make some rigid criteria about dose.

If you're trying to look at the system and where errors happen, where you can make changes, I mean, it's the near misses that to me are far more important because if it's a near miss, you've identified something that was in the process and then were able to take corrective action.

I don't think we're going to have to vote on any part of this particular agenda.

MEMBER NELP: See, nuclear medicine is only ten percent of the action anyway. So not necessarily going to get that --

MEMBER SWANSON: I don't follow your comment.

MEMBER NELP: Byproduct material.

CHAIRMAN STITT: I'm going to call this the end of our meeting for the day, and we'll be here at 8:00 o'clock tomorrow morning.

(Whereupon, the foregoing matter was recessed at 5:10 p.m., to be reconvened on Friday, April 11, 1997 at 8:00 a.m.)

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