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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

(ACMUI)

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FRIDAY

APRIL 11, 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

ACMUI STAFF PRESENT:

WILLIAM B. McCARTHY

ALSO PRESENT:

LARRY CAMPER

CATHY HANEY

SUSANNE WOODS

SALLY MERCHANT

MARK ROTMAN

DONNA-BETH HOWE

A-G-E-N-D-A

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

(8:20 a.m.)

CHAIRMAN STITT: All right. It's after eight o'clock. We're ready to go with our final half day of the session, and this morning first presenter -- are we just moving up the agenda from nine to eight?

MR. CAMPER: Yes.

CHAIRMAN STITT: Okay. Take it away Cathy.

MS. HANEY: Good morning.

What I would like to do this morning is to zip through some different projects we've been working on and give you a status report of where we are on a particular project. Being relatively new to this position, I might not be able to answer any in-depth questions that you have, but I do have the cognizant staff here, and if I run into trouble answering a question, I'll ask for assistance from the back row over there.

These are the items that I'd like to cover today. First is the advanced notice of proposed rulemaking. Then I'll discuss a little bit about the patient release rule and the associated regulatory guide; NUREG-1569; the temporary instruction and the quality management analysis; and then the Carbon-14 petition for rulemaking that we have.

Okay. As far as the revision of Part 33 goes, this was discussed at previous ACMUI meetings. On November

14th, 1996, there was an advanced notice of proposed rulemaking. This notice had 11 questions, and it also contained some proposed rule language.

On February 12th of this year, the comment period closed. We received 21 comments during this time period. We had comments from private citizens, from corporations, academic institutions, federal agencies, state agencies, and professional societies.

There were 11 questions that were raised in the Federal Register notice. I've grouped them into three different categories. The first set had to do with codifying licensing practices. The next had to do with more generic issues associated with broad scope licenses, and then a group that would be inclined in the defining of the broad scope licenses.

Under the codifying of licensing practices, these are the questions, more or less the content of the questions that was asked. What I'm going to do is go through and give you an idea of what the commenters provided to us.

The first one has to do with the responsibility of licensing management for radiation safety program. Here this question was meant to focus on the importance of the management structure, reporting paths, and the flow of authority.

There were 16 comments that we received in this area. The majority of the comments were against bringing this into the regulations. They said that the roles of the management vary significantly for the different type of broad licenses, and therefore, it would be very difficult to do, and that it was necessary to keep the flexibility for any size program in the Part 33.

Those that were in favor of it felt it was important to standardize the requirements for all broad scope licenses.

The next question had to do with the duties and responsibilities of the radiation safety officer and the radiation safety committee. Key in this question was the training and experience requirements for the radiation safety officer.

Again, the majority of the commenters were against this, felt that it was very difficult to do this in the regulation, given the different sizes of the programs, and it was better left in guidance space.

Those that felt that it should be included in the regulation felt that it should be performance based, and it should be commensurate with the licensed activities.

The next question had to do with the training and experience of the authorized user. Here we have the guidance currently in the regulatory guide, and we were looking at the

flexibility for developing program specific requirements for the facility.

Again, the majority were against bringing this into the regulations, feeling that it was not practical, citing diversity, and feeling that it should be left in guidance space.

Those that were in favor of this requirement felt that it was important to set high standards and increase the training for these individuals, given the types of the program and the rigorous nature of these programs.

The next question had to do with incorporating topics addressed that are in the regulatory guide right now, things like administrative procedures, inventory and accountability, audits and appraisals, and safety evaluations and exposure control.

In this case, all of the commenters were against bringing this into the regulations. There were no -- none of the commenters were in support of this. Basically it was left -- those against it felt it was best in guidance space. Things are working fine; leave it there; don't make any changes.

The last question had to do with permitting licensees to make changes to the radiation safety program. Right now in Part 35, licensees are allowed to make ministerial changes to their program without coming in for a

license amendment. Should something like this be brought into Part 33?

The majority of the comments were in favor of this, felt that it would be a good idea because it would avoid unnecessary license amendments, and it would encourage licensees to take advantage of rapidly changes in the technical improvements in technology that's out there.

Those against it felt that the current program was working well and let's leave it alone.

The next group of questions had to do with what I will call generic issues. The first one was should there be requirements for inventory and accountability of licensed material. This question is founded in should it be codified, and feeling that some of the requirements for inventory and accountability were inconsistent in the regulations.

The majority, again, felt that this was not needed in Part 33. They felt the current requirements were adequate and leave it in licensing and inspection place.

Those that were in favor of bringing this into the regulation said that we needed to. You could go ahead and bring it in, but make sure that there was some flexibility in the requirements, and any need should be based on the hazard of the material.

The next question had to do with separating risks from internal exposure pathway and external radiation. This

was brought into the ANPR, as you might be aware, because of Commission direction.

No commenters were in favor of separating this risk. All those that commented on it said that it's already addressed in Part 20 and leave it in Part 20. Do not bring it into Part 33.

All right. The last question had to do with the regulatory approach. Should it be performance based or prescriptive? Again, there were no commenters that were in favor or wanted it to go prescriptive. Everyone was in favor of performance oriented, citing reasons for flexibility due to the diversity of the programs.

One commenter said that you should be prescriptive for the training and experience, but as an average it should remain performance based. One of the reasons cited for not using a prescriptive range is that it increases cost without a concomitant increase in safety.

The last group of questions dealt with defining the broad scope licensees. Questions were: should we, rather than having an A, B, and C type of broad scope licensee, should we replace all of this with a single type?

The majority of the commenters were against doing this. They felt that it would limit the smaller institutions from becoming broad scope licensees, and it would also impose

an unnecessary set of rules on the smaller broad scope licensees.

Those that were in favor of it felt that it would streamline the licensing and the inspection approaches to broad scope licensees.

Another question had to do with should master material licenses be included in Part 33. The example of the master material licenses would be the Navy and the Air Force where we have a license with them and they go out and do the inspection and the licensing, and then we do periodic checks on their main office and do some inspection accompaniments with their staff.

Seven commenters were against this, feeling that the masters material license program has worked well to date. There's no need to codify it until NRC has more experience with this type of program.

Only one commenter felt that the master material license should be codified.

The last question deal with including multi-site facilities into Part 33. Again, seven of the commenters felt, no, that the current situation was acceptable, and the one that felt that it should be included just said that it should be included.

I'm sure you saw some general trends throughout the answers to all of these questions. So what I'll do is go

-- for those that were pretty much in favor of doing what was posed in the Federal Register notice cited the following reasons:

One, that it was good to clarify the regulations concerning broad scope licensees. There should be some standardization with common practices, and if we have the standard practices and standards, it will help the facilities in allocating resources.

The prescriptive requirements are impractical due to diversity of uses in management.

Part 33 should be performance based, and that performance based regulation empowers the licensee to continually develop their program and areas for improvement in their program.

Those that were against the changes said that there was really no reason for the proposed changes. Pretty much things are working well now. Don't make a change.

They felt that or it was cited that the small incremental increase in risk posed by the incidence of loss of control does not justify overhauling Part 33. There's too much diversity among the size of the licensees and the types to focus on one particular type of use, and it was felt that the details should go into the regulatory guides as examples rather than into the regulations.

So the next question that comes up is: where do we go from here? Right now we are waiting for the Office of Research to provide us with a rulemaking plan for Part 33. That's due to our office by the end of this month.

Based on what they propose, we'll review that and decide if we want to go forward with that. If we do go forward, it will go to the Commission. The Commission will make a decision whether we proceed on rulemaking, and along with those recommendations where we go.

We are due to have a proposed rule issued in the Federal Register by December of this year if we do go along that route. So we're pretty much in a wait mode right now. Once we get to the end of this month, then we'll be moving forward and back to the Commission with that.

And any questions on Part 33? Okay.

MEMBER GRAHAM: I have a question just on the whole issue of rulemaking plans. Is there an outline? That still from my perspective is a black box. I don't understand what those three --

MR. CAMPER: No, there's a management directive, 6.3 or 6.33, I think, that describes the rulemaking plan or the rulemaking process and the rulemaking plan is discussed within there. We can get you a copy of that if you'd like.

MEMBER GRAHAM: And is that truly an onerous document or --

MR. CAMPER: No, no. It's actually about half of a Tom Clancy novel.

MEMBER GRAHAM: But does it read as fast?

MS. HANEY: No.

MR. CAMPER: No, it doesn't read nearly as fast. I can tell you that.

MEMBER GRAHAM: Refresh my memory. The reason that we got into this discussion in the first place was motivated by why? We went out and asked, and from what I'm hearing the vast majority of the people that responded said it ain't broke; don't fix it.

MR. CAMPER: You mean what got us to Part 33?

MS. HANEY: What got us to Part 33?

MEMBER GRAHAM: What got us into this discussion of whether we ought to revise it?

MR. CAMPER: There were three reasons that got us looking at this. Let me do the one that is probably the least palatable first.

There was a couple of events that occurred involving P-32 in which individuals received uptakes of P-32, most likely through malicious intent, although the concern was or that grew out of that is are materials being adequately controlled, secured, and accounted for?

On a more positive vein, the two things that were going on about the same time, and these were going on before

the P-32 events, although one looks at Part 33 for broad scope licenses, you will find a very skeletal regulation. What has happened with broad scope licensing is that for years and years and years now a process has developed in licensing space and through guidance documents that support a very significant and large licensing program.

Broad scope licensees, as you know, are very complex entities, and it's difficult, frankly, to pick up Part 33 and see the regulatory framework for what we actually do in licensing broad scope licenses, and so the feeling was we really should be regulating this complex program through an appropriate regulatory framework that undergoes the public process rather than through an elaborate network of guidance and licensing protocols.

And the third thing is that there was a desire, as is allowed in Part 50, for broad scope licensees to have the clear authority for making substantial changes in their program without having to seek prior approval from the Agency, as allowed by the flexibility in a manner similar to what is currently allowed for Part 50 licenses.

So there were three primary motivating, driving forces to take a look at Part 33.

CHAIRMAN STITT: Aubrey.

MR. GODWIN: Just as a side comment, the compatibility group that reviewed the NRC regulations for

compatibility, I believe I'm correct in saying that they determined that all of 33 was not a compatibility requirements on the states. At least that committee did not feel it was needed as an absolute requirement for having a safe program.

MR. CAMPER: Yeah, what Aubrey is referring to is the Commission's entire compatibility or the agreement state program in terms of adequacy and compatibility has been undergoing some review by the Commission now for some time and significant changes are under consideration by the Commission as we speak, and as part of that process, a task group was formed consisting of agreement state regulators and NRC regulators in which they went through and took a look at every regulation that we have, and through the establishment of a set of criteria then tried to determine and make suggestions as to what levels of compatibility should be assigned to all the regulations.

And you know, we have Division 1, 2, 3 and 4, and what they actually created was a new nomenclature and some subsets and characterized how regulations should be assigned in terms of compatibility, and that's under consideration as part of the overall policy change under consideration now by the Commission.

CHAIRMAN STITT: Jeff, go ahead.

MEMBER WILLIAMSON: Yeah, my memory is rather foggy about what our consensus recommendations were at the last meeting. Could you summarize them?

MR. CAMPER: I can't, no. I don't have that in front of me. I mean we have to go back and --

MEMBER WILLIAMSON: Well, let's see. Was that the last meeting?

MR. CAMPER: Well, we have the minutes. That's what I'm saying. Was that the last meeting? If not, we can get them. I don't want to try to resurrect a consensus of this steam committee off the top of my head. I'd rather go back. We'll get it for you if we don't have it.

CHAIRMAN STITT: Jeff, I can't remember specifics, but there were a lot of general comments sort of along the line of John's phrase "if it ain't broke, don't fix it," but John.

MEMBER GRAHAM: Well, in light of the public comment that has been received, I would suggest that the ACMUI may want to communicate to the Commission that the board scope licenses are, by definition, broad, and an attempt to regulate these programs by rulemaking could limit the public benefit gain through activities performed by these programs with broad scope licenses, and that we recommend retention of the current regulatory approach, and I'll throw it out just for discussion.

CHAIRMAN STITT: Is this like a motion?

MEMBER GRAHAM: Right now --

CHAIRMAN STITT: Discuss it for the time being?

MEMBER GRAHAM: If it's going back to the Commission, I guess I'm questioning whether we ought to send a recommendation, and I think that is a summary of the discussion we had in November.

MR. CAMPER: Yeah, I was going to say I'm looking through the --

MEMBER GRAHAM: The only area I think we might have had discussion going the other way was on this issue of whether the broad scope licensees should be able to make amendments or changes. Let me find the verbiage.

MS. HANEY: It was the ministerial changes.

MEMBER GRAHAM: Exactly. If anything, they were proposing that they would widen it, open it up, make it more broad, more flexible.

MR. CAMPER: I don't see that.

MS. HANEY: That was discussed in the May meeting, Larry.

MR. CAMPER: Yeah, I was going to say it wasn't in the November meeting.

MS. HANEY: They gave a status report in the November meeting.

MR. CAMPER: Right. So it must have been the May meeting. What we'll do is we'll resurrect the minutes and share with you exactly what the Committee had to say in terms of its findings. I think John's point is right. As I recall, many of the Committee's comments were very similar to the comments that Cathy has shown here.

I think John probably characterized it just about where you ended up, but we'll pull that up.

CHAIRMAN STITT: I think that's reasonable. We've got all morning, but we could review what we said, think about it again, and make a summary statement. It makes it look like we are reviewing our work and that we do have some consistency to our approach. I think that would make a fitting -- I assume you wrote down what you were just saying.

MEMBER GRAHAM: Yes.

CHAIRMAN STITT: Good. Are there other comments for Cathy?

Jeff, did you have something or did you already say it?

MEMBER WILLIAMSON: Well, I guess perhaps I should wait till we see the minutes. I remember having some concern about the accounting and security requirements being driven by these one or two incidents, and so I was curious to know how the final rule --

CHAIRMAN STITT: Right. I remember we had a lot of discussion about closed door coffee breaks.

MEMBER WILLIAMSON: To what extent the rule was modified to reflect our recommendations, if it was modified at all.

CHAIRMAN STITT: Let's see what our own minutes show us.

MEMBER FLYNN: There was a lot of discussion also as to where to draw the line. If you go into a lab and there's a minute amount of diagnostic isotope in some column or some experiment that's going on, and should that lab be totally locked up and secured at all times if the building has some --

CHAIRMAN STITT: Right.

MEMBER FLYNN: We had a lot of problem with where to draw the line.

MR. CAMPER: Also, too, I mean -- and you probably know this -- but, I mean, depending on what happens, if the staff proceeds with the rulemaking plan or if it proceeds with a proposed rule, obviously you will be in the loop on that. It will be a specific agenda item in which you'll be asked to provide input, of course.

MEMBER SWANSON: Having not read the current broad license regulations prior to this meeting, is there some kind of a performance standard in there, in the regulations,

about reporting structures and insuring that it reports to the appropriate administrative person having authority over the program?

MR. CAMPER: My recollection is not, no. Part 33 is extremely limited.

MEMBER SWANSON: The only reason why I say that, there is, you know, a growing trend out there for fraud license institutions, big medical institutions, to be acquiring other practices, and you know, what we're seeing at the University of Pittsburgh, and I think actually a concern, is pressure being put on the institutional radiation safety office to assume responsibility for private practices that the institution has acquired.

And the concern that then comes up is: what is the -- you know, how does that private practice report administratively to the person in the institution that oversees that program?

CHAIRMAN STITT: Yeah, let's hear from John, and, Dan, are you in that same situation with some of the institutions being brought up there?

MEMBER FLYNN: Yeah. I'm not sure how it's being handled, quite frankly.

CHAIRMAN STITT: John.

MEMBER GRAHAM: Well, the first observation, most of those acquired private practices by definition cease to be

a private practice. So we treat it as it's become part of our legal entity. I've never met a program at a large health care system that was headed up by a physician or a group of physicians that were shy. They tend to be some of our heaviest hitters.

We throw the weight of the corporate structure behind them through the radiation safety program, the radiation safety committee. So their own egos tend to make sure they keep control of what they want to control, and we throw the weight of the organization behind them.

So I don't know that it's a true organizational issue. Corporations are struggling with the reality that you bought something. You bought everything. You didn't just buy the volume and the activity. You bought everything that goes with that practice, and you'd better make sure your whole corporation has talked through what it means.

So I agree that that needs to occur, but I don't know that there's anything you could change a regulation that would facilitate that process.

CHAIRMAN STITT: Aubrey, did you have a comment?

MR. GODWIN: The multi-site issues is one that's very real, but it's not limited just to broad licenses, and you need to recognize that. Whenever a hospital corporation buys several units in different cities and even in different states, they obviously want to minimize their payments with

taxes, and they want to get one license to cover them all if they could, and so you have to look at that and then realistically look at how are they exercising control, and a lot of times it goes to such things as who signs the paycheck, that kind of arrangement, and who signs the personnel evaluations on the personnel.

These are issues that probably are not real amenable in terms of just that one regulation, but it's a real issue both for broad and non-broad licenses.

MEMBER GRAHAM: Larry, maybe you can clarify. The issue of including multi-site facilities I thought at least was a suggestion to move in the direction that there would be one corporate entity, but that might not have the same level of control, and if I understood your feedback, seven of the respondees said you shouldn't change it.

MS. HANEY: That's correct.

MEMBER GRAHAM: And only one said change it?

MS. HANEY: Right.

MEMBER GRAHAM: So, again, I think if we left it the way it is, it's a balance of public safety versus broad scope license flexibility.

MR. CAMPER: A couple of things. Dennis' question first. No, it's not specifically addressed in Part 33, and if one looks at Part 33, you really find it's like two pages, two, two and a half pages in the code. There's very

little there. I mean basically the types of broad scope licenses are described, the need to have a license, some conditions which can't be done in a broad scope license, violations, criminal penalties, and so forth.

There's almost nothing there, and that's one of the things that troubled us immensely, was if we have a licensing process in place today for very large facilities, very complex facilities, that has grown up in licensing space and all of those practices and procedures and requirements that we impose have never undergone the public scrutiny of a rulemaking process, and that seems to be illogical, to license such complex programs in the absence of a clear regulatory structure.

So we wanted to try to get Part 33, you know, where it was much more clear as to how broad scopes are structured. Now, Donna-Beth was pointing out to me that, of course, other parts apply. For example, broad scopes are doing medical uses, you know, Part 35. Some of the requirements of Part 35 are imposed upon broad scope licensees and other parts can apply as well.

But, once again, it's done through license condition. Okay? And so what we're trying to do is make it very clear what the broad scope program is all about.

The question of multi-sites, I mean, we do have some licensees already that are not broad scope licenses, but

are multi-site licensees. I mean the one that comes to mind most readily is Syncor Corporation, recently consolidated, I think, something on the order of 30 separate licenses into one license that's multi-site.

Another large commercial radiopharmacy concern has expressed an interest in doing that as well.

CHAIRMAN STITT: Jeff first and then Dan and Judith.

MEMBER WILLIAMSON: Yeah, I'm kind of puzzled by some of the discussion concerning the management of acquired private practices by the home institution. Isn't that covered in Part 35 and has nothing to do with Part 33 if it's a medical facility?

MR. CAMPER: Well, what's covered in Part 35 is that there must be a license, and a license can be issued to either a private practice scenario or to an institution, but that doesn't get into, you know, these issues of who owns and acquisitions and so forth. It simply means that a license has to be in place, and the thrust of all of that, of course, is the conduct of the radiation safety program.

MEMBER WILLIAMSON: Yes. Well, for a medical use institution with a broad scope medical license, Part 33 is not operative; is that correct?

MR. CAMPER: No, Part 33 is operative for a broad scope license, and broad scope licenses have imposed upon them

some of the requirements of Part 33, and that's done through the license condition, but the license is a broad scope license issued under the authority in Part 33.

Part 30 applies. Part 33 applies, and conditions or parts of other subparts, like Part 35, are imposed by condition

MEMBER FLYNN: I had a question. On the Indiana, Pennsylvania accident in terms of the one entity having multi-sites and that under one license there were multi-sites that were distant from each other under the one license, does the licensing condition meet that situation in terms of, let's say, for example, the oversight of the radiation safety officer of each of these sites and the functioning, whether there's a functional radiation safety committee that could effectively cover multi-sites which are some distance from each other?

Did the licensing conditions -- did they break down in that situation? Could they address a future problem of that type or some other type where there doesn't appear to be enough oversight by the RSO on each of the facilities involved?

MR. CAMPER: Well, in the case of the Indiana, Pennsylvania incident, obviously there were some on-site, first-hand problems that, of course, created the unfortunate

fatality, and there were regulations that were not followed by the staff in attendance at the time.

In addition to that though, and when we looked at that organization in total, there were problems that were uncovered with regards to control and management of the complex at large, given that there were multiple sites involved. Yes, there was some of that, as well.

So there were really two separate kinds of things.

MEMBER FLYNN: Right. I'm talking about the second issue. I know about the first.

MR. CAMPER: I understand. I don't recall any clear indication that that management problem, you know, was the cause or at least a partial cause of the event that occurred in the one center though, but, yes, we did find problems, and, yes, we did cause certain changes to take place in that particular organization in terms of its multi-site complex.

Now, having said that, what we do, on one hand, we have to recognize and be flexible to the changing dynamics in the health care industry. I mean, clearly, as you all know, business is being done differently. We don't think it's appropriate, on one hand, for a regulatory agency to not recognize those changing dynamics.

What's essential though in that process is that we insure that an adequate set of controls and processes are in place to allow multiple sites to be managed.

For example, in the case of the Syncor situation, just as an example, they have a radiation safety committee. They have a complex management structure involving a corporate radiation safety officer. They have an organization in place that monitors the various sites, that conducts audits of the sites. They have feedback mechanisms where information is channeled to the radiation safety committee.

The radiation safety committee has evaluation processes they go through, and we looked for all of that before issuing the multi-site license.

So the licensee, if you're going to have multiple sites, then obviously you have to have a complex management structure to manage multiple sites.

MEMBER FLYNN: Well, my question is then: does New Regulation bring something more in addition to what you could control under just licensing conditions for specific situations?

MR. CAMPER: No, I think that you can certainly do an adequate job of protecting public health and safety and imposing management operating conditions on licensees through the licensing process. I mean we have done that and the agreement states have done that successfully for years.

The issue though is that when you impose license conditions, you're not doing that in the sunlight of the regulatory process, if you will. In other words, those requirements are never subjected to the rulemaking process and the scrutiny of public comments.

If one looks at Part 33 today and then one looks at a broad scope license and the conditions that are imposed, our concern was that we had this elaborate set of conditions that we impose. Yes, they work. Yes, they protect public health and safety. No, they're not broke, but they've never undergone the scrutiny of the public rulemaking process.

We thought that they should.

CHAIRMAN STITT: Judith is first and then Kenneth.

MEMBER BROWN: Well, I'm going to be bold because this is my last meeting. This is my last meeting, right?

(Laughter.)

CHAIRMAN STITT: We'll make sure that it is.

MEMBER BROWN: Well, I found this discussion so generic as to leave me struggling with what are we talking about, and I think I've caught on, but it's taken me the previous 20 minutes, and when you talk about incidents, I don't know if you're talking about the intentional thing at NIH or the accidental thing at Wilkes-Barre or the accidental thing at Indiana, Pennsylvania.

I just pity the next person who sits in my seat to try and keep up with what's going on here when people aren't really talking about what the impetus for even looking at Part 33 is.

I don't know how many people around the table use Part 33, you know, in daily conversation, you know, outside of this building, but I think just as a general admonishment that you all need to be -- "you all"; I've been sitting next to Aubrey.

(Laughter.)

MEMBER BROWN: I'm sorry.

MR. GODWIN: Pretty soon you'll say "you'uns." Okay?

MEMBER BROWN: That's right.

That I would like to see the staff be much more down to earth so that John, who's really bright, isn't saying, "Refresh my memory," and Jeff, who's really bright, isn't saying, "What did we say now?"

I don't think I'm the only one even though I'm in the best position to be confused. So I remember in the past people being more direct, and I would appreciate for the next person who sits here kind of a summary. The reason we're looking at this is because these things happened.

Now, having said that, I have some questions. Has anything else happened? And what exact incidents are we talking about that a revision of Part 33 would correct?

MR. CAMPER: Well, I have the minutes now from last time, and you'll find there's about seven or eight pages of the minutes are associated with the discussion of the revision of Part 33, and a lot of questions were explored with the Committee at that time. In fact, there's about -- I don't know -- nine or ten of them, and then there's some recommendations from the Committee, which we can step through if you'd like.

But the incidents that I was referring to that happened at the same time that we had already begun to look at Part 33 are the two Phosphorus-32 events, one of which occurred at NIH --

MEMBER BROWN: Right.

MR. CAMPER: -- and one of which occurred at MIT, and they were cases in which an individual ingested P-32 apparently from a malicious intent.

MEMBER BROWN: Okay. Thank you.

There has not been anything remarkable since the Wilkes-Barre thing that was shown to be a technician who made a mistake; is that correct? Nothing to add?

MR. CAMPER: No, that's correct.

MEMBER BROWN: So it really does seem to be a blip, not a trend, as people were afraid when those two things followed each other so quickly?

MR. CAMPER: Perhaps.

MEMBER BROWN: The other question I have is in the commenters that responded. In the list it says private citizens, and I'm wondering who were these people. Were these like former ACMUI members or are there any really private citizens who know anything about what we're talking about?

MS. HANEY: We can check and let you know.

MEMBER BROWN: Okay.

CHAIRMAN STITT: Good comments, Judith. Yeah, we're lucky we have John and you to make those "gee, could you refresh my memory" comments. Several of us were going, "I have no idea what this is regarding."

A copy of our minutes are still hot off the copier. Do people want to look through these while we're continuing our discussion so that we can get back to John's comment?

Jeff, did you have a question a while ago or, no, it was Dennis. You had a comment?

MEMBER SWANSON: I was just going to finish up on my concern about what's happening in the medical practice. I think what we're seeing out there is that the institution is acquiring from a business perspective these practices in such

a rapid manner that it's difficult for the infrastructure to keep up with the institution, and this goes beyond the radiation safety committee. This goes to IRBs. It goes to legal counsel, legal counsel being the people that would define the reporting structure, et cetera.

And at the same time, the infrastructures are asked to begin to assume responsibility for these other sites, and where our thinking is at sort of right now, because we're definitely in that mode -- the institution is acquiring practices every day -- you know, we're a little concerned and rightfully concerned that until we have that management structure fully defined and until we have the controls and systems in place, that we have to keep these other institutions with their individual licenses because it puts the whole program at jeopardy if we were to take them under our broad license at that point.

So that's just to summarize where we're at with this, and I think this is something that everybody is out there facing right now, that the NRC needs to be aware of when they go and look at these situations.

CHAIRMAN STITT: Aubrey.

MR. GODWIN: I think if you look at both NRC and all the agreement states you'll find that merely serving the institution doesn't really legally transfer the license or any changes to the license. So from a very strict legal point of

view, yeah, you can sell it, but you can't do any changes until the appropriate regulatory authority agrees with those changes, and that's a rather key point, and this is true whether it's for a broad license or a non-broad license.

The key issues the states felt now on the broad license issues, which I sort of separate these two out -- I see that multi-facility thing as being sort of a generic problem across the board, not just with the broad licenses -- but the states felt that the broad licenses could be issued without having Part 33 because there's really nothing in 33 that gives you that much guidance. It basically just says how you're going to classify things more than anything else. It really doesn't give you anything that, I guess, Parts 30 and 31 or 32 have in them. So the states didn't see any real advantage to having 33.

The philosophical point though that is very real is that many broad licenses have essentially the identical conditions in them that are repeated over and over, and that basically constitutes a rulemaking against a certain class of licenses that does not go through the administrative process, and it's sort of a key point, you know, that they have to keep an eye on in their regulatory business.

These conditions, when they're imposed routinely, without going through the regulatory process are being put on you in such a way that the applicant is not in an effective

position to argue about it. If the condition is put on there, he wants his license. He's out of business until he gets that license, and so he's at a tremendous disadvantage to say, "That's not a proper condition to be on my license," and once it's put on there, it's almost impossible to argue to get it off.

So that's where the regulatory people are coming from when they say, you know, we need to get some of these standard conditions that we're imposing routinely on broad licensees; at least give a chance for the public to have some input on it.

CHAIRMAN STITT: Larry Camper and then John.

MR. CAMPER: I have a comment and then a question for the Committee. I've gone back through the minutes, and the discussion of the Part 33, and I quickly counted about 13 or 14 positions expressed by the Committee on this rulemaking.

These are characterized as "ACMUI believes that" or "ACMUI agrees that" and so forth and so on. So you did have a substantial amount of thoughts and observations and suggestions.

Now, what I'm wrestling with though is a process question. I mean what we're doing here this morning is sort of giving you a status report. There's a number of things going on here, but obviously you still have a lot of interest

in this particular issue as a result of hearing the status report.

And I guess what I'm wondering is, you know, what's the best way to facilitate this level of interest by the Committee at this point. In other words, I look at this and I say: here was an issue that was discussed with you. You provided substantial input. There's some, you know, recall, and that's understandable. You know, what do we say about this? What do we say about that?

And I guess what I'm trying to struggle with is what's the best process so that you can readily recall or, you know, remember what you had to say or what your concerns were because here what I'm doing is we're dealing with a status report only. You have a lot of issues here, concerns about it. You did have a lot of input. Is there some better way or what do you need? What can help you deal with this issue better?

I mean obviously if we go forward, you're going to see this as a proposed rule and so forth. You'll have opportunities to impact that, and so forth. So I'm trying to understand what can we do more to help you with this issue.

MEMBER BROWN: What would help me, as I said, is just with a status report, more of an opening paragraph. "As you recall, we discussed this at your meeting, and it was because these things happened, and you all thought X, Y, and

Z, and I'd like to tell you what the rest of the world thought since we opened it up to discussion."

That would help me, and it would help the next consumer representative who sits in this spot or the next person who hasn't been with the Committee.

CHAIRMAN STITT: Well, I think, Larry, I'm not sure that the Committee wants to do something. I think that you assessed it correctly. There's a lot of interest in the Committee when you look at our minutes, and I appreciate having those to refresh ourselves.

We are interested, and we do want to make sure you understand we want to see it again and continue to be involved.

MR. CAMPER: I think one thing that would help would be, if nothing else, maybe just -- you know, we should always provide the minutes from the last time or maybe the minutes ought to be included in the book if there's going to be something on the status reports. At least that way you have it readily available at your fingertips to see.

And the other thing I think I'm hearing then is when we give these status reports, rather than just telling you where it is in the process, some recall of at least what it was about and what was motivating this initiative would be helpful.

Okay. That's great.

CHAIRMAN STITT: It would be, but as you know, there are some that are more pro forma, and there are others that we have a depth of interest in. So it is somewhat variable.

MR. CAMPER: Okay.

CHAIRMAN STITT: John, you have a comment?

MEMBER GRAHAM: Well, I think just two observations.

One is my understanding, and I'm remembering all the discussion back in May now that I've seen the minutes. It wasn't that broad scope licensees were complaining that all these weird quirks had been folded into the licensing practice which we're making their life impossible. So it wasn't like that was an issue they were raising, that if we brought it out into the bright sunlight of rulemaking, it would correct the situation.

And at the time it was brought to us stated as something that was inevitably happening, that this was an advanced notice of proposed rulemaking, and we were asked back in May to discuss questions that would be published for public comment, and a lot of our discussion was we don't know that you need to get into advanced rulemaking at all. Okay. We don't think questions need to be asked, but if you're going to ask them, then we spent a day debating what would be the responses.

So I think, you know, the only observation for the minutes that I'll make is that Dr. Siegel agreed that it appears that the staff is reacting to events that may not have been preventable by the licensees. Carl Paperiello, Director of Nuclear Safety and Safeguards, indicated that the staff already had plans to revise Part 33 before these events.

You know, we had this huge train rolling over us. We said, "Okay. The train has left. We'll talk about these questions."

Now the public comments come back, and I think we just need to consider as a Committee whether we want to reiterate that the broad scope licensing practice appears to be working.

CHAIRMAN STITT: Well, the last paragraph says that ACMUI will have additional opportunities to comment on your language after public comments are received and analyzed, and, folks, that's where we are today.

So other commentary? And then I'll go back to John for a summary. Anybody else want to?

I also think this is kind of the crowning blow of Barry got his yo-yo, too, and it's sort of a fitting end to his term.

John, do you want to restate your --

MEMBER GRAHAM: Yeah, I would recommend that the ACMUI communicates to the Commission that broad scope licenses

are, by definition, broad and an attempt to regulate these programs by rulemaking could limit the public benefit gained through activities performed by programs with broad scope licenses, and we recommend retention of the current regulatory approach.

So moved.

MEMBER NELP: Second.

CHAIRMAN STITT: Commentary?

Watch out, guys, is all I can say. She's on your side of the table.

MEMBER BROWN: What if I only like the last part, "we recommend the current regulatory approach," and I don't like the preamble? How do I vote?

PARTICIPANT: With your conscience.

MEMBER GRAHAM: This is a flexible group. I don't have any problem with the preamble becoming just that, preamble.

CHAIRMAN STITT: And that the motion would be the latter part?

MEMBER BROWN: You see, I think we should recommend --

MEMBER GRAHAM: Yes.

MEMBER BROWN: -- the current regulatory approach for very different reasons than you recommended.

MEMBER GRAHAM: All right. Fine.

MEMBER BROWN: And I would like to on my last day vote with the Committee. I'm really trying here.

MEMBER GRAHAM: So if I understand it, I'm getting a recommended amendment that ACMUI recommends retention of the current regulatory approach for broad scope licenses.

MEMBER BROWN: That would be great, and then you all could say whatever you all want.

MEMBER GRAHAM: I accept that amendment.

MEMBER BROWN: Oh, that'd be great.

CHAIRMAN STITT: I'm glad you moved from next to Aubrey because you used two "you alls" just in trying to make that statement.

MEMBER BROWN: I'm going to be bringing it home with me I know.

CHAIRMAN STITT: All right. Now, parliamentary procedure-wise, what are we stuck with?

MEMBER GRAHAM: We had a motion. We had a proposed amendment. It was accepted.

CHAIRMAN STITT: Okay.

MEMBER GRAHAM: I don't know if I ever heard a second in there even of the motion.

MEMBER BROWN: I'd second.

CHAIRMAN STITT: All right. We're in good shape then, Jeffrey.

MEMBER WILLIAMSON: I'm not sure it's a very good position for this Committee to take. I think that licensing guidance can be highly arbitrary and prescriptive and it might be better to have some framework of published rules that potential licensees can use as an argument against capricious licensing personnel and to argue that this, you know, going too far.

CHAIRMAN STITT: That presume that you know what the rules are going to be and that they are not detrimental to whatever one's viewpoint is.

MEMBER WILLIAMSON: Well, we did see a draft of the proposed rules, and I don't have them in front of me, but as I recall, there was some attempt to mitigate the prescriptiveness and have a performance based criterion in part. I think we have to assume that probably the current licensing guidance, which I don't know if we went through, is perhaps even more Draconian than the proposed, the advanced proposed rule or whatever one wants to call that version, was.

So I'm just not sure it's a very wise position to take. It might be better to take this position after we see the revised rule during the next iteration of review, and then if it appears unsatisfactory compared to the current system and the existing licensing guidance, it might be wise, you know, to reconsider and perhaps review John's amendment at

that time, in the light of a more considered review of all the materials.

CHAIRMAN STITT: I do think what John's just proposed is a reasonable summary of what the Committee said in May, after, again, reviewing our own notes.

MEMBER GRAHAM: Just one very brief comment, Jeff. If we were sitting in a perfect, rational world and we would have the most informed individuals developing that rulemaking in a perfect setting and they would be reviewed and approved in that context, fine. I will continue to express a fear that they'll fall inside a black box, and when they come back out, we'll be sitting here agonizing for a day and a half over the fact the final rules are going to place onerous restrictions on current broad license activities that are going to limit the ability to provide as much public benefit as I think they do now.

They're a very isolated class of license. There are very unusual organizations that have them. I think they're on the cutting edge of making improvements in health care. I'm not willing to risk losing all that because there's enough opportunity to lose control of that rulemaking process, and I'm not sure that we gain much.

CHAIRMAN STITT: Lou.

MEMBER WAGNER: As everyone notices, I'm wearing sunglasses. That's because I've become photophobic. I have a

terrible headache developing behind my eye, and the bright lights are bothering me here.

But I think the intent of your proposal is to give the message to the Commission that there's no need to tighten restrictions. I don't like the wording because I don't think it gets that message across completely, but I'm going to support it because I think that's the intent of it, and as long as that's the intent and the general message we're getting across, that's what should be said.

CHAIRMAN STITT: Thank you, Lou.

Jeff.

MEMBER WILLIAMSON: Well, I can certainly support the intent if that's the intent. So I would support the proposal if we could phrase it that way, to suggest that whatever happens, it should incorporate appropriate level of flexibility and not be prescriptive.

CHAIRMAN STITT: John, do you want to read it again?

MEMBER GRAHAM: Well, I think we stripped it down to the ACMUI recommends retention of the current regulatory approach for Section 33, and implicit -- okay. So that's the motion.

Implicit in that motion is the amount of flexibility that has been in it to date, and I'm truly trying to balance your concerns, as a major broad scope provider, and

Judith's concerns that we don't throw the baby out with the bath water.

MEMBER NELP: Call for the question.

CHAIRMAN STITT: All right. Let's do that.

All those in favor, raise your hands.

(Show of hands.)

CHAIRMAN STITT: All those opposed?

(Show of hands.)

CHAIRMAN STITT: All right. You get the opportunity to explain your vote.

MEMBER WILLIAMSON: Yeah, I feel that the implication of the motion is that the Commission should not undertake any rulemaking activities with regard to Part 33, and I don't feel in a position to be able to assess the rigidity and flexibility of the current process relate to what might happen at this time.

CHAIRMAN STITT: All right. I think we're done with that section then.

Who's next on the agenda?

MS. HANEY: I am.

CHAIRMAN STITT: Are you?

MS. HANEY: I stay. I feel that way.

Let me just add, to respond to Judith, the private individuals. One individual works for the Navy's

master material license, but he provided comments as an individual and not for the licensee.

The other individual was a certified health physicist that provided comments.

MEMBER BROWN: Maybe in one of the institutions that was affected by the incidents?

MS. HANEY: I can't tell from the one letter whether he does work for a broad scope licensee or not.

MEMBER BROWN: Okay. Thank you for checking that.

MS. HANEY: Okay. The next subject is the revision to 10 CFR 35.75. This particular item has been discussed with the ACMUI probably for the last four years on and off at different stages of it as we've gone through it. This particular rulemaking started in response to a petition.

Currently Part 33 requires that prior to releasing an individual from confinement after they've been administered radioactive materials, the body burden has to be less than 30 millicuries or the radiation level is 5 mR or less at a meter.

What this rule did was make it a dose based release requirement rather than putting in an activity limit. If someone that came in proximity with the patient -- their dose would not exceed 500 millirem -- the licensee could release them from confinement.

The final rule was published in the Federal Register on January 29th of this year. The effective date of the rule is May 29th of 1997.

Okay. In order to help our licensees in complying with the rule, Reg. Guide 8.39, release of patients administered radioactive material, was developed. It was issued in draft. We received numerous comments. The comments were incorporated into the final version.

I believe it was probably about four weeks ago we sent to the ACMUI the proposed final document for one last look. We did receive some comments from the ACMUI. Rather than going through them one by one at this time and using the time, I didn't plan to do that, but I would be happy to go through with the individual commenters what we did with their comments.

But I would like to make a couple of statements. The majority of the comments were taken. They might not have been taken verbatim, but the intent was incorporated.

The particular sections that you commented on we also got comments from our Office of General Counsel, Office of Enforcement, and we basically were blending all of the comments in together. So, as I said, I believe the intent of the comments were taken.

What are the big changes, at least that I felt the big comments that we received? Dennis Swanson provided us

a significant number of comments that had to do with defining our basis for determining the release criteria for exposures from some of the beta emitters, P-32, Strontium-89, and Nutrobium-90 (phonetic).

What we did in that case is we took the number out of the reg. guide and we put in a footnote there that said that the activity and dose rates were not applicable because of minimal exposures to the public. The draft version or the proposed final contained an actual activity level there, and on going back to determine how that activity was determined, we felt it was better to not put that activity in there and go with just the not applicable status.

There were some comments that we were not able to address because it really went back to the rule language, which at this point we did not have the flexibility of changing the rule language. So we were using that as a starting point and going from there.

But, as I said, I'll be happy to go through with the commenters their specific comments if they'd like.

Okay. As far as the inspection guidance goes on this particular rule, the inspection guidance was discussed at the last ACMUI meeting. I do not believe there are any recommendations that came out that related to the inspection guidance.

What we did, we needed to make some changes to our inspection procedure in the January time frame to get some guidance out to the regions relative to the constraint rule on air emissions. So we used this as an opportunity to also issue the inspection guidance 435.75. What we did is put a little disclaimer, if you want to call it, in there that said, "Don't start using this guidance until the rule becomes effective late spring."

Basically what the guidance -- we made it very performance based. In the inspection guidance we put in "determined by observing and discussing with the licensee." In other words, we don't want the inspectors out there doing just a paper work check.

We told the inspectors to look at the licensee's basis for release, whether they were using the charts in the reg. guide or whether they were actually doing case specific calculations.

As far as the inspection instructions, there are some requirements for the licensee to give instructions to the patients. We told the inspectors to review a sample of the instructions and then to discuss the content of the instructions with the staff, again, not a quiz sort of thing, but talk with the staff to see if, you know, they were aware of what they were giving as far as instruction goes.

The other thing was to check that the required records are being maintained. There is a record retention requirement in the rule for three years under certain conditions, and the inspector is just to verify that the record were being maintained.

Any questions on where we are on 35.75?

CHAIRMAN STITT: Dennis.

MEMBER SWANSON: One of my concerns in the draft regulatory guide dealt with some of the language in the guide actually made it appear that the requirements were very prescriptive. You know, there were specific statements that said these are reasons why somebody could be released earlier.

Was that corrected or addressed?

MS. HANEY: It was addressed. I don't know that it went to the level of your comment, but it was addressed.

If the licensee chooses to use the charts to release the patient, then that ends that, but your comment is more in the area if the licensee chooses not to use the chart. I believe the section you're commenting on is where we were saying that if you went this method and you were basing it on occupancy, these are the items you need to record.

Most of those were taken out. There were a few that were left, and they were not in there as "shalls," which were meaning requirements. They were in there as "shoulds,"

meaning that it was recommended, but, you know, if you didn't do it, it wasn't a problem.

So, again, I think there was a little bit of compromise there.

MEMBER SWANSON: Yeah, I thought it was probably more of a wording, the way it was worded than --

MS. HANEY: Yeah.

MEMBER SWANSON: -- than what we really intended to do.

MS. HANEY: And we did delete some of the items.

One thing I did not say was that the reg. guide should be out in two weeks. It has gone to the printer. So at least what I heard yesterday morning was probably one to two weeks. So I'm going to say two to be sure.

MR. CAMPER: Can we get copies?

MEMBER NELP: Can we get a copy of that?

MS. HANEY: Sure.

CHAIRMAN STITT: Larry.

MR. CAMPER: I want to add to what Cathy has told you by giving you a status report. I'm able to add to what I said yesterday as to what happened with regards to the Committee's recommendations, and what I will read to you from is a May 8 Commission paper entitled "Final Amendments to 10 CFR, Parts 20 and 35 on Criteria for Release of Individuals

Administered Radioactive Material." This is the paper in which the staff transmitted the final rule to the Commission.

And in that the staff does talk specifically about the Committee meeting conducted on the 18th and 19th of October of '95, and we discussed your motions, and there were three particular motions that you suggested.

First, the ACMUI suggested using the term "rationale" instead of "consequences" in the requirement under 10 CFR 35.75(b), to provide guidance on the interruption of breast feeding and information on the consequences of failure to follow the guidance, and so forth and so on. It goes on to talk about technetium and so forth.

The staff did not change the rule in response to the ACMUI comment because the requirement to provide information on the consequences is included primarily to protect the breast feeding infant from therapeutic administrations of radioiodine which could cause serious thyroid damage. Regulatory Guide 8.39 will contain guidance on the types of information, including expected consequences, to be provided to the patients to meet this requirement.

Second, the ACMUI suggested using the phrase "the retained activity" rather than "the activity administered," instead of "an activity other than the activity administered." That suggestion was taken.

Third, the ACMUI suggests that the term "discontinuation" should be used in conjunction with "interruption" in the requirement to provide guidance on the interruption of breast feeding. That suggestion was taken by the staff.

MEMBER SWANSON: I just might comment that one of my comments back on the reg. guide was to hold the feet of the NRC to the fire in requiring that they include example statements on what the consequences of breast feeding are. It will be interesting to see how they're going to approach that problem.

CHAIRMAN STITT: Other comments?

(No response.)

CHAIRMAN STITT: All right. We've got our feedback. Two out of three, Dennis. That's not bad.

Where do we go from here?

MS. HANEY: NUREG-1569. This is the document that has been referred to as the modules. This document was developed almost as an addendum to Reg. Guide 10.8. There are certain inspection guidance to the licensees that was not available in 10.8, some of the newer modalities.

This document is going to be issued in draft for comment. Right now it is within our concurrence chain. I think it's one signature from being finalized.

The document itself is being issued for public comment and not for use in preparation or review of applications for medical use licensees. This has been a disclaimer that is appearing at the top of the page. There was a concern about the early implementation of this guidance. So we wanted to make it clear to the public that it was out for comment.

Revisions to this document will probably be made based on revisions to Part 35, and then in addition to the comments, you know, based on the comments coming back and then depending upon any revisions to Part 35, those will also be incorporated into this document.

So this was just an attempt at bringing some or consolidating some license guidance into one document for some of the newer modalities.

MR. CAMPER: These are the modules that the Committee worked on.

MS. HANEY: So, in other words, this one should be out, again, within I would say a month, month and a half.

CHAIRMAN STITT: Jeff, you had a comment?

MEMBER WILLIAMSON: Yeah, a question about your last bullet there. The implication seems to be that this document is not going to go forward and be implemented at all, that it's going to be held pending revision of Part 35. Am I misunderstanding something?

MS. HANEY: No, I think it's a true statement. Given the timing that we're looking at, this document was worked on prior to us getting the go-ahead to revise Part 35. So it was one of those things that we kept moving, although we were waiting for this go-ahead on Part 35.

Now that the document has been finalized for comment, we'll go ahead and get some comments on it, but given our time frame and our staff efforts on revising Part 35 now, that's going to be where a lot of our resources are directed.

The two will probably come together again, and I believe Larry mentioned yesterday that when we are issuing rules right now, we have to at the same time be providing implementation guidance out there. So this may be the mechanism that we use as far as getting licensing guidance out to the staff and to licensees.

MEMBER WILLIAMSON: So it is on hold effectively then pending revision of Part 35, and we shouldn't spend a lot of effort reviewing the current draft.

MR. CAMPER: Well, the document was created because there was a feeling that there was a void in information on those subjects. Teletherapy, for example, the guide was created in 1985. There was nothing available in gamma stereotactic radiosurgery. Radiopharmaceutical therapy, some guidance was indicated as being needed.

So the whole project was initiated to try to fill an existing void in information. Now, the guidance document is being published, and as Cathy said, there's a caveat, and it's stamped on every page that it's for informational purposes and comment, not to be used for submitting licenses.

Now, the reality of the matter is that some licensees will look at that information, and they can say, "Ah, this can help me putting together an application for a gamma knife," or, "this can help me in dealing with mobile imaging." So there is utility to it if they choose to use it, but it's made very clear by the agency that it's not for that purpose.

And as Cathy said, the problem that we have is if we weren't where we are currently in revising Part 35, we might have characterized the guidance differently, but we felt that (a) it does serve a useful purpose, and (b) it does provide an opportunity for comment, which can be considered as we move to revise Part 35. We just may learn things, and that will help us out.

CHAIRMAN STITT: Go ahead, Jeff.

MEMBER WILLIAMSON: Well, just a follow-up. So should we on this Committee be looking at it as kind of an indirect suggestion of what the staff would like to see in the new Part 35?

MR. CAMPER: No, no, no, you shouldn't. I don't know why you would draw that conclusion. As I just said, the guidance, it was prepared to fill an informational void. The Committee worked with us to develop it, and it's, as we said, it's provided for comment.

It is structured clearly consistent with what Part 35 looks like today. Obviously, it may be substantially different depending on what Part 35 ultimately looks like, but, no, we have to structure guidance consistent with the regulations we have at the time, and that's the way that was structured. I don't think it indicates a preference one way or the other. It's just we have to develop guidance consistent with the current regulations.

CHAIRMAN STITT: Other comments on this topic?

MEMBER FLYNN: I have one. For example, let's take one example like HDR. Then if this is not going to be used by the field staff, would then NRC Bulletin -- is it 9301? -- govern how HDR would be looked upon by field staff visiting sites that has HDR?

MR. CAMPER: The HDRs, the guidance that the field staff uses is contained in FC 86-4, Policy and Guidance Directive FC 86-4.

MS. HANEY: Dr. Flynn, are you referencing inspection guidance or licensing guidance?

MEMBER FLYNN: Inspection guidance.

MS. HANEY: Inspection guidance is still the temporary instruction that was issued probably three or four years ago. Right now we have a major undertaking to revise all the inspection guidance, and as part of that, we are bringing the -- we will bring that temporary instruction on HDR, certain components of it, into the routine inspection modules that we have. We are not to that point yet, but because of that process coming on, we chose to just leave the TI out there with a guidance to the regions to continue to implement it.

So in other words, the same inspection guidance that has been used will continue to be used.

CHAIRMAN STITT: Okay. Why don't you keep going?

MS. HANEY: Okay. All right. The quality management temporary instruction. Where we are on that, I have Sally Merchant here who can give me some assistance in this area.

The temporary instruction was issued in August of 1994. Typically when we get temporary instructions for inspection they're issued for two years. That TI expired in August of 1996.

At that time, there were two draft inspection procedures that were developed, and they were issued in August of 1996 for comment and with an immediate use. We needed to go immediate use because the TI had expired.

Basically there was one procedure that was meant for reactive inspections. That would be the case where inspectors were going out to review an incident. It's very similar to the original TI. It was rather prescriptive in nature.

The other one was inspection guidance that would be provided for a routine inspection. In other words, if an inspector was going out to do just one of their regular, every three-year visits to a facility that had a QM plan, what should they be looking at? These were more performance based as compared to the prescriptive nature.

If an inspector was out on a routine inspection and they did notice that there was a problem with the QM plan implementation, they could kick over into the reactive inspection procedure and then go more in depth, but that was a case of more a nonreactive inspection. That would only come up if there was a for cause sort of thing.

These documents were issued, as I said, in draft. They were subsequently revised based on comments we received from our regional office, and then they were again issued in draft for comment.

We have gotten some comments back. I believe we've also gotten some comments from the agreement states, and those inspection procedures will be ultimately finalized.

As far as there was an assessment done on the quality management plan, this was done in response to a Commission directive. You have that assessment in your briefing book. It's near the back. It's titled "Assessment of the Implementation of the Quality Management Program and Misadministration Rule, 10 CFR 35.32 and 35.33." It's a fairly large document there, but what it contains is the analysis.

I brought up two notes here, but these are not the only conclusions there, and there is some analysis of the number of misadministrations, but one is that we noted that there was a correlation between the occurrence of a misadministration and an inspection finding of a weakness in the QM program at the time of the event.

In other words, if our inspectors were out looking at doing a reactive inspection because of what we expected, a misadministration, typically they found a weakness in the QM program implementation.

The other conclusion that we were drawing from our findings is that the routine inspection findings were not necessarily predictors of an occurrence of a misadministration. In other words, if we on a routine inspection found a problem in the QM program implementation, that did not mean that we automatically found a misadministration somewhere at the facility.

Any questions on that? Dr. Flynn?

CHAIRMAN STITT: I suspect there are plenty of comments on that. Jeff.

MEMBER WILLIAMSON: Well, I have some overall concerns about the tone of this report. Maybe it's I do not understand exactly what its purpose and scope is.

I'm most concerned about the statement on page 12. Here's what it says in the third full paragraph. "Although the QM rule, which was intended to insure that byproduct material or radiation from byproduct material would be administered as directed by a physician authorized user, appears to have been generally successful from a programmatic standpoint."

That seems to be kind of a conclusion that this program has been successful from a programmatic standpoint, but yet throughout the document it's reiterated several times that two years of experience with the implementation of this program did not significantly influence the incidence of misadministration.

So I'm sort of puzzled by the contradiction here. It doesn't seem to me it's been very successful use of resources at all.

MR. CAMPER: Well, we don't view it as a contradiction. What we mean by that statement is that licensees appear to have successfully from a programmatic

standpoint implemented the quality management role and have successfully managed those programs.

However, we did find certain issues. For example, a large percentage of them did not conduct the annual audit of quality management programs, and one of the tables in there depicts those percentages, and some of them are fairly large, but overall they appear to have had success in implementing the requirements of the regulation and have conducted successful quality management programs. That's programmatic success.

I mean that's what we mean by that statement.

MEMBER FLYNN: Judy.

CHAIRMAN STITT: Go ahead, Dan.

MEMBER FLYNN: The first bullet there, the correlation between the occurrence and inspection finding of a weakness occurring in the program at the time of the event, some of us who look at a lot of misadministrations as medical consultants -- I've probably looked at about 60 or 70 -- sometimes the on-site inspection at the time after a misadministration is reported is extremely detailed, with a lot of scrutiny and a lot of in-depth scrutiny.

The more in depth you look at something, the more apt you are to come up with other problems which may or may not be even associated with the event that occurred. To make that first bullet something that you could accept without

question would be that if you've done a study whereby you've had the same degree of scrutiny at licensees, comparable licensees, let's say, a random sample, in as much depth, as much scrutiny to the program, you know, where there was no misadministration to be able to tell if that's really true or not, or is it because you're finding weaknesses in the QM program because you're looking for them? You're looking for them in such depth that you're finding them, where you would find them in other programs, too, without misadministration if you looked in the same degree of depth.

CHAIRMAN STITT: I agree completely, and what concerns me, and we've been through this material in previous meetings on several occasions, a lot of trees were killed to generate this report, and being up to my eyeballs in my statistics class, I think you have to be very careful about drawing any correlations because I don't think this was looked at in a systematic fashion, and I think the comment that Dan just raised is one of the issues.

You can't make that statement unless you've also assessed programs where there were no problems, and I really would be very concerned to see this taken and turned into some vehicle where regulation is going to roll from.

MEMBER FLYNN: Because sometimes I believe that some of the people who are out there -- and I won't give examples of things I've heard anecdotally -- but who may not

be reporting problems. They may have the worst QM program, and they may either not recognize a problem when it occurs or, I hate to say, they do recognize a potential has occurred, but they don't report it. It doesn't get picked up on the periodic inspections.

Whereas you're selecting out people who voluntarily report a problem. Of course, there are also ones that are picked up during inspections by looking at radiation safety minutes and finding out whether this incident was a reportable event or a misadministration or not or whether it was just an incident, but sometimes it may be that some of those with the weakest QM programs may be individuals who are having misadministrations and are either not recognizing them as such or are not reporting them.

CHAIRMAN STITT: Dennis, you had a comment?

MEMBER SWANSON: I think I'd like to see the Advisory Committee take a look at this TI and what's being told to inspectors because I think it's going to be a while until we get new Part 35 written, and the QM rule has been a constant source of problems, and I'm not sure it's been all that productive anyway.

I think that it's going to remain in the regulations while we're undergoing a revision of the regulations. I would like to see the TI specify that inspectors do their review upon a performance based criteria

and that they focus on, one, whether or not there is a written prescription; number two, whether or not there are procedures to insure identification of the patient; and, number three, if there are procedures for review of the treatment program.

In other words, I'd like to see this come back before the Committee.

CHAIRMAN STITT: Okay. Hold onto that thought.

Sally.

MS. MERCHANT: I only want to comment the TI is no longer --

CHAIRMAN STITT: Sally, wait, wait. What is in use?

MS. MERCHANT: Did we pass out the inspection guide?

CHAIRMAN STITT: No.

MS. MERCHANT: We will pass out the inspection procedures that are in use. The TI is no longer in use.

MEMBER SWANSON: Okay, fine.

MS. MERCHANT: Not at all.

MEMBER SWANSON: We'd like to see the inspection review.

MS. MERCHANT: We pulled it. It was a very prescriptive TI. We collected every single piece of data. We admit that we did not do a big analysis of the data that was found. Mainly I ask that you keep in mind that the reason for

doing this report was the SRM from the Commission at the time the rule passed -- I mean, the question was: should we expand the QM? The staff did not believe, based on the data that we collected, that we should expand the QM.

In fact, you will see from the new guidance, which I will pass out, that the bottom is the more important finding, and that's in most of the inspections. We couldn't make a correlation that a routine inspection finding would be a predictor of the occurrence of a misadministration, and the point being that many good programs still make errors, and that when you look in there, the real causes, the best that we can come up with, we are left with human errors.

We seem to be at a plateau where it would be just entirely too expensive to try to reduce that any more than we have, and if that didn't come across in the report, I apologize.

We just tried to give the information that we collected. That was the intent. We tried to draw enough conclusion to make a case for the Commission to say there is no reason to expand, and in fact, in our original draft, we began to develop where we thought it should be changed, but since we're at a clean slate, we pulled that out -- and anyone is welcome to look at it -- but, I mean, once we went to the clean slate premise, we did not want to try to impose our views of what we thought ought to be changed.

But we came to some very clear views that certain things could go; that there was really no value from them. You can look yourselves and see that there is no value in some of the things that we've collected, but really the intent of the report was only to give you the information that we have.

I know that it's big. I know that it's extremely boring, but I didn't want to send a paper up to the Commission saying, "These are our conclusions," and not provide any data. So I wanted to give everybody what we looked at.

This is everything we had, and it is long. It is boring. It is redundant. It is -- you know, but it's what we found.

MEMBER SWANSON: Thank you.

CHAIRMAN STITT: Larry, go ahead.

MR. CAMPER: Two things. One, back to Dr. Williamson's comment. On page 11 of that report, the statement is made, which I think is what I was picking up in your comment; the statement is made that there has not been a significant reduction in the total number of reported misadministrations, the performance indicator most closely linked to this issue.

Okay. So I mean, you know, we captured your point, too, and you're right. The number of therapeutic misadministrations is about 40 per year. It hasn't changed. That's point number one.

Point number two is -- and Sally just said it -- I mean, we have changed. In December of '96, we changed the inspection guidance. The temporary instruction is just that. It's a temporary instruction to inspector. They typically have a two-year life span.

Once they're closed, we then provided guidance which the regions are now following. It is more performance oriented, and it essentially captures the points you were making.

The third thing I want you to be aware of is to kind of look at where you are. This is a report that was requested by the Commission when the QM rule was put into place. We have also made it available publicly if someone wants to read it.

There's a lot of very good information in there. I think most interesting from my perspective is if I were out there, I would be looking at the therapeutic misadministrations that occur because you can learn a lot. It really has a lot of valuable information in there.

But bear in mind the following. The Commission had this report when it considered its position, which you will find in Item 6 of the SRM. So they have weighed in on this, and they say the quality management program provisions in 35.32 should be reevaluated and revised to focus on those requirements that are essential for patient safety, that is,

for example, confirming patient identity, requiring written prescriptions, and verifying dose. 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.

So they took a look at what we have learned over the last three years, and that's where they weighed in on it. So that puts it in perspective at least.

CHAIRMAN STITT: I'm thinking. Give me a minute here. Time out.

We're going to take a time out. So hold those thoughts because we have a special occasion and a photographer to verify our special occasion.

Larry Camper and our member of the public, Judith Brown, are going to say their last goodbyes.

(Whereupon, the foregoing matter went off the record at 9:48 a.m. and went back on the record at 9:51 a.m.)

CHAIRMAN STITT: Well, that was worth the time out, and I knew we couldn't get our discussions concluded.

Thank you, Judith. It has got to be a hard role to play, to know when to jump in and try to steer us in the right direction.

I was complaining that I probably won't see her again. Are you going to be with us on the 8th?

MEMBER BROWN: I will.

CHAIRMAN STITT: I thought you would, but she's --

MR. CAMPER: Yeah, she's in effect until June, I think.

MEMBER GRAHAM: She invited all of us to stay at her home, too.

MEMBER BROWN: I did.

CHAIRMAN STITT: I didn't realize that. Oh, that's terrific.

MEMBER BROWN: If hotel accommodations are tight, you can all stay at my house. We'll have like popcorn and discuss the issues.

(Laughter.)

CHAIRMAN STITT: I don't think we can do that. I think that requires a notice in the Federal Register.

MEMBER BROWN: We could arrange that.

CHAIRMAN STITT: All right, great.

MEMBER BROWN: Sure.

CHAIRMAN STITT: All right. Big deep breath, back to business.

Sally, thank you. I feel less distressed, and thank you for reaffirming, Larry, Point 6, which you say is a

response of the Commission to some of this material, and again, a direct toward 35.

What?

MR. CAMPER: Is it time out time?

CHAIRMAN STITT: Oh, that kind of time, yeah, because we have more talking we want to do on this issue. So it's break time until ten o'clock.

(Whereupon, the foregoing matter went off the record at 9:52 a.m. and went back on the record at 10:19 a.m.)

CHAIRMAN STITT: All right, group. We're ready to roll.

We are back on the agenda, and, Cathy, did we finish our last discussion?

MS. HANEY: Oh, I guess you didn't.

CHAIRMAN STITT: I don't know. I'm asking.

MS. HANEY: No, you didn't.

CHAIRMAN STITT: No. I was looking over at this side of the room. The topic was?

MS. HANEY: QM.

CHAIRMAN STITT: Oh, yeah. How could I forget?

MEMBER SWANSON: QM and whether we're going to see a copy of the inspection guidance.

CHAIRMAN STITT: Right.

MS. HANEY: And we can provide the ACMUI a copy of the current inspection guidance that's out there.

CHAIRMAN STITT: We have some things that have appeared on our table. These are?

MS. HANEY: While we were on break, Donna-Beth handed out the regulatory guides that pertain to the radiopharmacy rule. They were recently issued for comment. So in case some of you had not gotten copies of them, we wanted to use this as the opportunity to provide them.

CHAIRMAN STITT: All right. Other comments then? We were talking about QM.

Lou.

MEMBER WAGNER: I just have one question that I'd like to bring for a little discussion, not much, but you know, if we have all this data now that says or that points to the idea that the QM rule really has not reduced misadministrations, has been rather ineffective, then it indicates to me that the standards of the industry are sufficient in terms of what they achieve in regards to misadministrations, and I would question why there's an incentive to keep the QM rule, particularly in light of the IOM's recommendation that it be removed as soon as possible.

And I would wonder whether or not this Committee should take a position supporting, again, supporting to the Commission, the idea that the QM rule has been proven now to

be ineffective, and continuation of it as a regulation is unneeded and unwarranted and simply should be abandoned.

CHAIRMAN STITT: Any other comments along that line and then we'll --

MEMBER NELP: I have one. Would it be better to say it's apparent that it's become unnecessary rather than ineffective?

MEMBER WAGNER: That would be fine.

CHAIRMAN STITT: Larry, tell us where you -- my understanding is from Number 6 in the DSM -- I'm trying to get the --

MS. HANEY: I'm sorry.

CHAIRMAN STITT: Oh, I got it wrong. Okay. The comments from the Commissioners were a bit of a hands-off approach on the QM rule right now, and if you view 35 as being something that can be started from a fresh piece of paper, that would include the QM. I don't know that. I'm just suggesting we don't need to spend time taking action on this at this point. I don't think anybody's going to pay attention to it.

My feeling is that it's being sort of dead in the water right now, not dead in the water, but there's no active management of the QM rule taking place right now.

MR. CAMPER: No, there is active management, but the quality management rule remains on the books. It's currently a regulation. It is currently being conducted.

The Commission and the SRM has sent a clear signal to the staff. The signals that I read in that are retain the quality management rule, modify it to focus upon those three elements, that being the written directive, redundant identification of the patient, and verify that the administration is consistent with the written directive. Those are Objectives 1, 2, and 3.

They then go on to say, however, make it more performance oriented and so forth. I don't know if they commented on it on the vote sheets or not, but I think what the signal they're saying is that they believe that there are components of the quality management rule that are worthy of retention, and it's those three essential elements, but that how it is structured and how it is conducted should be changed to make it more performance oriented, and that you'll probably end up with a combination of prescriptive and performance oriented requirements.

So the regulation that we have continues until it's changed, and that seems to be the signal the Commission is sending the staff.

CHAIRMAN STITT: Go ahead, Lou. You want us -- what do you want us to do?

MEMBER WAGNER: Well, and to address that point, and I think this is a very important point because I think it reaches at the heart and philosophy of the regulation.

I do not disagree with the principles of retaining that practice. What I'm pointing out is that the data indicates to me that the rule as a regulation is unnecessary, not that it isn't good practice, but that as a regulation, it's unnecessary.

And for that reason I would like to see this Committee come to a consensus on giving the Commission, again, the message that we feel the rule as a regulation is unnecessary and they should abide by the IOM report that says get rid of it.

CHAIRMAN STITT: My comment would be, I mean, I thought the words from the Commission about their feelings of the IOM report were -- their feelings were pretty strong. I'm not sure I want to link anything I have to say with the Institute of Medicine report.

I mean parts of those comments, my opinions and their comments may be similar. I'm not sure I'd want to put, "I uphold the IOM" whatever it was and send that to the Commission. They have sent us a pretty strong opinion about the Institute of Medicine report.

Lou.

MEMBER WAGNER: I understand that, and I agree with the point about that, but if they look at what we've said about the IOM report, we were not nice about the IOM report either.

CHAIRMAN STITT: Right.

MEMBER WAGNER: We're on the same grounds in that regard, but I think it's unconscionable not to look at the report and try to see are there good things in this report, and when you find something good in a bad report, you still take the good, and that this is one good thing.

CHAIRMAN STITT: If there's something we liked out of it, I'd rather have us just state it rather than refer to it. I think it's a hot button, and whatever it is, if we feel strongly about it, we can phrase it, state it, but I would not like to reference it.

MEMBER WAGNER: Okay. That'd be fine.

CHAIRMAN STITT: Several people over here. Well, Dennis and then --

MEMBER SWANSON: I think I'm a little concerned about trying to tell them to take it out of the regulations right now in consideration of the fact that we're going to be undergoing a major regulation revision process anyway. I'm not sure if this is the appropriate time to come and ask them to remove it, and I would appreciate perhaps some comment back from Larry on that.

I think what I was trying to get at in taking a look at the guidance to the inspectors is can we realistically achieve that through inspection guidance where we're telling the people that their inspections should be performance based and focus on perhaps these three issues.

It's another way to accomplish, I think, a reduction in the prescriptive nature of the quality management rule while at the same time we're debating as part of the rulemaking process. That's kind of where I'm coming from.

MR. CAMPER: Well, to try to answer your point, I mean, it's clear that the Commission certainly could pass a resolution such as Lou is suggesting. If you wanted to send that message to the Commission, that's entirely within your prerogative. I don't think I could comment as to the utility in doing that. I think that either one way or the other, I think, clearly at this point at least the Commission has sent a direction to the staff. The direction as we read it says, "Retain the quality management rule as it relates to those three essential elements," as I said.

So I would think then that the working group that will be working on the quality management rule would certainly develop ultimately -- that issue would certainly be discussed in the public meetings that the working group will participate in. I suspect there'll be pro and con expressed during those public meetings about it.

Ultimately I would think, unless they hear things along the way that would cause them to do otherwise, that they'll ultimately include that in the revision of Part 35, and then, of course, that will be debated an discussed as well.

But, I mean, we certainly have a signal from the Commission at this point in time on this issue. I would expect then that it would be included in the Part 35 along the lines of the Commission direction, but, again, it's certainly the Committee's prerogative to comment or not comment in terms of your feelings about continuing with the quality management rule. That's up to you.

CHAIRMAN STITT: We have in front of us reactive inspection of quality management programs and QM inspection procedures.

MR. CAMPER: Yeah. Let me say something real quick about the inspection procedures. We went back and after the TI closed, we modified the inspection procedure for three reasons. One is we felt that, you know, the quality management rule had now been in place for three or four years. Licensees, as I said earlier, had programmatically implemented the program with success. I mean, there were still about the same number of misadministrations. You know, you can argue about the efficacy of the whole effort as a result of that, but the licensees had generally implemented the program

successfully. They seemed to have viable quality management programs, and it seemed to be meeting the intent in that context.

And, therefore, it was an opportunity to throttle back on the rather prescriptive and aggressive inspection procedures.

The second was to try to make it more performance oriented, and at least in part it is fair to say that that was motivated to some degree by that component of the IOM report, which of course the IOM report suggested that the agency should remove the QM rule right away.

Well, obviously the Commission didn't want to do that, but by the same token, it was felt that certainly amongst the staff and management that we could moderate the inspection process to make it more performance oriented, not compromise public health and safety, and that the licensees appear to have successfully implemented the program, and therefore, we felt comfortable in adjusting the inspection procedures, and they were adjusted rather substantially and it made them much more performance oriented, less obtrusive, less time consuming on the licensees as the inspector was evaluating that component of their program, and only in those cases where there was a reactive inspection would the inspector go into much more detail, particularly with the focus upon trying to discover the root cause of the

misadministration or to see if there were other problems within their entire program of a similar nature.

So it was changed rather significantly.

CHAIRMAN STITT: Go ahead, Jeffrey.

MEMBER WILLIAMSON: Well, I think that it might be more productive at this point, rather than passing a motion, to immediately remove QMP from the books. It might be more appropriate to have a motion that responds to the Commission's tentative or preliminary position that aims one, two, and three of the current QM rule be maintained in some form in the new Part 35, and we might change, you know, our resolution to question the utility of having those in the regulatory sphere at all, especially given the information in this report.

CHAIRMAN STITT: Other comments about Jeffrey's point? And then we'll see if anybody wants to make a motion.

MEMBER FLYNN: I just wanted to say that I agree with Dennis, and I think if we had revised Part 35 with something that you might call a quality management rule, but it has very little resemblance to the present quality management rule requiring patient identity, requiring a prescription, requiring a dose verification. That's much different than what's required now in the quality management rule.

And I think as we revise Part 35 in the next two years that we should just do this as we go along.

MEMBER NELP: That was my question, Larry. You read from a Commissioner's -- would you read that? It's a short paragraph, what they said about the QM rule.

My feeling was if we revised 35, the QM rule sort of becomes redundant. Is that a possibility?

MR. CAMPER: Well, what they said was -- and this is from the SRM -- "The quality management program provisions (10 CFR 35.32) should be reevaluated and revised to focus on those requirements that are essential for patient safety, for example, confirming patient identity, requiring written prescriptions, and verifying dose. 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."

CHAIRMAN STITT: You know, as I hear this read, it sounds like it's coming back to this long discussion we had yesterday on the medical policy. Several phrases in that were actually incorporated in our suggestions, particularly Point 2, patient safety, elements of risk that we talked about.

I think we're on a similar wave length. This also sounds very different than the QM rule that we have been

reviewing in the past and this report that Sally Merchant has worked on for us.

Other comments? Dennis.

MEMBER SWANSON: In just taking a quick look at your revised inspection procedures, they still appear to be very specific and focused on some rather details of the quality management plan. Again, what I would really like to see to address both some relief from the quality management rule without going through the process of removing the regulations is to simply have your inspection instructions focus on those three things.

You know, they should be doing performance based inspections to determine has the given institution -- do they have written prescriptions; do they have mechanisms for identification of the patient; and do they have mechanisms in place for verifying the dose.

That would make your inspection performance based upon the things that the Commissioners are actually telling us that they think are important.

CHAIRMAN STITT: Do you feel that that's the form of a motion?

MEMBER NELP: May I make one more? Isn't it true that 35.32 we will be revising, and 35.32 is the quality management rule, and therefore, I mean, we've been given the ticket to revise it, and even if we voted today, I don't

presume it would create any action in the next year or two for the QM rule.

MEMBER SWANSON: The point being that I think you can change your inspection guidance fairly rapidly, if I'm not correct. Am I?

MS. HANEY: It's in the five months range. I mean it can be done.

MEMBER SWANSON: A month's range.

MR. CAMPER: Yes, you can modify inspection guidance. You have to, on one hand, insure that your inspection guidance satisfies the requirements of the existing regulation. You have to be sure obviously that it's doing the appropriate job of protecting public health and safety, but, yes, there is flexibility in inspection procedures.

Now, I would look at it this way. We did modify them. Okay? I think what I hear you saying though is two things.

One is that, okay, you modified them. Perhaps they could be modified even more. In particular, they could be modified more because now the staff has perhaps more explicit direction from the Commission about what it believes is the important components of the QM rule as compared to what we had when we finalized this in December. That is certainly an accurate statement.

And the concept then that the staff can go back and look at the inspection procedures again in view of this more recent definitive information from the Commission, I mean, that is logical. That makes sense, yes.

MEMBER SWANSON: And to address Dr. Nelp's issue, yes, we're going to be revising the regulations, but there will be an interim of time until we get to new regulations that I would like to see some relief on the quality management rule, and I think we could accomplish that fairly rapidly through the inspection guidance.

MEMBER NELP: I thought the Commissioners said, "Knock it off. Lay back. Focus on those issues." Isn't that what he said? Didn't he say the same thing?

MR. CAMPER: Well, they certainly directed the staff in its revision of Part 35 to deal with the QM part of it in certain ways. Yes, that's true.

CHAIRMAN STITT: But I think Dennis is trying to hook --

MEMBER NELP: He's trying to get at --

CHAIRMAN STITT: -- that statement with some very specific actions that are involved by inspectors as they do inspections. I think he's trying to sharpen it.

MEMBER NELP: Trying to implement it now.

MEMBER SWANSON: Now.

MEMBER NELP: Through guidance.

MS. HANEY: If we did that, would you leave the reactive one as is?

MEMBER SWANSON: Yeah, not having had time to take a look at it.

MS. HANEY: Right, right.

MEMBER SWANSON: But I think I'd like time to take a look at it before I responded to that. Okay?

MS. HANEY: Okay.

MR. CAMPER: Well, again, I think, not to put words into the Committee's mouth, but certainly I can readily understand why the Committee might want to suggest that the staff would reexamine the inspection procedures in view of this recent direction from the Commission to see if further adjustments could be made to them to capture what appears to be the preference for the Commission as we move to revise Part 35.

MEMBER SWANSON: So moved.

(Laughter.)

CHAIRMAN STITT: I was going to say that sounds --

MEMBER SWANSON: That was not a motion. I would not say --

MEMBER WAGNER: Second.

MEMBER NELP: I don't think you should inspect them. I think you should modify them to come into compliance

or come into confirmation or whatever you say with the comments of the Commission at this time. That's really what you want to do, isn't it?

We don't want you to go and look at them. We want you to modify them so that they are in keeping with the Commission's attitude toward the whole process.

CHAIRMAN STITT: And you want to turn that into a complete statement and make it in the form of a motion?

MEMBER NELP: I would be -- if I can get the right words.

CHAIRMAN STITT: I was going to say: who has this? Dennis, do you have this on the tip of your tongue?

MEMBER SWANSON: Help me out here, Larry.

We'd like to direct the NRC staff to review the current inspection guidelines with the intent of modifying them to come into compliance or to come -- "compliance" isn't a good word --

MEMBER GRAHAM: To reflect the spirit of the Commission direction.

MEMBER SWANSON: -- to reflect the spirit of the Commission's direction.

MEMBER GRAHAM: In the SRM related to DSI-7.

MEMBER SWANSON: Yeah.

MEMBER NELP: That's pretty close.

MEMBER SWANSON: I'd say we'd like to direct them to modify them to come in keeping with the spirit of the direction of the Commission so that we don't want them to just look at them with the idea of modifying them.

(Laughter.)

MEMBER SWANSON: We want them to modify them.

CHAIRMAN STITT: Need a second.

(Show of hands by Mr. Williamson.)

CHAIRMAN STITT: Was that a second, Jeffrey?

MEMBER WILLIAMSON: Yes.

CHAIRMAN STITT: Okay. Now discussion. Did you have your hand up for discussion also?

Okay. Aubrey.

MR. GODWIN: I think it's only fair to point out to you you may get some complaint back from OGC saying that the inspection procedures have to be detailed enough to assure that they are capturing the problems in the regulations because the regulations is what they have to enforce, not the Commission's spirit, and I think that might be a comment that may come back. So I just wanted to make you aware of that.

MR. CAMPER: That is an excellent and accurate point.

CHAIRMAN STITT: Right, but it will certainly give them something to do in the meantime.

MEMBER SWANSON: I think that is, in fact, why I'm hesitant to comment on the reactive portion of the inspection guidelines at this point in time. I think if we're truly moving to performance based regulations, that the way I see this would work would be you would go out and do inspections on a performance based type of things, and if you identified problems, then you would go into the reactive mode which would address the regulations.

So I think what I'd like to see is on the front end a performance based approach to taking a look at this.

MR. GODWIN: Yeah, I think those comments need to be on the record somewhere so that that's conveyed, and I think that may alleviate some of the OGC's concern. You're doing a screening at this point. If you find a problem, you get the evidence you need on this next one, and I think that might help you some.

CHAIRMAN STITT: Are there other comments about the motion on the floor or on the table, wherever it is?

MEMBER NELP: Call for the question.

CHAIRMAN STITT: Jeffrey, you had your hand up?

MEMBER WILLIAMSON: Well, I want to qualify my statement that I obviously have not had time to read the reactive protocol for inspecting licensees' QMP programs, but I'm concerned in some ways about the overall enforcement strategy. I, based on anecdotal experience, believe that it

is basically used as a tool to try and punish an institution that does have or has reported a misadministration by digging through everything and trying to find some one form that doesn't have a signature so that they can be cited for something even though maybe there may be no violation associated with the misadministration.

I mention this not because I want to just complain, but as we embark upon our study or preceding our recommendations vis-a-vis the revised Part 35, I think it's really important to recognize that many of the problems we have as licensees arise not so much from the endpoints as codified in the regulations as the enforcement strategy, and I think it's really a very important issue that has been raised about this inspection guidance and the response of the agency to events.

And I'm, you know, rather concerned that the inspection guidance focuses on an attempt to sift through everything and find isolated violations that can be used to punish an institution as opposed to making a kind of a general, more qualitative assessment of whether the program is in good working shape.

That's really, from a practical, common sense point of view, the question that needs to be answered when there is an event, not was there an isolated violation.

MR. CAMPER: Well, I must comment. Clearly the inspection guidance is not designed to be such a tool. I mean the inspection guidance is structured in such a way that the inspectors are to go evaluate the quality management rule to see if it complies with the regulations, to see if it's meeting the intent of the regulations, and so forth.

I mean part of that is records review. Now, if you look through your QM TI findings, you'll find that less than half of the 140 or so misadministrations that occurred during that period of time resulted in escalated enforcement, less than half. So, I mean, not all misadministration and not all inspections of QM programs result in violations.

Now, there's no question that there have been violations associated with misadministrations, and I know that there are those in the medical community that take exception to that, and I can understand that, but there's no intentional effort. The inspection program is not designed to go out and find the kinds of things that you're alluding to.

And as I said, I think what's really very telling is that if you look at those 140 or so misadministrations, less than half resulted in escalated enforcement. So I'm just trying to give a balanced perspective on it.

CHAIRMAN STITT: Lou Wagner.

MEMBER WAGNER: I call the question. I believe the parliamentary procedure is that after you call the

question you have to take a vote on whether you're going to have further discussion. Then you vote on the issue.

CHAIRMAN STITT: Never argue with a hospital administrator. So we're going to --

MEMBER GRAHAM: Bless your heart.

(Laughter.)

CHAIRMAN STITT: They've taught me well, haven't they?

MEMBER GRAHAM: They have.

CHAIRMAN STITT: So what do we have to do, Lou? We have to vote on the --

MEMBER WAGNER: I called the question. That's to stop discussion.

CHAIRMAN STITT: All right.

MEMBER WAGNER: We have to vote that we're going to call the question. I think it's a two-thirds majority says --

CHAIRMAN STITT: All right. We're going to vote to decide whether we're going to vote.

MEMBER WAGNER: Right.

CHAIRMAN STITT: Anybody who wants to move to the vote, raise your hand, who wants to move toward voting.

(Show of hands.)

CHAIRMAN STITT: Okay. That's two-thirds.

We now have before us -- who can read this back to us so that we at least know what we're saying? Is that something you have? Who has it written down well enough? We don't know what we're voting on.

I was just looking for the specific wording. The issue is we want the NRC staff to --

PARTICIPANT: Modify.

CHAIRMAN STITT: -- modify the --

MEMBER SWANSON: Inspection guidance.

CHAIRMAN STITT: -- inspection --

MR. McCARTHY: I have it written.

CHAIRMAN STITT: You do? That's what we're looking for. Read it to us.

MR. McCARTHY: Modify inspection guidance with intent to reflect the spirit of the Commission direction in the SRM regarding DSI-7.

CHAIRMAN STITT: All right. Those in favor, raise your hand.

(Show of hands.)

CHAIRMAN STITT: Oh, my gosh. Those opposed?

MEMBER BROWN: I'm going to abstain. I haven't given it enough thought to intelligently vote one way or the other.

CHAIRMAN STITT: Okay, and does an abstention also require comment or just a negative vote?

MEMBER BROWN: I commented.

CHAIRMAN STITT: Yes, you did. That's a comment. Thank you, Judith.

All right.

MEMBER FLYNN: I have a question, and the two documents are titled differently. Specifically QM inspection procedures, and the other one is reactive inspection of quality management programs. Do you want to specifically say QM inspection procedures, therefore you exclude the reactive?

CHAIRMAN STITT: What as the --

MEMBER FLYNN: If we had said -- now you're including both.

CHAIRMAN STITT: Right. No, I think our discussion, we were not trying to include both. In the --

MEMBER FLYNN: It's called QM inspection procedures, and it has its exact title to it, but then --

CHAIRMAN STITT: Right. So that's what our motion that we voted affirmatively on needs to reflect, that we are talking about the QM inspection procedures, and I'll look for that in the minutes.

Lou?

MEMBER WAGNER: I wish to go on record with my opinion regarding the fact that I still feel that with the QM rule as a regulation, it's unnecessary. I still feel that it is wrong for the NRC not to look at the IOM report and take

the good things out of the report and implement them as soon as possible, and I believe that the QM rule is unnecessary and should be removed immediately while we deliberate for the next two years on how to change 35.

CHAIRMAN STITT: All right. Shall we keep going? Cathy, you have another at least one item.

MS. HANEY: I have one more and then I'd like to take two or three minutes and tell you about another petition that we have besides this one.

This is what we refer to as the Carbon-14 petition. This goes back to October 4th of 1994. The Commission docketed a petition for rulemaking from Tri-Med Specialties.

Tri-Med amended, requested an amendment to the regulations to allow for the general licensing and/or exemption for the commercial distribution of licensed pharmaceutical manufacturers of a capsule containing one microcurie of Carbon-14 urea for in vitro diagnostic testing.

On December 2nd, 1994, the petition was noticed in the Federal Register for comment. We received 315 comment letters. Three hundred and 13 supported the amendment to the regulations; two opposed.

On October 18th and 19th of 1995, this item was discussed with the ACMUI. The ACMUI endorsed the general licensing or to handle it as an exemption.

In March of this year, a final rulemaking plan was developed. This went to our Executive Director of Operations, and then it was approved by the Commission, and what we were looking at was allowing for the exempt distribution of the Carbon-14.

Where we are right now is a proposed rule is being developed. This will go to the Commission at the end of this month, and again, it will allow for the exempt distribution of the C-14. It will then go out for public comment, and based on those comments, we will take it final.

CHAIRMAN STITT: Comments from the Committee? Dennis.

MEMBER SWANSON: I just might comment that in the interim, a Carbon-13 test has been developed and approved by the FDA.

CHAIRMAN STITT: I think one of the reasons this was on the agenda is the frustration of Tri-Med that the first line has 1994, and I know we as a Committee discussed this. Dr. Siegel had sent us -- had done a literature review -- sent us a lot of background material on this particular test because it is something that really is able to make a difference in the clinical practice of medicine, and the question is it's two years heading on to three.

Is this a standard length of time that something -- is this going to be the same with Carbon-13? Is there

something that was a glitch in here? How can we smooth this process?

MS. HANEY: On this particular rule I don't know whether there was a glitch or not. Maybe Larry is more aware.

MR. CAMPER: Well, I think there are two reasons why this rule has taken so long. Number one is it is time consuming following the procedures that we use for a petition, publishing the rulemaking, plan for comment, and so forth and so on. It takes time. It is difficult to move any rule, frankly, faster unless there's an immediate public health and safety issue. It is very difficult to move rules faster than, say, on the order of two years. That's probably standard operating procedure.

This particular rule was complicated by the fact also though, as you may recall we discussed with the Committee, the fact that the petitioner was requesting to distribute the product to be an exempt pathway.

I mean the material can be used by a limited -- specific licenses and broad scope licensees, but the essence of the petition was the exempt pathway.

Now, the Commission's regulations have heretofore as a matter of policy not allowed administration to human beings via an exempt pathway, and that's specifically stated in Part 30. Therefore, the staff did spend some time, I think it's fair to say, wrestling with what is the most effective

approach to propose in terms of the exempt pathway possibility, and it really had to do with what has been the longstanding policy of the Commission and its regulations in trying to develop a justification for pursuing it via the exempt method and to make sure that if you're going to allow it to be distributed exempt, I mean, all these questions about, well, who can actually administer it as exempt, the questions of can only physicians do this; can others that are non-physicians do this; and those kinds of issues did take time for the staff to work with and to attempt to resolve.

MEMBER NELP: I imagine it's a prescription item, isn't it?

MR. CAMPER: Yes, it is.

CHAIRMAN STITT: Jeff and Dennis.

MEMBER WILLIAMSON: Well, I'm wondering, Larry, if you could comment on if similar products using different radionuclides are developed, what sort of pathway they will have to take in order to --

MR. CAMPER: That's an interesting question.

MEMBER WILLIAMSON: -- market their product.

MR. CAMPER: Well, rulemaking plan, Dr. Howe, the rulemaking plan itself is specific only to this product, is it not?

DR. HOWE: That's correct.

MR. CAMPER: Therefore, if other products were developed and the exempt pathway were pursued, there would have to be efforts taken to add it to the exempt distribution pathway because the rulemaking plan the staff is pursuing is specific to this particular product.

But having said that though, obviously if the Commission ultimately decides to allow this product to be distributed exempt, it would be far easier to add another radionuclide than it would be to -- you wouldn't have to go back and reblaze the policy change. It would just be a matter of adding a different radionuclide.

MEMBER WILLIAMSON: How long would that take?

MEMBER NELP: Do you have something in mind or is this theoretical?

MEMBER WILLIAMSON: Well, it's out of my area of expertise. I understand from what Dennis said there is another product being developed, say, Carbon-13. So how long would that take?

I'm just concerned that the --

MEMBER SWANSON: Carbon-13 is not radioactive.

MR. CAMPER: Well, again, the petition process involves a number of steps. That typically is on the order of certainly a year to two years. Now, it would not take as long because, again, the policy issue has complicated this one somewhat, but again, if one looks at all of the various steps

in the petition process, development of rulemaking plans, solicitation of public comments, it is a time consuming issue.

And this is one of the dilemmas you get into in the regulatory process. The more steps that you add to a process to allow public interaction, reaction, comment, et cetera, the more you spread out the time line. It's just unavoidable.

CHAIRMAN STITT: Dennis, did you have a comment?

MEMBER SWANSON: This is probably regulated under Part 30, manufacturing?

MR. CAMPER: Thirty-two.

MEMBER SWANSON: Thirty-two?

MR. CAMPER: Well, Part 30 and then 32, yes.

MEMBER SWANSON: Is there any way to take the general considerations that eventually led you to making this exempt and making a general rule out of that?

MR. CAMPER: Well, when you say "general," well, the staff's proposal, I believe -- and, Donna-Beth, help me out here because you're very familiar with this -- contain --

MEMBER SWANSON: A non-product specific rule.

MR. CAMPER: The proposed rule, I believe, contains conforming language for Part 30 that would remove the existing restriction in Part 30 as it relates to exempt materials to human beings.

DR. HOWE: At this point it would slow the process down if you were to try to make it a general rule because the basis for making this rulemaking change is on an environmental assessment on the effect of Carbon-14 to the environment, to the public, and a number of other factors that were added as response to the petition.

And so at this point the quickest path would be to let it go through as Carbon-14 urea and at some later point if you want to go to a more general, then you have to address that issue.

MEMBER SWANSON: That's the point I'm getting at. Can you take the considerations that you looked at in approving Carbon-14 urea and can you generalize that so that they're not product specific, so that you have a general rule on board, and if it meets the requirements of this rule, it would go through without a three-year delay?

DR. HOWE: In this case the basis is all based on this particular product in a capsule form for Carbon-14 for the amount of activity per capsule and for its medical use. It would be difficult to broaden that at this particular point.

MR. CAMPER: Right. You would have to go back and reconsider your environmental impact issues and your regulatory analysis would have to be changed because all of the cost considerations and so forth are germane specifically

to this particular product. So those two areas would have to be reexamined.

If I understand your question, if you simply wanted to broaden it to allow other products like this to be, you would have to deal with those two issues.

MEMBER SWANSON: Yeah, but one microcurie of Carbon-14 whether it's attached to urea or sugar probably doesn't have much difference from an environmental impact consideration. Okay?

MR. CAMPER: Oh, I agree with that.

MEMBER SWANSON: Well, then if you agree with that, then why can't we come up with some kind of a general rule to address those types of things?

MEMBER NELP: Madame Chairman.

CHAIRMAN STITT: Go ahead, Wil.

MEMBER NELP: I don't see a problem. I don't see any other carbon labeled radioactive diagnostic materials this has gone through, and I think we ought to focus on --

MEMBER SWANSON: I don't want to do anything to prevent this one from going through. Okay? I'm just looking to the future.

MEMBER NELP: But I don't see anything in the future that needs our attention.

MR. CAMPER: Well, and again, the petition was to distribute this product.

CHAIRMAN STITT: Other comments? Oh, I took my glasses of and I can't see that far. Yes.

MR. GODWIN: The Commission very easily could adopt a rule that would allow, say, any isotope that doesn't deliver above X amount of dose and under these conditions doesn't exceed that as a general rule. You wouldn't want to touch this petition at all, but what you may want to look at is perhaps tritium might come along as a potential. Perhaps some other isotope might come along, and if you had a general provision in there that would say that if you meet these conditions, you qualify for this either GL or exemption. That might be the way to go, but you'd have to have a generic impact statement developed to evaluate it and economic considerations to address it.

So that would be a fairly large undertaking on the part of the Commission staff, but it can be done, and you know, somebody out of the public could petition the Commission to do it as sort of a goodwill public gesture.

The more likely thing would be probably some organization like this or some other professional organization do it, make a request, not the general public, but it could be done, and if it's viewed as potential matter of urgent public necessity, somebody should petition them and get them to do it.

CHAIRMAN STITT: Dennis, do you want to add to his commentary?

MEMBER SWANSON: Thank you. That's what I was trying to get at. Okay? You know, to me what troubles me is this has gone through three years for these people to be able to distribute this product. It's almost a conflict of trade in a way. Okay?

In the interim --

PARTICIPANT: Restraint of trade.

MEMBER SWANSON: Restraint of trade.

In the interim another product's been approved that does involve the use of radioactivity. I'm not sure that's in the best interest of the public, okay, if it takes three years to get a very valuable procedure on the market. Something to consider.

CHAIRMAN STITT: Thank you.

Lou, did you have something to say?

MEMBER WAGNER: No, it's just a fine example of where we run into the problem where I believe that there's not enough -- I don't believe there's enough consideration given in regulatory process for the down side of what occurs any time you write any regulation, and this is a fine example where something that is very beneficial to the public is actually now somewhat detrimental to the public because we haven't been able to get it out, and it continues to --

MR. CAMPER: But bear in mind the product is available, and it can be used.

MEMBER NELP: The product is available to practitioners throughout the country.

MR. CAMPER: The only issues is --

MEMBER NELP: And there's no patient who needs the test who can't access the test through a qualified nuclear medicine physician or licensee. So, you know, it's really an exaggeration to say that the public has been denied access to this material. The public has had access to this material the whole time.

What they want to do is to send it to gastroenterologists and have them use it in their offices, et cetera, et cetera. We do the test, and it's not easy to do really.

CHAIRMAN STITT: John, do you have a comment?

MEMBER GRAHAM: I think what the group is trying to express is some frustration that --

MEMBER NELP: Over the time.

MEMBER GRAHAM: -- that in the spirit of capitalism upon which this country has been developed we have thwarted a potential commercial application which appears to have had low public risk, and if it came up in the future, we would encourage staff to try to develop a more generic

procedure that it would not be kept off the market for as long as three or four years.

CHAIRMAN STITT: Nicely put. That's why we allow these administrator onto our Committee.

All right. I think we're done with this topic.

MS. HANEY: Well, I have one more petition that we are working on.

CHAIRMAN STITT: Go ahead.

MS. HANEY: It's a petition that we received. I believe it was the end of last year. It was from the University of Cincinnati, and what the request was was to allow caregivers to patients that are confined under 35.75 to receive a dose up to 500 millirem.

Right now those individuals are limited to 100 millirem. We are in the process of developing a rulemaking plan that would go up, again, to the EDO and to the Commission on it.

What we are looking at right now is 500 millirems to the caregiver. The caregiver would have to be an adult. The facility, it would be based on a physician determination that the individual could exceed the 100 millirem.

There would be no badging, no explicit badging requirement. However, the licensee would have to limit the dose to 500 millirem, and we would require documentation of ALARA instruction, and that a consent was given.

I would expect that the draft ruling, which would probably come before the ACMUI at the next meeting, but if you would like to take a few minutes and give me any comments on it, we can consider that in the plan development.

CHAIRMAN STITT: Larry, do you something on that?

MR. CAMPER: No, I just have one more thought on the petition just so you'll have, again, the perspective. The product has not yet been approved by the FDA either. They have the letter of approvability, as I understand it. They're in their final negotiations and discussions with FDA.

So, again, just for the record, we're not holding up this issue in that context.

CHAIRMAN STITT: Dan.

MEMBER FLYNN: So I guess we'll get more information later. I was curious about a 500 millirem single exposure to some procedure, and then there's no film badging or no exposure reports on these people who could get multiple -- I mean, I'm not sure what this is all about, but maybe you could give us about, but maybe you could give us more information the next time we meet.

MS. HANEY: Sure. I'll be able to give you more information, but basically it would be if an individual was in the hospital, was confined under 35.75, the caregiver could come in. There would be the potential that if the patient was in more than once and it was the same caregiver, that this

caregiver could get multiple instances of 500, and that's why to a certain extent the physician discretion is allowed in there when they're deciding that this person could go greater than 100 and could go to 500.

DR. FLYNN. Well, I was thinking about multiple patients with the same caregiver.

MS. HANEY: Again, that's the same. That possibility exists in this framework, and the rulemaking plan will go out to the agreement state for their review, too. I don't know. I saw Aubrey's hand go up. Did I guess what the hand went up for? But that'll go out for 45 days to the agreement state, and that's why I say I'll probably bring more in-depth information to you at the next meeting.

CHAIRMAN STITT: All right. I think that concludes that portion of the agenda, and I remember the agenda correctly, the next item is to discuss plan for the Commission briefing, and, Larry, didn't you and I say that that would be off of the --

MR. CAMPER: No, it has been transcribed historically.

CHAIRMAN STITT: Okay.

MR. CAMPER: So we'll keep it on the record.

CHAIRMAN STITT: Okay. Do you want to introduce this segment?

MR. CAMPER: I can do that.

You're at the point now where you're to focus upon preparation for your Commission briefing in May. You know, at the outset what we challenged you to do was to give your preliminary views on the SRM or DSI No. 7. We indicated to you that we would like for you to prepare a written set of comments on the SRM and DSI-7, for that matter other issues that had not been addressed in the DSI or the SRM in particular, and then we had a number of topics on the agenda this time that dealt with, you know, the real benchmark topics, such things as the quality management misadministration rule, the medical policy statement, and so forth.

So I think what you should do now is focus among two things. Clearly, what is it that you want to say to the Commission when you brief it in May about the SRM on DSI-7, about, you know, the positions that they're taking, your suggestions how they might achieve some of the things that they want to do as set forth in that SRM.

You know, these topics we've discussed. The medical policy statement, you might want to convey to them your position on the medical policy statement, your position on the quality management misadministration rule, the use of industry standards, the various topics that we've talked about here.

But I think more importantly, kind of stepping back for a moment, you know, you're briefing the Commission at a time when we are early in the process revising Part 35. What do you want to say to them? What do you want them to hear from you? What are your suggestions and advice?

How might you help us to achieve what it is the Commission -- I mean, obviously the policy makers, that being the Commission, have deliberated on this issue now for, you know, a couple of years. They've gone through the strategic assessment initiative. They've gathered public comments. They've considered the IOM report. They've considered your previous recommendations, and now they've done what they get paid to do. They make tough decisions.

Now, what would you like to tell them about how those decisions can be implemented and how you might help the staff in doing that and what your perspectives are on some of these topics that we've talked about and perhaps others?

You've got a short fuse. Really the 8th of May is going to be upon you very quickly, and Dr. Stitt will decide how she wants to proceed in achieving that, but I think that's the mission before you, and obviously it's a very important briefing for you because of where we are in terms of revising Part 35.

MEMBER NELP: How long? How much time is the meeting?

MR. CAMPER: It's an hour and a half, I believe.

CHAIRMAN STITT: All right. Let's talk about what we want to do. Show me who has been to a Commission briefing before. I think the vast majority.

(Show of hands.)

CHAIRMAN STITT: All right, terrific. So we know what we're doing.

MEMBER SWANSON: Well, we know how to get there.

CHAIRMAN STITT: Right. Lou, I want to know if I should take my mug with me or do you think it would be more prudent to -- in case you've forgotten, this came from the Commission at my first meeting. "I have sworn upon the altar of God eternal hostility against every form of tyranny over the mind of man," and I added "woman." I think that's Lou on one of his bad days. Maybe I'll leave it at home for that meeting.

Here's some of the things we've done in the past procedurally. I believe at our last meeting with the Commissioners there were slides that Barry presented. We as a Committee interacted with him by phone and by E-mail. We E-mailed things around, meaning the content of the slides around for people to comment, to make changes. It was very interactive.

It was essentially all done by phone, fax, and E-mail with an emphasis on the E-mail. Now, I've got

everybody's E-mail address, except John's is changing, but I'm going to still use your current one. Dan, I need a fax number from you.

MEMBER GRAHAM: A procedural question. I assume if I give the new one to Bill he would forward it to all of the Committee members?

CHAIRMAN STITT: That's a good idea because he and I are on line.

So any changes in E-mail or fax, please send to Bill because that's going to be an important way that we can interact quickly.

So I'd like to recommend that method. How does that sound to the group?

Now we need to talk about what we would like to be saying. I have some general comments, and I think that some of our comments to the Commission should be rather general as opposed to coming up with our blank piece of paper and fixing Part 35 between now and May. I think we ought to look at the aspects of 35, and it does have several subsections: general administrative, general technical, and other subsections. So I am just suggesting that the Committee not try to come with a fixed, down to the word because we don't have time for that, nor do I think it's appropriate, but I'd like to have the Commission get a feeling

from this Committee which has now been working together for several years.

I mean most of us have now been on it so that we have some cohesion here, not necessarily agreement with all the ideas. Some of you are going to have very specific ideas on very specific parts, and I find that valuable. Others are going to be looking at it -- we rely upon you, John, to have the overview. John, I'm speaking to you. Okay.

(Laughter.)

CHAIRMAN STITT: So you seem to be particularly adept at that. So I'm not going to assign parts. Anything is fair game, but that is certainly one of my ideas, that we should address any part we want to, and we don't have to get down to the sentence structure.

So I'll stop talking there and let the committee continue. Jeffrey, then Dan.

MEMBER WILLIAMSON: Well, I think there are broad areas of concern that we, most of us, agree on. I think it would be helpful to talk about, you know, the discussion we had on the medical policy statement and where we think the boundary between regulated and unregulated activity should be in the practice of radiation medicine and why and how that impacts, you know, the development of the new Part 35.

Maybe it's only my own hobbyhorse, but I'm really concerned about the associated enforcement process.

CHAIRMAN STITT: Say that phrase again. Dissociated?

MEMBER WILLIAMSON: Associated.

CHAIRMAN STITT: Associated.

MEMBER WILLIAMSON: Yes. I'm very concerned about the associated enforcement process. I think, you know, many of the specific aims and endpoints and even prescriptive suggestions are those all of us in our institutions would implement in one way or another, but the enforcement process, at least in the hands of some individual inspectors, is a highly torturous, time consuming activity and one that I think creates a lot of animosity between the user community and the agency.

So, you know, my feeling would be that we should try and get the thought out there that not only should we be designing a set of regulations that define endpoints and required procedures, but somehow the body of the regulations themselves should address the enforcement process and sort of set limits to try and make it more likely that this enforcement process will follow common sense and be more consistent with the clinical practice at, you know, institutions deemed to have an adequate program.

CHAIRMAN STITT: I'd like everybody around the table to have an opportunity to make statements about strong

feelings that they have on the medical policy statement and DSM or 35.

MEMBER WILLIAMSON: So just as a general theme, that's something, you know, I would like to see.

CHAIRMAN STITT: But I'm looking for general themes here.

Dan.

MEMBER FLYNN: No, I agree. I think at this meeting we should look at it as a great opportunity. I think you can start off with this basic philosophical issue about the medical policy statement, but don't take up the entire meeting on that.

I think if you look at this tab that says "SRM re DSI-7, Topic Page," and then page 2, there's just eight topics that cover only a half a page. It's what the Commissioners would like the staff to focus on, and they're looking for advice from the staff as being the high focused area.

We should use this opportunity to focus on these eight items, you know, revising Part 35, high risk, low risk, changing -- well, changing nomenclature from this administration -- that's a given -- Part 35 redesign. The quality management rule will become totally different. You know, using industry standards.

These issues, I think we could address these during a presentation which could take a half hour to 45

minutes, starting off with 15 minutes of the basic philosophical issue about the medical policy statement.

But putting that aside, I think we should address the specific things that they're asking for help on because this is our chance to have an impact in the beginning.

CHAIRMAN STITT: I agree with you.

Jeff.

MEMBER WILLIAMSON: Well, another thought. We might communicate with you via E-mail and complete maybe our -- maybe you could collate our thoughts about the sort of relative risks in different sub-areas. To some extent, you know, if we follow through coherently with our point of view, even something that would be in some sense deemed high risk by virtue of the severity of the possible complications, if there were medical events such as high dose rate. We're saying you shouldn't make reactive regulations based on single incidents. There should be some evidence that the problem exceeds, you know, some threshold which is defined by looking at areas of medical practice.

But still, they did ask us to do that, and I think it's maybe a useful point of discussion because it has a benefit for the nuclear medicine community of excluding from, you know, some levels of regulatory scrutiny a whole lot of procedures, which I think we should support that.

CHAIRMAN STITT: Well, and as we've had our meeting this past day and a half, within these Points 1 through 8 we have spent certain amounts of time discussing aspects of several of them, including high risk, low risk. We were able to focus on diagnostic minus Iodine-131, and I thought that was a pretty good step for us to begin with. So we can again use those opportunities that we've had for discussion in the other part of our report.

MEMBER WILLIAMSON: But I'm suggesting we all sort of do a little homework and maybe each of us, at least each of us that are interested, write out maybe our thoughts about the other areas of radiation medicine, send it to you, and you can look at them and see whether there's a consensus that we could present.

CHAIRMAN STITT: I agree with that.

MEMBER WILLIAMSON: Following the framework that we've kind of established for diagnostic.

CHAIRMAN STITT: And include in that as you're thinking through what are the close, personal, meaningful aspects of these Points 1 through 8 and Part 35 -- I am going to, since we voted as a Committee with Judith as the negative vote on the medical policy statement -- I mean, I think we can state that that was our intent, recognizing Judith's concerns, and that we don't on E-mail have to discuss that too much except as you have points to make to me as your points relate

to the modifications that we have brought up for change in the medical policy statement, it would be helpful to see how those relate.

So your homework assignment will be to decide what is meaningful to you from the eight bullets here, and that what you would like to write back to me personally and what is meaningful, you know, what strikes your fancy from Part 35, because you represent not only yourselves, but your institutions and the different parts of the medical community, as well as the patient, and I'm looking at you on this, Judith. Okay? I'm pleased that you're going to be part of our group since you've been with us so long for our presentation.

So that's your homework assignment, and then as I receive things, I'm going to pass them to the Committee. So everybody's going to be seeing what I get. I'll be the central clearinghouse.

Okay. Let's keep going. Larry's being the clerical supervisor here.

MEMBER NELP: I have a --

CHAIRMAN STITT: Philosophical concerns in general? Line Items 1 through 8. Okay. Medical policy statement, Part 35, okay. So those are things we're saying.

Dennis and then Wil.

MEMBER SWANSON: A comment on Number 3 there. If you look at what the Commissioners have asked you to do, they say focusing on Part 35 and those procedures that pose the highest risk. They're not asking us to define low risk and high risk procedures, and I think as a general point if you look at the definition of risk, okay, which is probability of event times the consequence of the event, based upon the NRC's own documented history on the reports of abnormal events and misadministrations, all of medical use of ionizing radiation is low risk.

That's not really what they're asking us to do here, is classify them as low risk versus high risk. They're asking us to focus on those procedures that pose the highest risk. Okay?

So I think we need to be very careful in talking. I guess the general point I want to make is that everything we're dealing with is low risk. Okay?

Now, I've come to the realization, the conclusion that we're going to be regulated. They're never going to stop regulating us. There's no way that we can convince them that they're low risk, but, you know, we've got to be careful how we use that term. Okay?

CHAIRMAN STITT: And do you feel better about yourself now that you've come to that realization?

MEMBER SWANSON: No.

CHAIRMAN STITT: But is it easier to live in the world that you work in?

MEMBER SWANSON: My low risk world or high risk world?

CHAIRMAN STITT: I think there are areas that will be regulated, and it's up to us to try to help focus on those areas that we think we can be helpful with.

Wil's next in line and then Jeff.

MEMBER NELP: I would think preliminarily we might want to look at Items 1 through 8 because some of them are really lightweight items that we don't want to spend any time with, and some are much more appropriate and meaty.

For example, Item No. 4 is changing a word or a concept versus some of the other things. So I was wondering if we could maybe -- it would help you. You wouldn't have to harvest comments from things that we really aren't interested in discussing with the Commission. We wanted to focus probably on three or four major items.

CHAIRMAN STITT: I doubt that we will make comments on all of one through eight. I'll see what the Committee's sense is, although the shortest sentence in the whole body appears to be Number 4. I don't think it's the most lightweight. I think that there's a charged environment about those phrases, and you know, it's our opportunity to have some impact or to at least get our opinions out there,

but we could have -- and I'm sure there will be hours of discussion through all of this process about misadministration, medical event or replacement terminology.

Jeff, I think you were next.

MEMBER WILLIAMSON: Yeah. I don't know if I understood Dennis to say that you think all radiation medicine procedure -- there are no radiation medicine procedures that fall into the category of high risk? No? I'm sorry. I just wanted to make sure I understood your comment.

MEMBER SWANSON: You know, I'm so confused about the definition of risk and how it applies to this, okay, because if you look at the classic definition of risk, it's the probability of an event times the consequence of an event, and I think we've got pretty good data to suggest or not even suggest; we've got good data to support that the probability of misadministrations, the probability of occupational exposures, the probability of public exposures associated with the use of ionizing radiation in medicine is very low, and if this is a product, probability times consequence, that would make everything low risk. Okay?

So that's a general philosophy. Now, you know, what they're asking us to do here is to focus Part 35 on procedures that have the highest risk. They're not saying pose them on high risk versus low risk procedures. It gets

confusing within the definition of risk and what we're supposed to be doing here. Okay?

I think it's important for us to emphasize that by classic definition of risk, everything that we do is low risk.

MEMBER WILLIAMSON: Well, can I follow on that?

CHAIRMAN STITT: Well, let me make a comment and then you and then Lou.

I mean, if you look at radiation medicine in the context of other areas of medicine, Dennis is exactly right. However, this is a regulated medical -- this part of the world is regulated by the NRC. So we, I think, have -- it's up to us to suggest areas that need higher surveillance than others, and I don't want to get this Committee caught up on definitions of risk, although that's a good one, but ranking risks.

I mean, I think you have to look at this as an overall picture, but there are areas of radiation medicine that need more surveillance than others, and in that sense, I'd be glad to, you know, develop some sort of a step-wise approach.

Jeff.

MEMBER WILLIAMSON: I think we do have to be careful. I think something like high dose rate brachytherapy or stereotactically guided external radiation, you know, the

inherent risk to the patient is high. If you do it badly or carelessly, you can really hurt the patient.

Now, having said that, the way the medical profession conducts the operation or execution of these procedures, the actual risk is quite low because we, as professional practitioners, incorporate all kinds of safeguards and procedural details to greatly minimize the incidents of these unfortunate events and to mitigate the severity of the consequences if they occur.

So I think maybe this has to be one of the points we hammer away at, is how basically the professional sub-communities conduct themselves, but inherently the risk is higher compared to something like diagnostic nuclear medicine, where I understand from the statements of our esteemed expert colleagues you could really, you know --

PARTICIPANT: You can screw up in a moment.

MEMBER WILLIAMSON: -- not know what you're doing at all and really not hurt anybody very badly.

So there are some inherent differences, and I think perhaps we need to sort of highlight this and be real honest because we wouldn't be devoting the resources within our professions that we do to quality assurance and operation of a skilled and trained treatment delivery team if we didn't think that was so.

CHAIRMAN STITT: Thank you, Jeff.

Lou Wagner.

MEMBER WAGNER: I think it's important that we look at this in a little bit different light. I don't like talking about risk. I think we should talk about the potential for risk, the potential risk.

Potential risk, if this type of work is done in an unregulated environment, that's what we're looking at. What's the potential for risk if it were unrelated? There we are.

And I think Dennis' comment is correct that we want to look at the higher risk activities, the activities at which there is the higher potential for risk. That's all, and let's keep it in that focus and not try to define risk itself. It's potential for risk if we were working in an unregulated environment.

CHAIRMAN STITT: Thank you, Lou.

How about this side of the room? Wil?

MEMBER NELP: Well, I think if we told the commission two things, one, that if you look at the risk of radiation in medicine statistically, that the group has done an excellent job because it is a very unrisky business or low risk business, and I think what they want to hear is exactly what you said. What procedures are there that you have to be careful about because you're going to harm a patient if you don't do it correctly? And that's what I would envision to be

a high risk procedure, and if you screw up in some process of the control or the administration, then you could potentially harm that individual patient in that individual procedure, and I think that's what they want. That's what they're directing us to focus our attention on, and I think we should probably agree on that.

CHAIRMAN STITT: I think we do.

MEMBER NELP: But I think telling them it's not a risky business is a pretty good idea, too, to say overall this business is conducted at a very effective low level of risk.

CHAIRMAN STITT: Right.

Dan Flynn.

MEMBER FLYNN: I think I'd try to keep it a positive viewpoint as to what they want, try to keep a positive attitude, and I would look upon it this way. If I was a Commission and if I was a nonmedical person and I just came on as being a new Commissioner and I found out that there's no full-time medical people in the entire organization, and if I did have the viewpoint that maybe we want to start backing away from activities which don't have a high risk associated with them, I would want to be able to at least cover myself in the event, since I'm responsible for the public health and safety, to get the medical people involved to help me define what is low risk so if certain items are removed from regulation, and then let's say something should

happen, that I've done due diligence by involving the medical experts in a process to remove that low risk item, and therefore, I cannot be held accountable for having not protected the public health and safety.

So we should look upon this as a positive event as much as possible and put ourselves in their shoes, if we were Commissioners with no medical background.

CHAIRMAN STITT: Let me ask that question a little bit stronger. What is the opinion of the group about the clinical perspective? That is, the NRC staff, the Commissioners are from a variety of backgrounds that relate to radioactivity, health physics, health safety. I think this group provides the only clinical background as far as the practitioners of medicine, dealing with patients. How far do we want to go with that kind of statement or perspective?

It can always be used as a clause in any statement that's being made, a phrase, rather than anything very direct, but I think that's a lot of our frustration, is when you're sitting there with a patient, it doesn't matter what issue we've been discussing. Certain areas that we've been through in many of our meetings just come across differently when they're in the regulatory framework of a piece of paper and try to translate that to taking care of a patient.

Jeff.

MEMBER WILLIAMSON: Well, I think it's unfortunate that there are no ex-clinical practitioners involved, you know, in the operation of this group that are actively writing regulations and functioning as regulators. I think it would be really helpful and go a long way towards introducing this sort of theme of common sense throughout the whole organization at the level of writing regulations, developing guidance for inspections and licensing if it were possible for NRC to recruit from the ranks of, you know, nuclear medicine pharmacists, physicians, and physicists.

I have heard all of the arguments about, well, you'll lose your clinical skills and so on, but hire them not as clinicians, but as regulators. I think there are all kinds of questions about salary structure, differentials, and so on, but that would really be, I think, helpful if, in addition to hiring from the ranks of radiobiologists, nuclear engineers, peer health physicists, if there were some component of the important people in the agency that came from the ranks of clinical practitioners, not as medical specialists, but as actual regulators.

CHAIRMAN STITT: Thank you, Jeffrey.

Other comments? Wil.

MEMBER NELP: I think inherently we also not only speak for ourselves, but we do not officially, but unofficially represent a tremendous group of people out there

in our own groups, societies, colleges, or whatever, and when you were talking about we're the only guys who -- this Committee has so many people who are involved in looking at the medical aspects of things. I think it would be of some value to say we also represent the thought line of thousands of other physicians that we're in close professional contact with on a very regular basis.

CHAIRMAN STITT: That's kind of an alarming statement to even see up there, Larry. Clinical practitioners as regulators. I think you have to give up your license or your society membership or something.

But, no, I think that point's well made, and it is something that we have been discussing and that we do find frustrating.

Lou.

MEMBER WAGNER: I think the President ought to appoint Barry Siegel to the Commission.

MEMBER WILLIAMSON: Hear, hear.

MEMBER NELP: Is he a Democrat or a Republican? That's the first thing I have to ask you.

MEMBER SWANSON: He's a registered independent. I asked him that yesterday.

CHAIRMAN STITT: But he said he sent a lot of money to Ronald Reagan hoping he would decrease his taxes. So I don't know where that puts him.

Aubrey, and, John, you're going to have to say something. So be thinking about it. So get ready to be clever.

Aubrey.

MR. GODWIN: I would offer another subject you might want to consider taking to the Commission, just as a passing comment. There are some of these regulations in Part 35 that really could be pulled out now, 35.20 probably being the most outstanding one, but you have some related ones like 35.70 and 35.21(b)(4) and (5). I assume that they could just revoke entirely and they wouldn't lose anything, and that would, I think, show some progress in trying to help things.

There are a lot of others which I guess individually some of us might like or not like, but I think those would probably be the unchallenged ones to go.

You know, if you have time, I think that might be a good one you might want to bring up and get some very specific things the Commission can look at in the short term and do something.

CHAIRMAN STITT: Lou, that woke you right up, didn't it?

MEMBER WAGNER: Yeah. As a matter of fact, at one of our previous meetings we were asked that very question. What could be pulled right now? What could you do right now?

We gave them recommendations. Nothing's happened.

MR. GODWIN: You'll have their attention personally at this time.

CHAIRMAN STITT: Let's take this as an opportunity. Turn to your book.

MEMBER WILLIAMSON: Part 35.

CHAIRMAN STITT: Part 35 is in there. Just the face page, 35-1, and let's look through the --

MEMBER SWANSON: Can I make a comment?

CHAIRMAN STITT: Let's consider that and see if we want to go anywhere with it.

Yes, Dennis.

MEMBER SWANSON: Can I back up and make one comment about the need to emphasize that all of what we do is generally low risk when you look at the standard definition of risk?

I think it's important and one of the approaches I always take with regulatory agencies is quoting their materials back to them. Okay? If you look at all of this stuff which nobody bothers to look at, DESY-12, these things on probabilistic risk, I mean the agency itself has defined risk as probability of the event times the consequence of the event, and I think we need to use that definition to document, okay, that these are low risk activities.

And the importance of that comes back to our need to develop performance based regulations because if you look at the definition of performance based regulations, it states, "Performance based initiatives are considered for activities where failure to meet the performance criteria results in tolerable conditions for which appropriate corrective action will be taken."

So if we're going to push ourselves, and I think we want to push ourselves towards performance based regulations, it's important to emphasize that these are low risk activities, to begin with. Okay?

CHAIRMAN STITT: I think you've said that. You just wanted us to hear it again.

MEMBER GRAHAM: Point of clarification.

CHAIRMAN STITT: Your question is has the NRC defined risk in that fashion. I think I saw it in something from '93. Does anybody -- can anybody confirm that or not?

MEMBER SWANSON: It's in these documents.

MEMBER GRAHAM: Well, the ACNP/SM document we received.

MEMBER SWANSON: No, it's in the NRC documents also.

CHAIRMAN STITT: I think I saw it in an NRC statement.

MEMBER WILLIAMSON: It's a pretty standard definition --

MEMBER SWANSON: Does anyone in the staff know where that is?

MEMBER WILLIAMSON: -- working in this area, isn't it, Judy?

CHAIRMAN STITT: Yeah.

MEMBER WILLIAMSON: So I don't think we want to argue with the whole profession of factors analysts and so on.

CHAIRMAN STITT: No, and we don't want to be saying to the Commissioners, "This is your definition," if that, in fact, is not correct.

MEMBER WILLIAMSON: We don't have that competent --

CHAIRMAN STITT: One of my favorite definitions is even looser. It's variation around an expectation. That's kind of cool.

Are you ready yet, John?

MEMBER GRAHAM: No, I would just like staff to verify that because I want to know whether we're going in and simply affirming the NRC's stated definition of risk or that we are citing some other definition of risk put forward by some other group.

MR. CAMPER: We can get for you -- there is a Commission position on the use of probabilistic risk

assessment in its regulatory approach. I can certainly get for you the documents that seem to espouse the Commission's perspectives on risk and the use of risk in its regulatory schema. I can get that for you.

CHAIRMAN STITT: And I think that's where I've seen it. If you can, we don't want to look real stupid.

MEMBER GRAHAM: Yeah, ideally I'm looking for staff to find a one-sentence definition of risk.

MR. CAMPER: Now, in this context, one of the things that they do talk about in DSI-12 is that clearly the use of risk assessment in the materials world is certainly not as refined or used as much as it is on the reactor side of the house. I mean DSI-12 does make that point, and that even in these NUREGs, which are, you know, prepared by contractors for the agency, they do make that point, that the use of risk in the materials world is not nearly as refined.

CHAIRMAN STITT: Under the tab that's labeled "Misadministration and QM," quality management program and misadministration, Point 1, there is a Commission paper dated 3/10/93 entitled "Frequency in Consequences (Risk) of Misadministrations." I think that's one of the places where I have seen it.

So they're tying those two statements together.

Larry?

MR. CAMPER: Let me toss out something for you to think about as you go through your deliberations. You know, where you are has been a long time coming and you have about an hour to make your points, and I think there's about a half hour discussion, and these things tend to move right along, and so it's my suggestion to you, having witnessed a lot of Commission briefings and having participated in quite a few, you know, what are the big points you want to make?

I mean, let me just toss a few things out on the table for you to think about.

For some time now, certainly I've heard this Committee talk a lot about, you know, the prevailing regulatory philosophy, and this is a question of the degree of performance orientation versus prescriptiveness, and it transcends into implementation. It affects licensing, inspection, and enforcement. So I suspect you have something that you want to convey to the Commission about the underlying regulatory philosophy that has been used or should be used. That's a big take-home point.

Government by yo-yo, we've talked about that. You know, we can refine Part 35 and make it, you know, as perfect as it could be, but if over time ten years from now we continue to do the yo-yo thing, we will probably find ourselves with once again an oppressive set of regulations.

So this idea of the way in which the Commission chooses to react to even singular events, I mean, I think I've heard this Committee talk about that over time.

Clearly, the reaction to the SRM. I mean, I know the Commission is going to want to hear what your thoughts are about the SRM. You've got these Items 1 through 8. You can step through those in fairly short order, but I'm sure they want to know what this Committee thinks about the SRM and how the staff might go about taking that direction.

Medical policy statement. I mean, you've spent a fair amount of your time over the last two meetings talking about the medical policy statement. If you think the medical policy statement is problematic or could be improved, you probably ought to tell them that. That's a big deal because, again, everything that the Commission does on the medical side should flow from the medical policy statement. It is the underlying policy that the regulations are borne from and that inspection and licensing procedures flow from.

Risk and the appropriate level of regulatory presence for that risk. I think that you can get terribly bogged down in trying to describe risk. Risk is a very difficult thing to put into a small box, but it seems to me one of the things I'm hearing your committee saying is that, you know, there's relative risk in terms of all kinds of things or there's relative risk if we draw a narrow box in

terms of procedures that we do in medicine involving byproduct material.

Now, some of those functions are more higher risk activities, and perhaps they warrant a higher level of regulatory presence, but by the same token it's almost impossible not to look at risk in the broad spectrum.

So it seems to me that your point is two things. One is you should not look at medical use of ionizing radiation in a very narrow perspective. It should be borne out of all risk. Okay?

And training and experience. We haven't talked about that yet. I mean, how many times have you talked about training and experience over the years? What is the appropriate level of training and experience? What's the role of the authorized user today in 1997 and what should their level of training and experience be? What about training and experience requirements, if any, for other practitioners involved in the application and administration of radioactive materials?

So training and experience is a hot bud. We talked about it a lot. It seems to me like it's something worthy of thinking about.

Quality management rule and misadministrations. Now, your quality management rule you'll have an opportunity to react to the Commission's perspective as you address that

particular item, but it seems to me that you've had some fairly strong feelings about the quality management rule. Certainly Dr. Wagner once again today said, "Look. I just don't see the efficacy for this. You haven't established it. It wasn't there to begin with, and you haven't shown it for four years."

So, I mean, you know, the QM rule is a big deal. Now, you can react to and you should react to what they're asking the staff to do. Okay? But you might want to say something about quality management rule. Should it be used as a rule? Should it not be used as a rule? Those types of things.

Misadministrations. The item tells the staff to change the nomenclature. That's the tip of the iceberg. That's the tip of the iceberg. I've heard you over the years say a lot of things about there's no other place in medicine where such events are required to be reported. These events seem to be treated in a punitive fashion.

It started off, if one goes back to 1980, as being a reporting of certain kinds of things, but over time it's had enforcement issues associated with it, you know, violations and so forth.

So it seems to me that misadministrations is something that you probably have some feelings about, and you want to at least give some philosophical perspective on.

Emerging technologies and the flexibility of Part 35 or the capacity to accommodate those emerging technologies in something that resembles a reasonable time frame. I mean just a few minutes ago you spent some time talking about the fact is we can't even get this Carbon-14 passed in some timely manner, and it's compromising American capitalism, and so forth, and it's not a safety consequence, and so I think I've heard the Committee over time talk about the flexibility and the capacity of Part 35 to address emerging technologies.

And then finally, it seems to me that if I were in your shoes, I would want to tell the Commission how the ACMUI process is working. You know, we spent some time in this meeting talking about further ways of enhancing communication. I think there are some positive things to say, and I think there might be some things that you still think warrant improvement.

How do you feel? What do you want to tell the Commission, if anything, about the ACMUI process, and in that context, what role do you want to play as we proceed to revise Part 35? Because clearly the Commission has said to the staff: use the ACMUI and professional societies and so forth.

So, anyway, those are just some big ticket items that come to my mind. Given that you have about an hour and given that as time marches on, you'll have, you know, quite a

bit of opportunity to address specific adjustment so the rule language and regulatory guides and all of that.

So, anyway, just some thoughts to share with you, just some observations.

CHAIRMAN STITT: Okay. Comments on this list that we've been putting together?

MEMBER FLYNN: Yeah, I agree with Larry that we've been talking about these things all along, and I think if you think of this as let's say it's a 40 minute presentation, the first half could be the regulatory philosophy, which brings in the medical policy statement, which brings in their classical definition of risk and our feelings about that, and then in the second phase, on Items No. 1 through 8, which can include the quality management rule because we're discussing Part 35, which also would include emerging technologies because we're discussing the modules that will go with Part 35, and trending experience which can go in there also.

But I think when we get to -- there's one item that I'd like to focus on. I think we should distinguish their definition of risk as part of the first, in terms of the philosophical issues and the medical policy statement, their definition of risk, because it's in our new recommended definition of medical policy statement.

But when we get down to the medical process, I have to really assume that the Commissioners are asking our input for us to tell them as medical practitioners who deal with patients what we think is -- let's forget the word "risk" -- a procedure which, if gone wrong, can result in dire consequences to the patient, and forget about risk. Medical consequence.

And technetium is not, and HDR maybe is, and I think we should be able to define medical consequences of procedures and classify them in general ways that way. Outside this formal definition of risk, they're looking for medical input from medical people who take care of patients as to what we think our procedures with significant medical consequence if they go wrong, and we should tell. Them they have no one else who take care of patients to tell them that.

CHAIRMAN STITT: Well put.

Yes?

MEMBER WALKUP: There's a definition of risk in this NUREG that we have on page 9.

CHAIRMAN STITT: What's the binder tab thing on it?

MR. CAMPER: Six, two -- give them the number.

MEMBER WALKUP: Sixty-three, twenty-three.

CHAIRMAN STITT: Okay.

MEMBER WALKUP: It's on page 9.

CHAIRMAN STITT: On page 9. Read it to us.

MEMBER WALKUP: "The definition of risk must be stated in operational terms. The ICRP discusses risk in Publication 60. Before the publication of this document, the ICRP had defined risk as a probability of a harmful effect, mainly terminal cancer or severe genetic effects. However, outside the field of radiation protection risk has several other meanings, such as a threat of an undesirable event, including the probability and character of the event," and so on.

CHAIRMAN STITT: Okay. I think that's saying probability and consequences.

MEMBER SWANSON: Consequence.

CHAIRMAN STITT: Yeah, Jeffrey.

Thank you, Theresa.

MEMBER WILLIAMSON: I think the third of the Big 3 in Part 35 we've had a lot of criticism of is ALARA principle, the way it's treated. So I really think that should at least be mentioned.

The other thing that's very difficult to quantify, but the last briefing, I worked with Barry and kind of developed the outline, bare bones, of a sort of alternative regulatory paradigm that relied more on a certification process than an inspection and looking for specific violations and failures to put signatures down and so on. I don't know

whether that would be -- it's a possibility though if we could build some consensus around it.

Lou and I have talked, and I think maybe we're closer in our views on that topic than we were.

CHAIRMAN STITT: Okay. I think it would be difficult to get a long discussion going and a group consensus in this short period of time. That could well be something that the Committee wants to bring out and discuss in detail as we continue to work, and I believe Larry was saying that we should potentially consider a subcommittee of the ACMUI to work with the working group as this process continues.

MEMBER WILLIAMSON: We might just suggest it. You know, there may be some relatively radical departure from the regulatory paradigm they're no using, might be considered, and this would be an example.

CHAIRMAN STITT: Other comments?

I guess I'll have to take John's advice because it looks like we're going to be wrapping up by noon. Is that how the Committee consensus is?

MEMBER NELP: The example would be --

CHAIRMAN STITT: Well, then we'll do it just for you, Wil. Well, we started an hour ahead of the printed agenda.

So let's make another trip around the room for comments. Go ahead, John.

MEMBER GRAHAM: If I'm hearing correctly, it sounds like the ACMUI is in agreement with the concept of risk that was stated by the -- what is this thing called? -- the International Commission on Radiological Protection in Publication 60, the product of the probability that an event occurs and some measure of the potential loss or consequences associated with that event.

I think that becomes a solid point of reference. I don't know that we're going to find that the NRC Commission ever passed that, but it's clear that the International Commission on Radiological Protection passed it, and they published it in that document.

So I would recommend that the start of a philosophical discussion, as Dan was saying, the introduction of this presentation, would be that the ACMUI supports the ICRP-60 concept of risk, quoting that thing.

I think I agree with Dennis. I think we need to point out to the Commission that the history of risk from the medical use of isotopes has been very low. It's the history. It's the actual reality that I keep hearing from Lou and Dennis and Jeff.

The history has been a result of the standards, policies, and procedures that have been voluntarily developed by medical practitioners and as a result of a portion of the regulations that have been established by the NRC.

I mean, as a hospital administrator I will not sit here and say that every hospital would have built an interlocking system to prevent entry into an HDR room if it hadn't been right. There are administrators out there that wouldn't have been enlightened enough and they could have saved a few thousand bucks, and they would have left it out.

So I think it's important that we as a committee agree that there are regulations that have been on the books that have had benefit, and I'd like to pause there because I realize that statement may be a point of contention.

MEMBER SWANSON: No, I don't think so.

MEMBER GRAHAM: No, it's not?

CHAIRMAN STITT: I presume you have it written down so you can E-mail it to me?

MEMBER GRAHAM: Yeah, I do.

CHAIRMAN STITT: I also want to tell you I know we've discussed this. Is your HDR unit bolted to the door, the wall, et cetera, et cetera? There was a blurb in this morning's paper. Somebody hauled off a time machine from a bank. I don't remember which part of the country.

MEMBER GRAHAM: Oh, an ATM.

CHAIRMAN STITT: It wasn't bolted to anything, and he carted it off with $5,000 in it. So I think I'd rather have that than an HDR source, but one never knows.

MEMBER GRAHAM: I agree.

CHAIRMAN STITT: All right. Do you want to go ahead and make some more comments, John?

MEMBER GRAHAM: Well, I think that, sort of having worked through that background, that the ACMUI agrees with the Commission that the NRC should, one, continue the ongoing program with improvements, which is Option 2, and, two, decrease the oversight of low risk activities with continued emphasis in high risk activities, Option 3.

I think to the extent that we can concur with what they've written into the SRM, it's awfully hard for a Commission to argue with what they've already told their own staff to do, and I think we tend to agree with those two options.

MEMBER NELP: Tend to comply with that option. We've said that we didn't agree, but we are willing, certainly willing to comply.

MEMBER GRAHAM: Well, and in the E-mail we can debate --

MEMBER SWANSON: I think --

MEMBER GRAHAM: -- the nuances of verbs.

MEMBER SWANSON: I think you want to add in there to develop performance based regulations because actually the justification that these are low risk makes it justifiable to do performance based regulations.

MEMBER GRAHAM: Correct.

MEMBER SWANSON: Okay.

MEMBER GRAHAM: I think Lou has an observation he'd like to make.

MEMBER NELP: I thought we were on this other table, John.

I did have a comment. I think we have a pretty big platter, and the things that Larry mentioned I thought were all relatively important, and I like Dan's point of view. Well, we're going to tell them one or two or three things, and we're going to group them, and I see that happening, and I think that's the most important thing we can do, say, "We have three things we want to tell you, and this is what they are," and these will be part and parcel of those things.

CHAIRMAN STITT: Right. I need to have some comment from the group about training and education. Do we want to be bringing this up? If so, what do we want to say and where?

I also agree with your overall statement that we can't be fixing the world here. We want to be --

MEMBER NELP: I don't think that's very controversial at the moment, is it? I mean I don't want to --

CHAIRMAN STITT: A couple of shakes no.

MEMBER GRAHAM: I'd like to hear Lou's feedback on what I had said so far before we move on.

MEMBER WAGNER: Yeah, what my comment was going to be is the following. Most of the regulations that are written reflect common sense, and personally if you go through the regulations like Mr. Adler in the former IOM report, many of the regulations are just reflecting common sense.

A lot of times when these regulations become onerous, it is not the regulation. It's the enforcement of the regulation, and therein lies a lot of the difficulty.

I think this Committee can make all of the recommendations it wants regarding changes in regulation, but with that has to be reflected a change in enforcement, and I believe that the change in enforcement of regulations should be that they, too, must be performance based, and we must stop this attitude that if there is a violation, then even though you run this enormous organization and you have several minor violations, we're going to go make them public and advertise them to the world that you're a bad institution because you've got three violations.

And I read that in the newspaper not too long ago about violations at one institution, and we read it in front of our radiation safety committee, and the conclusion of the newspaper was that this was a serious problem at this facility because here is a history of violations at this facility, and when we looked at all of the violations, we said, "Well, my

God, they're rather minor and actually they're running a damned good program."

This is the problem. We have to tie the idea that not only must there be a change in the regulation to a performance based regulation, but also to a performance based inspection so that the enforcement looks at the facility, and there may be several minor events, but then because they're minor, the score overall for this facility is very high, and they should not be issued violations or citations, but what they should be written is as a complimentary program saying you're running a great program. You have a few things that we have spotted as potential deficiencies, and you may want to address these in your radiation safety committee as to how to make them better or something.

Such a type of enforcement would go a long way in improving the relationship, and, God, we need improvement in the relationship between those who are regulated and the regulators. If you did that, the problem about the information flow on events and things of that nature would start to be alleviated and you'd learn more. You'd open up doors.

CHAIRMAN STITT: Nicely put.

MEMBER WILLIAMSON: Very good.

CHAIRMAN STITT: Dan?

MEMBER FLYNN: I'd ask Larry: with the various regions now, four regions now instead of five, but when there are so-called, quote, misadministrations, my understanding is they would come up to headquarters, and headquarters is involved in somehow advising or determining enforcement so that a region, let's say, Region II, doesn't react in a much more different manner than Region III, for example. There's some kind of balance or proportionality involved.

Are you looking at those issues in enforcement right now?

MR. CAMPER: Right. What happens is the regions have the capacity to make a call on misadministration, that it's clearly and obviously a misadministration. If there is any question whatsoever, they are directed to send them to headquarters under a technical assistance request for review.

It turns out that probably, oh, a very large percentage, probably as high as 80, 90 percent, actually are sent to headquarters under a technical assistance request. We review them as a staff. We make a determination as to whether or not there's a misadministration, and we coordinate it with the Office of General Counsel.

MEMBER FLYNN: The enforcement part, you're heavily involved in the enforcement part in terms of --

MR. CAMPER: Well, the enforcement aspect of it is, I mean, the regions are following the established

enforcement procedures, and those are, certainly should be and I believe they are to varying degrees of success, conducted consistently throughout the four regions following the inspection or following the enforcement guidelines.

MS. HANEY: Let me add that if it does go into escalated enforcement, which would be severity level I, II or III, that our Office of Enforcement gets involved in the case, and the regions review it here with the headquarters office, and we have staff from IMNS that sit in on those enforcement conferences.

So between our office, the headquarters office of OE, there is some uniformity between the regions about how a misadministration is handled once it is determined it is a misadministration.

MR. CAMPER: Right, and we're only in an escalated enforcement space, as Cathy said, at severity level III or higher.

MEMBER FLYNN: I guess I always thought, getting back to that point, if there were medical people here, medical fellows or medical people here, that minor -- what might be minor incidents -- don't get blown out of proportion in terms of not so much fines, but in terms of how information is presented when it is in the Public Document Room or when it's released to the public. The way the information is presented might be important to the public.

MR. CAMPER: Well, that's an interesting point. I mean, if you stop and you look at it, at severity level II and I, you are into events of consequence to the patient, and I think those are much more straightforward. I think the rub comes with regards to severity level III violations because what can happen in severity level III is the thing that Lou was getting at. I think this causes some people some problems.

You can have a misadministration that, on one hand, doesn't result in a violation at all or you might have a misadministration that does, in fact, result in escalated enforcement at the severity level III, again, setting aside the more extreme cases of Is and IIs.

And what happens sometimes is that it is an aggregation of violations to the severity level III that I think causes people some heartburn, and what happens is that usually occurs when there's a misadministration and we go in and we find multiple violations associated with the conduct of the quality management program, and the net result is following the enforcement procedures, it is aggregated into a severity level III, and then it becomes an escalated enforcement issue. It becomes published publicly, et cetera.

I think that's what causes the rub for some.

MEMBER FLYNN: And then the news media picks up on it and portrays it as multiple violations in a center with

a history of violations, and it can really be very damaging to a center if these are, in fact, a number of minor violations. I think it's the news media interpretation of what information is being made public.

MEMBER WAGNER: That was a very interesting thing we brought up in our committee because it was, I think, a Northeast institution and a large institution. It's a big problem for the institution to manage all of these things, and you go through a lot of expense and difficulty in really getting at minor issues when they can be handled in a much more efficient way. When good people are trying to do things and there are some minor problems, they don't shun them. They look at them and they say, "Okay. What can we do about this?"

And we're not trying to regulate the good people. We're trying to find -- the regulation is designed actually to try to make sure that we don't have bad people out there, and the bad people are those who are chronically doing the wrong thing, whether at minor levels or at major levels. They're sloppy at what they do, and they're bad, and that's what we really want to stop.

We want to prevent that because that's bad for people in general, but when you have good institutions that once in a while make minor mistakes or that have a few things that they just can't control absolutely to 100 percent all the time, but it's not hurting anybody; it's a minor thing, but it

doesn't show a chronic problem, well, then they're a good institution. They're trying to do the right thing.

CHAIRMAN STITT: Unless there are other cogent comments to be made, Larry has got some things to discuss at the wrap-up.

MR. CAMPER: Right.

CHAIRMAN STITT: Anything else that people have to get out in front of us?

Jeffrey always has to have the last word.

MEMBER WILLIAMSON: Well, one last comment. We've talked in the past in this committee suggesting that the regulatory presence should be, you know, uniform for all sources of ionizing radiation, which in radiation oncology would include Lin. Accs., and nuclear medicine, I suppose, includes cyclotron produced things. Do we want to comment on that at all? Just something to think about. It's an extensive topic, but it does sort of follow from our previously adopted position that, you know, we should be thinking of a regulatory scheme that would work for everything.

CHAIRMAN STITT: Well, they know that they can do that. I think maybe we'll just let them sit with it.

Larry, do you want to go into the kind of finalizing things here?

MR. CAMPER: Yeah. Okay. Let's talk about the briefing first. We certainly will need from you the slides which you want to make, the points you want to make. We'll turn them into the appropriate slides following, you know, the prescribed format and all of that for you.

Number two, you need to decide how you're going to handle the actual briefing itself. I mean obviously I'm assuming the chair would take the lead role there.

In the past what has happened is that all Committee members are invited to attend. They all do sit at the table. The chair normally obviously leads the way in the discussion. Sometimes the chair has asked other members of the Committee to make particular comments in an area that, you know, the chair feels that person is best suited to do. I'll leave that up to the chair, of course.

Again, and I think you're doing that, I would encourage you to make your points clearly crisp and global to the extent that, you know, in view of the fact that you have only an hour. I mean, if you get bogged down in a lot of detail, you'll miss the opportunity to make those key points you want to make.

You need to be thinking about -- okay. I think that's all on the briefing. Cathy, anything else you can think of?

MS. HANEY: No.

MR. CAMPER: Okay. Let's talk about the revision of Part 35 and the working group and so forth. If we assume for a second --

CHAIRMAN STITT: Let me interrupt for a second because I had a question. You just talked about the formal part. We need to allow some time for questions and answers or --

MR. CAMPER: Yeah. What's going to happen is I believe you have an hour and a half. I would think that your presentation and so forth, you know, would run on the order of, you know, 45 minutes to an hour, and then the Commission would have about a half an hour to ask you all questions, and I'm sure there'll be a lot of questions from the Commission.

MEMBER BROWN: Do you know what time of day it is?

MR. CAMPER: I'm not sure. I'll find out.

MEMBER GRAHAM: Could we find that out because that affects me?

MR. CAMPER: I will find out. I think it's --

MEMBER GRAHAM: Before we leave?

MR. CAMPER: I want to say 10:30, but I'll find that out. We'll get that.

Can we get that answer quickly?

CHAIRMAN STITT: And as we put this together, Committee, we'll end up with a presentation which I may make

all of or part of, and I may well make assignments. One of the reasons to do that is because this is not a Committee of one, and you know, I'm just Robert up here with the rules of order, which I don't even know very well, and I think it does indicate that if part of the presentation is made by other individuals, it helps to illustrate that we work as a group.

But, again, that's not a free association time. It would be very prescribed in the manner that we'll put it together, and you can count on the fact that questions, if they're given to me and I want to turf them, will be turfed. So be on your best and dress appropriately.

Okay, Larry. Go ahead.

MEMBER BROWN: And don't drool.

CHAIRMAN STITT: Don't drool, right.

MR. CAMPER: That's right. Don't drool.

Okay. Other issues, non-briefing. We're going to be submitting the plan or the program to the Commission. We have that June date to do that. Our goal is actually to get it up in May, but we can't get it up obviously any later than the June date, and if for the sake of discussion we assume that the Commission will adopt the staff's plan or something like it, one of the things I think the Committee ought to be asking itself is: how might we best interface along the way and interface with the working group, in particular?

For example, you might consider establishing a subcommittee that would be in place to interface with either the staff or the working group as we move along because what's going to happen is, if you stop and you think about it, if we get that plan approved in June and the working group needs to get a proposed rule to the Commission the following June, it's going to start to get very busy very fast, and there will be a significant flurry of activity in the second half of the year and into the first quarter of next year.

So I think a mechanism for the Committee to interface along the way is probably in order. That's probably something to think about.

The participation or observation of public meetings that will take place with the working group. If we assume this model is approved, then what will happen is this working group will actually -- there will be facilitated public meetings with the working group, and I guess the Committee might ask its, the ACMUI might asking itself, you know, what is the role that we want to play in that process. For example, do you want to have members of the Committee observe and be able to report back to the Committee, for example?

I mean obviously the staff will be giving you status reports on these public workshops and so forth and so on along the way, but, again, I think it's just a question for

the Committee to resolve in terms of a subcommittee or some interface in that regard.

And then the last thing I wanted to mention was really just a minor administrative point, and that is yesterday when I was going through the talk on the Committee process, one of the things that a couple of you noticed, and I had thought about that, too, was that your bylaws need to be adjusted.

So what I want to do is I will have the bylaws provided to you, and what I'd like for you to do in view of some of these changes we discussed yesterday is take a look at the bylaws and provide some comments on them because I think what we'll need to do is at the next meeting have an agenda item to reexamine and make some changes to the bylaws.

CHAIRMAN STITT: You're making gestures, John.

MEMBER GRAHAM: Well, just a point of clarification. Any member of the Committee or the NRC may propose an amendment. The proposed amendment will be distributed to the members by the chairman and scheduled for discussion at the next regular Committee meeting. I think that's what Larry's referring to because then it goes on to state in 5.3 that the final proposed amendment may be voted on not earlier than the first regular meeting after it has been discussed.

So we're looking at a year from now before we can modify these bylaws.

MEMBER NELP: They really don't constrain us in any way.

MEMBER GRAHAM: No. At least I'll forward some language to the federal officer in charge because I think they're just too restrictive right now. So we can't live up to our own bylaws.

MEMBER NELP: We've outlived our bylaws.

MR. CAMPER: So we'll start the process. That's it.

CHAIRMAN STITT: All right. That's all you have then.

Any other comments?

MEMBER NELP: I move we adjourn.

CHAIRMAN STITT: Everybody wants to get to the airport. Nobody wants to comment.

We have our work cut out for us. This is a unique opportunity.

Dennis and Larry.

MEMBER SWANSON: You know, I don't know if it's worth -- this is obviously, the rewrite of Part 35, going to be an extremely complex problem. Okay? You know, we sat and discussed or attempted to discuss the various areas, and we'd

just get started, and it would be time to go on to another area.

I think that, you know, getting back to the issue of how ACMUI interacts, it seems to me like each of these issues that you presented here needs to go through this type of process.

The other side of the coin, I don't think any of us have the amount of time, you know, to commit to that. I mean, it's probably worthy of a little bit of discussion right now.

CHAIRMAN STITT: Do you have some suggestions then?

MEMBER SWANSON: Well, do you see your working group as breaking out into various specific topics?

MR. CAMPER: Our working group?

MEMBER SWANSON: Yeah. Do you see your working group taking on just like the issues you presented to us, quality management rule?

MR. CAMPER: Yes. I think that the working group will divvy up amongst themselves certain subject areas to work on. I think that the working group will probably also ask the staff to provide certain information to it.

For example, I can envision that we might be asked to provide, you know, a white paper, if you will, on, you know -- I don't know -- misadministrations or, you know,

violations associated with QM rule or something. In other words, the working group as it goes about its work.

Ultimately under our thinking at this point, you know, the working group would actually ultimately create the proposed rule, and so I think that, yes, the working group will probably divvy up things amongst itself and will probably ask for certain staff support along the way to assist them.

In addition, of course, the working group during these public meetings that will be held, the working group will have laid at its doorsteps issues that are raised by the professional societies or the public, and those will need to be explored and worked on.

MEMBER SWANSON: Now, will this working group as you defined it yesterday -- would include members of the states?

MR. CAMPER: Right. The thinking has been that it would consist of members of agreement states, non-agreement states, and the NRC, and that there would be consultants that would be used also to interface with the working group to provide counsel and expertise.

MEMBER SWANSON: Should the consultants be members of this ACMUI?

MR. CAMPER: That's a possibility. We haven't gotten that far yet, but that is something we've talked about. That's a possibility.

MEMBER SWANSON: Is there going to be a need for more meetings of the ACMUI so as you develop a package on, let's say, quality management as a topic, we ought to have an ACMUI meeting where we just discussed that package? Okay? I mean it's too much to discuss all of this stuff from the one meeting.

MR. CAMPER: Yeah, I was wondering about that earlier, too. It's an interesting question because I can certainly see where the October meeting could be a very full agenda. You may need to have a two-day meeting, in fact, because at that point, you know, the working group might have begun to congeal some of its issues and have things it wants to get feedback from the Committee on.

Again, I think this is a question of, you know, should there be a subcommittee that would work with the staff and with the working group to process some of these issues. Then that subcommittee could report to the committee during its regular meeting.

The question of whether an additional meeting is required or not I don't have an answer as we speak. Obviously I'll need to let it mature a bit, but I can certainly see where that might happen, yes, but I think we'll have to kind of wait and see how things begin to materialize, but certainly you're going to have a very full agenda at the fall meeting. You're probably going to have the need for a subcommittee.

There's probably going to be a need for that subcommittee to interface with the working group along the way, and there may be a need for an extra meeting, in fact.

I think Aubrey had something.

MEMBER SWANSON: Yeah, you know, I guess the only thing I was saying is, I mean, I have a real problem dealing with about five or six issues, and I think this Committee has a real problem dealing with five or six issues at once, especially considering the amount of discussion that's going to have to surround all of these issues.

MR. CAMPER: Well, for example, if one looks ahead in your April meeting of next year, for example, you're clearly going to be dealing with proposed rule language because by that time the working group will have some kind of draft of the proposed rule language. I think their time line is to get that up at the Commission next June. So in that springtime meeting you'll be spending a great deal of time looking at actual proposed rule language under consideration by the working group.

MEMBER SWANSON: Is it within the budget to bring this Committee together more frequently?

MR. CAMPER: Oh, yeah. Yeah, we can do that.

MEMBER SWANSON: So as specific components of this rule are developed, we can come here and discuss those specific components?

CHAIRMAN STITT: Or are there other ways to do it without having to physically get together? What's allowable?

MR. CAMPER: Well, I mean, you know, we have to be careful. Some of the public notification can be a big problem. I mean, we have had conference calls in the past. We do have a notification issue there.

I think, you know, there's many ways to communicate. The big thing you have to be careful about is FACA guidelines for public notification and awareness. That's the biggest problem. I mean it's the operational issue to overcome.

MEMBER SWANSON: If we did this as subcommittees, do we have to address the FACA guidelines?

MR. CAMPER: Yes, you do.

MR. GODWIN: Yes, absolutely.

CHAIRMAN STITT: But conference calls that you establish ahead of time on some sort of regular basis so you can meet those guidelines -- it's certainly one thing to spend dollars. It's another thing to spend a lot of time that's required, and I think we could probably have more meetings if we'd do conference calls.

You both have your mouths open.

MEMBER GRAHAM: I'm waiting.

CHAIRMAN STITT: Aubrey and then John.

MR. GODWIN: Having just come off of one of these work groups, anybody who gets on it had better be prepared for a lot of telephone calls and a lot of time. You typically meet either by telephone or in person every couple of weeks to every month. Like I said, you divvy these things up.

We had ours set up where we had conference calls. We've had the notice posted on the NRC bulletin board, and my office was an official place to receive public comments during the thing so people could come in and, you know, be a part of the actual circuit, and other people could be part of that, too.

It worked rather well. Initially we divided everything out into little chunks and assigned each person to deal with each regulation. Eventually everybody has to come back and become an expert in every one of them. It does take time. It takes you a while to get up to speed. It's really a tough issue, but it's fairly efficient at getting things studied in depth.

I would assume that this group, when it comes back to it, will want to go do an in-depth study, and that will take time, depending obviously on what all is in the final version.

CHAIRMAN STITT: Yeah, I strongly suggest we look at that mechanism because it's physically, emotionally and mentally tiring to come here and get everybody up to speed at

the same time, and this issue is so broad and there are so many subdivisions that I think we need that time and the repetition to get everybody as close to being together as possible.

MR. GODWIN: One small comment about it. Keep the calls less than three hours.

CHAIRMAN STITT: Absolutely.

John.

MEMBER GRAHAM: Well, in that context I would request that staff review with legal counsel of the NRC the extent to which we can become involved in electronic communication without violating the existing regulations.

MR. CAMPER: We will do that.

MEMBER GRAHAM: If three of us end up on E-mail together, are we a subcommittee? If five? At what point have we simply de facto moved the meeting into cyberspace? But we need to know that fairly quickly.

MEMBER NELP: Larry, is there any way you can circumvent the need for public notification legally? I mean we have a job to do, a working session, dah, dah, dah, dah?

MR. CAMPER: Well, we have to be very careful. There are clearly FACA guidelines dealing with public notification. I can't entertain the term "circumvent them." We have to be careful that we do everything consistently.

MEMBER NELP: Well, this meeting can be extended.

MR. CAMPER: No, I understand.

MEMBER NELP: Which if we tell people here this meeting is going to continue next week, and if you want to show up, we'll finish the meeting then, et cetera.

MR. CAMPER: No, I understand. What we will do is we will meet with the folks in OGC who are our FACA gurus. We will carefully explore -- say that four times -- we have to be -- we will carefully explore the issue of electronic communication and what those guidelines are. We will also carefully explore what we must do and how much flexibility do we have with regards to notification versus workability.

We will definitely get clarification on those two points, and we will get back to you with that information.

CHAIRMAN STITT: John.

MEMBER GRAHAM: Specifically you may want to discuss with them whether the NRC can set up an Internet bulletin board to which we would then post E-mail, which is open to public access so that it is just that, public.

MR. CAMPER: Well, one of the things we are doing --

MEMBER GRAHAM: Because otherwise I'm already struggling with who do I send -- I'm going to E-mail this to the chairperson, but how does she assure that it gets to everybody else.

MR. CAMPER: Right. We'll get answers to those questions.

MEMBER GRAHAM: Okay.

MR. CAMPER: One of the things we are doing is we are going to be using the Web site in the Office of Research, which they have, and we're going to create a Part 35 Web site that will be open for public access and review.

But I understand all of those administrative issues, and we'll get a handle on those in the very near future.

CHAIRMAN STITT: The meeting with the Commissioners is at nine o'clock, from nine to 10:30 on the 8th.

MEMBER SWANSON: Whatever communication mechanism we use, I think it's important that it has this type of interaction because I can tell you I come to this meeting with certain ideas and perceptions as to how things are to go, and the interaction changes it because of good comments. You know, this is an excellent format to develop regulations in.

I'm just trying to figure out how you do that, okay, and still recognize our time constraints.

CHAIRMAN STITT: I think conference calling on a regular basis, just set it up as an agenda for whatever time, a several month period of time, and it really works. You do need to make sure you have a head phone so that you can stand

up to three hours on it, and it also has a mute button so that when you're talking to the dog or flushing the toilet, it doesn't -- oh, that's on the record.

(Laughter.)

CHAIRMAN STITT: I have a conference every Tuesday night for two hours. So I know these things.

Are we ready to finish this meeting?

MEMBER NELP: I move we adjourn. I move we adjourn, Madame Chairman.

CHAIRMAN STITT: Second?

MEMBER WAGNER: Second.

MR. CAMPER: The meeting is closed.

CHAIRMAN STITT: Thank you.

(Whereupon, at 12:25 p.m., the Advisory Committee meeting in the above-entitled matter was closed.)