FLORIDA DEPARTMENT OF HEALTH

ADVISORY COUNCIL ON RADIATION PROTECTION

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Reporting:
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ADDITIONAL GUESTS:

RAY DIELMAN

TERRY FRADY, RADIATION CONTROL

P R O C E E D I N G S

THE CHAIR: Why don't we all get seated. Good Morning, everyone. I don't think there are any new members of the council, but why don't we all introduce ourselves.

MR. TINEO: Alberto Tineo, Halifax Medical Center, Daytona Beach.

MS. BONANNO: Carol Bonnano.

MR. SEDDON: Mark Seddon from Florida Hospital, Orlando.

MS. DROTAR: Kathleen Drotar, Keiser College

MR. GUIDRY: Perigee Technical Services, Environmental.

DR. SCHENKMAN: Randy Schenkman, retired radiologist.

THE CHAIR: She loves to say that.

DR. SCHENKMAN: That's also because if something comes up that's very current and I have nothing to say about it, you know why.

MR. RICHARDSON: Tim Richardson, Marion County School of Radiology Technology.

MS. GILLEY: Debbie Gilley, Florida Bureau of Radiation Control.

DR. JANOWITZ: Warren Janowitz, Baptist Hospital, Miami.

MR. FUTCH: James Futch, Florida Department of Health, Radiation Control.

MR. PASSETTI: Bill Passetti with Radiation Control.

MS. LIVINGSTON: Janice Livingston, Radiation Control.

MS. GRANT: Vicki Grant, MQA.

MS. CURRY: Gail Curry, Medical Quality Assurance.

DR. WILLIAMS: Tim Williams, Radiation Oncology, Boca Raton.

DR. ATHERTON: Bill Atherton, Chiropractor, Miami.

MR. FRADY: Terry Frady, Radiation Control.

MR. DIELMAN: Ray Dielman, retired.

THE CHAIR: Has everyone had a chance to look at the previous minutes? Janice, did you send out an e-mail?

MS. LIVINGSTON: Yes, I did send out an e-mail a couple times. I do have a hard copy if anybody wants to verify corrections.

THE CHAIR: Comments or questions about it?

(No response).

THE CHAIR: Motion to approve the minutes.

UNIDENTIFIED: So moved.

UNIDENTIFIED: Second.

THE CHAIR: All in favor, raise hands.

(So signified by aye.)

THE CHAIR: I guess we move on to Item C, update on 64E-5, Rev 10, Medical Use Amendments

MR. PASSETTI: That's me. I just wanted -- as you know, in the last several Advisory Council meetings we've been talking about the radioactive materials, medical use of the rules, we've been working on for a number of years, trying to keep compatible with the NRC and update our medical regulations. Just wanted to let you know they became final effective in February of this year, and you should have a copy in your folder. Does this have all of 64E-5 or is this (referring to CD enclosed in member packets)--

MR. FUTCH: I think it's got everything.

MR. PASSETTI: It's got the whole 64E-5 on here, but it has the new medical regulations. I noticed yesterday all the changes are highlighted, makes it a little easier to see where the changes are.

As with any new rule, especially this larger rule, we're going to go through some growing pains, so I know Debbie and a number of others have made some presentations on the new rules and getting a

lot of questions. Surprisingly enough, we don't have all the answers yet, but actually Debbie started working yesterday on a list of frequently asked questions on the new medical rule, and James is going to get those on our website.

So keep looking at the website, and as those questions come in, we're going to try to get that updated to get some consistent answers to all the questions that are coming up. I'm trying to think of any controversial — really the biggest feedback we have gotten was on the medical physicist, their presence during HDR and Gamma Knife treatments.

So that is something that we had tried for a number of years to let people know that it was coming. The NRC put it in place, and we knew we had to adopt it. We tried to ease it in to let people know.

We still got a surprise when the rule came out. So I think it's calming down a little bit. Right, Debbie? No, maybe not.

MS. GILLEY: We'll know as inspections are being done.

MR. PASSETTI: So we're hoping that the licensees realize there are a lot of questions when

rules come about like this. We're trying to answer them. We'll be understanding of them, too, as we do our inspections.

So I think that's all I have to say. If you have any questions or need any additional copies of these, just let us know.

THE CHAIR: Do the doctors need to write a written directive for I-123 —

MS. GILLEY: For a diagnostic?

THE CHAIR: Yes.

MS. GILLEY: — would be in clinical procedures manual now (unintelligible) and any therapeutic application.

MR. PASSETTI: We don't have microphones, so if you could identify yourself and speak up, it would help our court reporter.

THE CHAIR: Any other comments?

MR. SEDDON: Yes. I think most of them were aware of the issues coming on board. I've heard most actually more of after the original (unintelligible) for the HDR and Gamma Knife right now. That is what I'm hearing.

THE CHAIR: Has there been any fallout from the state for some of the publicity that radiation therapy overexposure that's been in the papers

recently? I'm sure you're aware.

MR. PASSETTI: Yeah, I think that's a big issue that's been coming up nationally and in the state, and we are going to try to address some of those issues this morning with some of our presentations.

THE CHAIR: Okay. I guess we can move on to MQA radiologic technology update.

MS. GRANT: Good morning, glad to be here again today. Got a couple exciting things to tell y'all about.

One will be our new online application status check for the Rad techs and the basic x-ray machine operators (BXMO). They will be able to apply online hopefully beginning March of 2011, so we'll begin that process soon.

We do currently have online application status check, which allows an applicant to follow their application all the way through the process. That's very exciting for us. And we've had approximately 3,000 hits to that site so far.

The only other thing that I need to tell you about would be we are working on allowing our expired licensees to do online renewals, and

James and I are working on that together. So that's about it for us.

Gail, you have anything?

MS. CURRY: No.

MR. FUTCH: James Futch, Rad Control. A couple things, in our past few meetings, we showed you a new application for the radiologic technologist and also a rule amendment for Chapter 64-E, which governs the licensure process.

As part of that rule process, the applications were adopted. They became effective back in February, and so we now have two applications; one for basic x-ray machine operators and one for everybody else and other types of modalities.

The rule amendment as we went through the process came to council twice, made some changes, got your unanimous consent last time, which included a fee increase, you may recall, for several aspects of the Rad tech licensing process, for renewals, initial application, things like that.

Those went through. We had no negative comments from any member or organization in the state. Pretty much everything was proceeding according to plan, and unfortunately, as it went through the department for the last sign-off,

before we could make it official, apparently some things had changed.

And we did not get final sign-off on the part of the package that included the fee increases. A very small part of the rule did go into effect, which governed the four hour (unintelligible) update that all the technologists (unintelligible) as part of the initial licensing process, but the fee part of it did not go into effect.

We'll try again, I guess, probably sometime in the fall, and I don't anticipate any problems. I guess I'd appreciate your guidance as to whether you want us to proceed again as you had unanimously told us before with the same exact package that we had last time.

DR. SCHENKMAN: Do you know why it didn't pass?

MR. FUTCH: Well, to put it delicately, it could be seen as a tax increase. Try again in 11 months. That's that.

I did get a very polite reception and audience to listen very attentatively to all the technical reasons why this was very much important and very much needed. They completely agreed with all those reasons, and then

said, we're just not doing those right now, try again in a year.

So we'll be putting that back in again this fall, and we'll probably have the exact same as the October meeting. So we'll —

MR. TINEO: Alberto Tineo from Daytona. What was the — I can't recall, the PET CT and the SPEC CT. What is the requirement for the technologist? What can they do and not do?

UNIDENTIFIED SPEAKER: It's essentially the same. The statute, it's not specific enough to distinguish between a PET and a SPEC CT.

And what the statute says is a nuclear medicine technologist can do the CT portion. It's the only type of x-ray that a nuclear medicine tech can do, but there are several restrictions on it.

And also there's a qualifying 16-hours course they have to take in order to be able to do it.

MR. TINEO: Oh, but we didn't differentiate between PET CT and SPEC CT.

MR. FUTCH: The rule actually says Pet — the statute (unintelligible) so we've been — it's the CT portion of the training is really the majority of the 16-hour course.

UNIDENTIFIED SPEAKER: They still can't do any

diagnostic?

MR. FUTCH: No diagnostic. This comes up many, many times. And we have Ray, a former manager of our inspection office in Tampa, shaking his head, and he's now a consultant, and he's probably answering this question to many of his facilities as well.

They can't do the diagnostic portion. They can only use — excuse me, just getting over a cold — they can only use the CT portion for the combined nuclear medicine procedures, and it's only to do the attenuation coefficients and to produce the image of the body to paint the CT image of the body, the nuclear medicine data. So that's it for applications and rule amendments.

And, oh, statutory. We should probably mention statutory changes. We've had a couple statutory proposals from the council in past meetings. You may remember the change to the statute to allow us to issue specialty technologist licenses to people, for example, those who have passed the national registries in their post primary categories for which we have no current Florida analog.

I think you've seen that one probably for the past three years, and you voted unanimously on the

past two or three versions. Long story short, it didn't make it into the recommended statute changes this year as in past years. We will be proposing that again to the best of our ability for the coming legislative cycle.

And was there any other x-ray stuff in —

MR. PASSETTI: No.

MR. FUTCH: I guess that's it for those. Any questions on any of that?

MR. RICHARDSON: James, if that should go into the rule, that would allow the nuclear medicine technologist to take a post primary CT exam and then practice general CT in the state of Florida, correct?

MR. FUTCH: That's correct. And it wouldn't be in the rule; it has to be a launching of the statute change. We actually had a CT category many, many years ago, and we are prohibited right now by law from issuing a CT-only license by the closure of that old category, basically, the way they closed off any future CT only licenses.

So it's actually even worse than not having any licensure categories. In the one case of CT, not MR and all the, you know, the ultrasound and the rest of it, but in one case of CT, it's not only do

we not have a licensure category, we actually have a law that says we can't issue one, so.

MR. RICHARDSON: Why I brought that up is because there are a number of community colleges that have opened up post primary CT courses, and the people who are registering for these are nuclear medicine technologists. And I think their thinking is that once they pass that course and once they pass the CT advance registry, that they're going be able to do general CT in the state of Florida.

Is there any kind of information sheet that we could send out that would notify them that that's not the case —

MR. FUTCH: Sure.

MR. RICHARDSON: — until that law changes?

MR. PASSETTI: I think it would be really critical to communicate with those groups because the only way this law is going to pass, in my opinion, is if somebody like the community colleges are the ones that bring it to the legislators saying it's needed.

We're not having any luck getting it through the department as a priority, so if we can find groups like this that are promoting it, they're the

ones that really need to be talking about a launching.

MR. FUTCH: Especially, you know, when we have this change in the statute to allow the specialty technologist. We talk — you know, I talk to some of the lobbyists, and they're not hearing anything from their constituent organization about this.

And so in this grand bad economic time as well as all of the other normal things that the lobbyists are trying to protect their professions from happening, they tend not to want to spend any political capital on this particular issue because no one's telling them this is a problem, except for me and Bill. And that's got to change if this is ever going to happen.

MR. RICHARDSON: There's not a shortage of CT techs right now.

THE CHAIR: Quick comment. I've heard there's a reasonably good chance that the Care Bill is going to be passed by Congress this year.

MR. FUTCH: Yes.

THE CHAIR: I doubt if there's any effect in Florida, but have you looked at it to check on that?

MR. FUTCH: Not the most recent version. The

previous versions may force us to do something with the basic machine operators. It depends on how the final wording, you know, of course, once the law passes, the secretary just has to write the regulations, and I'm sure there will be plenty of lobbying at that point.

But, you know, Florida is one of the few states that has a limited scope radiographer that has no minimum educational requirement for prerequisite training before they sit for the state exam. They have to do a self-review of the state study guide.

So if the Care Bill were to pass and would require some sort of minimum educational requirement, then that would be one impact that we would have. But again, it's a minimum standards bill. At least that's the way it's been characterized in the past.

MR. TINEO: For the PET CT and SPEC CT, once they finish the education requirement that we passed here, the 16-hour course, do you submit that to the state or do you keep it in the institution for inspection purposes?

MR. FUTCH: No, it does not get submitted to Vicki's office. It stays with the technologist in the facility.

Now, the inspector can request it when he's in the field doing an inspection, but it doesn't come back to us.

THE CHAIR: Any other comments?

(No response).

THE CHAIR: I guess we're up to the presentations and medical regulation issues.

(Discussion about lunch plans off record).

THE CHAIR: Dr. Williams.

(Presentation was given by Dr. Williams).

(Paul Burress entered the conference room at this time.)

MR. WILLIAMS: With that, I'll be happy to take any questions.

THE CHAIR: Wasn't St. Vincent's closed this week?

DR. WILLIAMS: Yeah, they were. And they were seven hundred million dollars in debt, and nobody wanted to buy them. The whole hospital closed.

There's already been one patient die because they had a heart attack and went to St. Vincent's, and they just couldn't get them across town in time to the trauma center. So they're the only hospital that serves really the village and the lower left side of Manhattan. That's all there is.

Nobody's got that kind of money, you know, to take over hospitals. They have been hemorrhaging money for many years. But the oncology program closed long before the hospital did.

(Presentation given by Ms. Gilley.)

(Presentation given by Don Steiner.)

THE CHAIR: It's time for lunch, so what time are we going to reconvene? Let's reconvene at 1:00.

(Lunch recess.)

MR. PASSETTI: I'll start. I just really appreciate Dr. Williams and Mark and Debbie and Don for giving their presentations this morning. It's a real important issue.

What I'd like to do is have some discussion on the whole gamut, the therapy and the CT issues. I know there were several suggestions on things we can do or should do.

One, my concern is I think something is going to happen at the federal level, and we don't know what it is, so we are trying to figure out as a state what, if anything, we should do right now or what can we do right now and maybe just some education, maybe regulations, I don't know. I'd like to have discussions that we as a state need to

think about doing or if we need to wait (unintelligible) what the federal government is doing. Or how we should a approach it.

I'd appreciate getting ideas on any of the others or even the fluoro issue, because I think that's probably going to get to the federal level, when they start looking at radiation, they will start looking at everything. I'd like to have discussions or ideas on what you guys think we may or should not do.

DR. SCHENKMAN: Can I ask what happened to the letter we talked about that —

MR. PASSETTI: Actually I can talk about that now, and we wouldn't have to worry about Tab L. Oh, the letter is actually in Tab H, the final version of the letter is under Tab H.

We finally — we are having some difficulty getting it to the Surgeon General. They put up some road blocks and everything. She's got so much going on. One day my (unintelligible) was meeting (unintelligible) hearings letter we've been working on, you put it in her hands, and she'll really be interested.

I think most of you know she's got a background in radiology. We've been talking to her quite a

bit about the medical radiation issues and the CT issues, and she's really interested in it, and I'm suspecting in the next week or two, she'll sign this letter.

And she's also interested in — whatever else we do in the medical radiation field, she wants to stay involved with it. So she's really supportive of it. So that's kind of where we are with that.

MR. DIELMAN: For the record, I'm Ray Dielman. My hair loss is not due to CT. I do have a couple points of view, if I may, briefly.

And the first is, I am the CRCPD liaison to the joint commission, and they are visiting many of these same issues, as you know, and then two, as sort of a semi-retired — well, not sort of, I am a semi-retired health physicist and a radiation safety officer at a couple of facilities in the area.

You know, what, kind of speaking globally from all of it, my suggestion would be that we do something proactive and do it now. There's — because what I'm hearing from various sources, and I think Mark can speak to this too because he has some of the same sources that I do, maybe more, the federal government is going to do something.

And the problem is they're not sure what it is they're going to do, and that's scary. But one of the words that I hear, the sentence that I hear from time to time is that they're willing to — they're going to go in and put something in place particularly for those areas that don't already have it in place, and that's why I'm suggesting proactivity.

A couple things come to mind. We talked at this meeting before about them, on the fluoroscopy side, because that's something I've been dealing with the joint commission for a long time. The joint commission did adopt the sentinel event criteria as you know. Don alluded to it this morning.

That's the first step, but there's — it's one thing to have a sentinel event criteria. That's a pretty high criteria, by the way. A lot of people think it's too high. A lot of people think it's not enough.

But then there are a lot of caveats getting there. Sometimes the case takes a long time. Sometimes the case is done by persons who perhaps could have a greater skill level, so those things have to be weighed in.

So the bottom line of that on the fluoroscopy side, what the joint commission is trying to enhance — they already have it in place, just trying to enhance it — is that there should be a requirement at every health care institution that uses fluoroscopy, that there be some credentialing and privileging criteria.

I'll give you an example of that. If you came out of Baylor University, for example, in the last 15 years, or actually 20 years now, I think, you would have come out with a certificate that says, I have — in my residency program, I received specialized training in radiation safety and equipment operation, fluoroscopy equipment operation, and I'm qualified from that perspective to do it. All right.

Well, you take that same criteria at one of the hospitals that I'm working with, they have created their own criteria along that regard. Rather than — there are some, by the way, some programs out there that you can adopt. Everybody doesn't have to recreate the wheel and create their own program.

There's some programs already out there. Again, Wagner and Baylor has such a program, and

it's a good one. And it's actually fairly inexpensive, I think. They downsized. For most physicians it's six CMEs.

And getting physicians to spend six hours to get six hours credit is rather difficult, at least in the acute general hospital environment where we're dealing with cardiovascular surgeons and pain management folks. So there's an opportunity there for, I think, the state as part of the CRCPD or as — I mean, you know, the states are the CRCPD, as it were.

But for a letter again, Bill, maybe from you or maybe from Don, however you choose to do it to get out to every registrant that does fluoroscopy and say, this is what we'd like to see. Everybody knows what the regulatory aspect is, but when you say it, it's helpful. That information there that you send out — what is it 32? What is it, Don? Whatever it was — very helpful.

I had to explain that to some people though. I have to tell you. I would suggest you might break that down to like the fifth grade. I don't mean that facetiously. It's just that people — and particularly, when it has to do with SI units and so forth, people just don't get it. Or maybe some

little chart that helps in that. That's one step.

Second step, in therapy, I know we haven't talked a great deal about therapy in that regard, but years ago, Don and — well, there was a group, all right, actually led by that young lady over there on the right-hand corner, who created, worked on creating — being the coordinator, as it were, Don was very much involved in it and others at the time, creating essentially a quality control process for, I think the goal was inspections at that time and so forth, but a whole quality control criteria.

And we might want to resurrect that. That's as good today — it's probably better today than it was then in a sense people can see the need for it. But there's a whole list of steps to take in order to have a good quality safety program in every radiation therapy operation.

And it was not too prescriptive, I think, but the point is it raised a little bit of the same thing the CT document did. It raised, you know, elevated the subject, so there's an opportunity there.

And on the CT side, I think Mark said that — I heard two variations of that in the last two weeks

because we all go to the same meetings all the time. But both times it's been excellent. And I think the clinical aspects of those or clinical summaries that Mark had — perhaps you would repeat them again — are very helpful, if we can get to that point, you know.

And then the final issue I think on a global is appropriateness. That's very difficult. But appropriateness criteria. You won't be able to solve it, but, you know, we can move forward.

So I think I've covered the four modalities in that. Thank you.

MR. SEDDON: Mark Seddon. Actually, there is a FDA white paper that came out in spring, minimize radiation exposures. Actually sort of my recommendations on operator clinical outcomes for suggestions, kind of mirrors what they say from the FDA as far as they (unintelligible) in three areas.

One is giving patients their dose information and another two are on both appropriateness criteria and property (unintelligible.) I mean, that's something that actually is out there currently from FDA.

THE CHAIR: Let me just make a few comments,

because certainly this committee, I think, could deal with appropriateness of optimized — the operators are trained to properly do the studies and record the doses. And that's, you know, the minimum that we should be able to do.

But the other issues are obviously harder and kind of beyond the scope of this committee, but I think they need to be addressed. And some of the things, at least from the physician viewpoint, obviously appropriateness criteria are important. However, they're pretty easy to get around in terms of ***watering cases, *** watering studies.

You have to have to know the right diagnosis to put in, and it's going to come out okay. Changing physician behavior is going to be tough. A large part of the problem, I think which is a much bigger issue than we can address is number one. Over utilization due to malpractice issues.

If you don't have tort reform, people are still going to order a lot of unnecessary tests. In addition to that, you've got the issue of self-referral, which is another probable cause of over utilization.

Again, it's something that's going to be real tough for this committee to address, but unless the

legislature is willing to look at it, I think that's going to be really difficult. I think we can take a role in educating physicians concerning over — concerning radiation exposure from different diagnostic tests.

I think I suggested last time that we maybe approach the Board of Medicine about having some sort of radiation CME requirement similar to the domestic violence and the (unintelligible) safety, and some of the other requirements required for licensure.

I think if we can get every doctor in the state to have one or two hours of a required course on, you know, radiation exposure for medical imaging, I think that might help. Certainly, I'd say 90 percent of doctors have no idea what that is. It's not a topic that's covered in medical school, and it's probably something that I think the Board of Medicine might embrace.

I think they would have to be the ones to look at it because they require — or they're the ones that set the standards for CME for physicians. I think that would be a worthwhile thing for physicians to know, what are the dangers of radiation, how are we looking at risks, what is

exposure from a CT scan and so forth.

And I think that's something we could encourage as a committee. But, you know, from the big picture, patient dose cards, you know, it's probably something that the patients like. It's kind of empowering to the patients, but it doesn't — I'm not sure what that really accomplishes.

Is the patient going to say, well, I reached my limit for the year, I'm not going to take this brain CT that my doctor wants to get because radiation is too high. I think you'll be scaring patients.

No one really knows what are too high, or what is too high. You know, how do you determine, you know, are you going to stop doing tests on a patient because his card has reached a limit. I don't think that's going to happen, and you're going to scare patients.

So it's a really complex issue. I think the goal should be an overall decrease in unnecessary testing and certainly optimize imaging protocols, all sorts of imaging procedures. And then, you know, other issues such as the self-referral and the tort reform probably would have a major

effect.

But again, that's something that's going to be real tough for us to have any effect on. My two cents.

DR. WILLIAMS: I can tell you that, you know, this committee is not going to solve all these problems this afternoon. I know you guys are looking towards that as a goal. It's going to take years to get any type of meaningful change in this situation.

What I can tell you, what Astro knows about the national situation is that the health, or they just call it health — it's the subcommittee on health, but Frank Malone's health committee will draft some legislation this summer. They haven't started yet. Nobody knows what it's going to involve.

There's been some solicitation, you know, in the immediate time after the hearings. Some questions went out actually from Energy and Commerce. It came out under Dr. ***spg*** Waxman's name. I was asked six questions to apply to, and other people got other questions as well.

And that will form, I guess, some initial, you know, information, from which they will write some legislation. Most likely, the specialty

that will take the biggest regulatory hit is diagnostic radiology and the CT scanning in particular.

At the hearings there was a presentation made from a lady, I believe she was at Mayo, on radiation biology and the idea of, you know, how radiation affects living tissues. At these hearings, you got six minutes to make a presentation, and the clock is ticking the whole time; six minutes. So that's it.

It's not about you. It's about the legislators and the congressmen having a chance to get stuff out into the public domain.

This lady made a presentation that was as complicated as Chinese algebra. It didn't make sense to me, you know, a lot of it, and I've been, you know, studying this stuff for 20 years.

There's no stomach in the subcommittee to deal with radiation therapy, cancer therapy beyond making sure that they do everything appropriate, so they're reaching out — they have reached out to Astro. They're interested in our six point action plan.

Without speculating on the work product of a government subcommittee, it's likely that we'll end

up with Astro-type stuff. A CT scan though is another matter. It is of larger social significance, number one. You're talking about millions of CT scans being done potentially unnecessarily.

And there's a fair amount of rank, you know, from some of the congressmen on this. They don't like the idea of their constituents being radiated with unknown doses, with no, you know, registration of them or anything.

So it's pretty likely you're going to see mandatory reporting of doses to the patient of each scan and lifetime, you know, registration the cumulative dose. And then they'll say, that's between you and your doctor if you want to order the test or not.

But you need to know the patients have a right to know their lifetime exposure to radiological therapies. That's a probability; although like I say, at this point, everything is purely speculative.

I don't think there is any doubt that the ACR will have a major hand in CTMR accreditation. They're already, you know, all over that, and there will be new efforts, probably regulation efforts to

control the, you know, differences in dose exposures. There will be probably some more training required, things like that.

But it's probably going to — the bill itself will probably be 80 percent diagnostic and 20 percent radiation therapy, just as a guess, you know, I would say. So I think that you have to sort of be prepared for that.

Florida is already a pretty good state, you know. It's not that we don't have to be concerned with it or anything, but we're not Wyoming or Nevada where there's nothing out there from the patient's standpoint.

So those are the states that, you know, not that they have an advisory committee, but if they did, they would be sitting around thinking, you know, oh, my God, what are we going to do. Well, they're going to end up looking a lot like Florida by the time it's all over actually.

And so Florida is already probably one of the top five states in the country for this situation. So I think it's likely that many of these other states will look to Florida as a model. It doesn't let us off the hook or anything.

But as far as what the committee should do now,

I think number one, Debbie's already on this. It's typical. We should -- you know, there's going to be a representation at the upcoming AAPM Astro ACR Quality and Safety Meeting in Miami June 24th and 25th.

That's the first coordinated effort between the specialty societies to develop a cogent and responsible response to the patient's safety question. It's already almost completely met its registration maximum, so we'd probably have to have another one at some point.

But we should go to that meeting -- we, in the Debbie Gilley sense. I'm actually a co-host for that meeting.

MS. GILLEY: You're going to be there, too.

DR. WILLIAMS: Yeah, I'll be there too. I have some presentations there.

And there should be a report back to this committee from that meeting because that would be sort of, I believe, an initial distillation of where we stand. I think this committee should endorse the Astro six point patient safety quality action plan.

And I think that gives a little bit more of legitimacy, saying that the advisory board supports

it. You know, my humble opinion, it's a good work product. It's appropriate to the situation.

So that would be something that we could do, you know, as a committee. And I've always wondered — I think I brought this up before — we had kicked around the idea previously of inviting a representative from the American College of Cardiology committee because they're the ones that are out there roasting these chest walls with the fluoroscopes and everything, and so, you know, maybe we should make a place for them at this table so that we can ask, what's your society doing about all this stuff.

Because they clearly have a role to play in radiation safety, I mean, and all the nuclear cardiology that they do and questions of over utilization come immediately to mind, you know, in this type of thing. And so I think it would be appropriate to solidify, you know, a position for the ACC on the advisory board.

And then, you know, beyond that I think all we can do right now is just monitor the federal regulation and see what comes out in the summer and have a report on that, if it comes out in time, at the fall meeting and just recognize that it's going

to be part of the agenda item for the foreseeable future, I think.

There's going to be an ongoing evolution of these, you know, projects and programs, and, you know, regulations for probably a year or two. And so just to give you an example of some of the logistical realities. There was an initial push when the matter came out, well, we just need to accredit everybody. If everybody met a certain level of standards, we would be perfectly fine.

Okay, well, that's a good idea. There's 2500 radiation oncology centers in the country, you know, and there's about 40 accreditors right now in Astro ACR. And they currently have a fifty-center back log.

So if each accreditor can do two centers a year, these are lowly compensated volunteers, radiation oncologists. If they did two a year, it would take 15 years, you know, to accredit all the programs.

So there's no administrative bureaucracy in place to even start to take on the number of programs accreditations that would be required to reach this nirvana level of, you know, of quality. And, you know, so there are a lot of issues from

where we are to where we need to be.

But I think another thing we can do here, my last comment is that we already have volunteer reporting in this state, or I guess mandatory reporting, anonymous. I think we need to revisit that again and see.

I know the physicists and RSOs know and everything, but that could really be a model for the rest of the country. New York has one as well.

But I think it would be reasonable for this committee to review the processes and procedures of our mandatory reporting program to see if there are any suggestions or upgrades we could recommend for it and see if we could, you know, provide more of a clearing house for the centers, because ideally, the anonymous reporting is for the value of the centers not making the mistakes so they can look at them and say, well, am I doing that, did something like that happen in our center.

And it's supposed to have value beyond just, you know, making sure the state knows when someone makes an error so they can get a slap—on—the—wrist fine. I'd would be interested actually and willing to participate in some type review of that and

report back to the committee, the advisory board.

DR. SCHENKMAN: Are we on this committee allowed to address equipment issues? I mean, if there are ranges of standards for each type of CT scan, for each generation of scanners, would there be, especially since facilities can't be accredited, and I'm sure diagnostic facilities are probably just as far behind, can we request or do something about the equipment so that when a scan is being done that's outside of the range of whatever body part that is, a light flashes, something makes sound, so that it brings the attention of the technologist, you know, to show them that there's something not right, that they need to address that.

It doesn't necessarily mean it's going to turn the scanner off, because we all know that, you know, I mean, if you have a 600-pound patient, you're going to have to use a little more dose than if you have a 60-pound patient. But I think that maybe making the technologist more alert to when there's a problem might take care of some of this until you can get all of the things in place that you're talking about. Because those are going to take years. And we're talking about a more

immediate problem now.

MR. PASSETTI: Actually the equipment stuff — Don, tell me if I'm wrong — but that's really under the purview of the FDA. They regulate the manufacturers of the equipment.

They can tell them what they have to have on their machines as far as displaying dose or whistles or warning bells and all those things is under the purview of the FDA. We would not be allowed to, as they say, be more restrictive than what they put in place.

MR. SEDDON: Actually, there's a working group right now with the vendors and (unintelligible) standardize the terminology between the different vendors and also standardize the interface, user interface, so that everything means the same.

So an example at the seminar last week where they show like a speedometer on the right of the display for the technologist to see where they fall for the range of doses for a particular exam they have set up. The problem is that the more — the heavier the patient is, like me versus you, there's going to be a huge difference in the dose of the patient SSTI display, because you have to give more dose for more continuation. So it's not a

simple — it's an interpretation part as well.

Right now the numbers are actually displayed on the console so they do see what type of dose is going to be given to the patient. There's a comprehension of what that means is part of the issue, which is why the information under 132 is very proactive and very positive because it forces all the facilities out there to re-educate what it means.

You know, surprisingly, most of them don't know. A lot of them when I talked to facilities, they weren't even aware that they did display lists, and they were not aware of what it meant.

And again, it goes back to the old issue of, you know, there is no CT registration here in Florida so a lot of folks have just on-the-job training.

There's x-ray techs who jumped into CT down the road in some regards. So that part, the technology education is the key. Key to point.

THE CHAIR: You know, one thing I think this committee could do or the department could do, you know, we recently, I guess in response to your letter 32 advisory, we reviewed all our protocols for CT to make sure that they were more or less

optimized.

When you do inspections, do you look at the protocols? Do you look to see if they have different protocols for different size patients? Do you maybe pull cases to see if the 100-pound patients are getting the same machine settings as the 300-pound patients? Is that done at all?

MS. GILLEY: No.

THE CHAIR: I think we could develop some sort of criteria that at least for CT protocols there is specific protocol set up for different size patients and that they're optimized and that you do occasionally check to just pull a CT and look at the machine settings and see if it was appropriate for a 100-pound patient versus the 250-pound patient. And that could make a significant difference because we didn't really have that in place ourselves for a lot of this.

And we have since changed it so that we do lower the KVP if it's a small patient, and we use less MA, and each protocol gets set up based upon the patient's weight. That's something a good technologist should be doing.

MR. FUTCH: Is there a requirement that that information be recorded so it could be checked —

MR. STEINER: It's not required under our rules, but it is recorded on the films, and so it is possible to make that type of check while you were in the facility. I would say two things. One is — I just say it bluntly, because I'm terrible at sugar coating things.

The dose from CT exams is a product of what the manufacturers make at installation. They install the machines, and they say, use 200 MA station at 120 KVP and adjust the density and contrast to suit the viewer, you know, or reader of the film.

And so when we did studies back in, you know, back in the eighties for what is the typical dose for a CT head exam and abdomen exam, it was whatever GE said it was because they had the market share, everybody used 200 MA. But at some facilities, some operator, I'll call them unknowledgeable operator, pushed the four hundred or 600 MA because they were on the panel, they went from 200 to 800, pushed one of those buttons, and guess what, the picture got a little bit nicer.

And then they pat themselves on the back and went to the radiologist and says, look how much nicer this film looks.

And the radiologist says, cool, what did you

do.

I pushed the 600 MA button.

Well, they did that for a couple of months, and the tube burnt out.

But since then the tubes are getting much better, and they can push the 600 MA button and run that thing for six, seven years until they get tired of it, or something newer comes down the line.

I'm trying to say it's self-fulfilling. They don't make a lot of adjustments. I would bet a significant amount, at least one paycheck, that when you start looking at these techniques at facilities, it's whatever GE put in there as a set-up at the facility.

Where they ran into problems in LA County and stuff is somebody monkeyed around with the technique factors, and the manufacturer won't admit it, and the facility won't admit it. And so my guess is, it was a service tech or something said, hey, you want your pictures to look nicer, push this button, and they told their friends, and a small circle of those people had those problems.

MR. PASSETTI: It comes down to education?

MR. STEINER: It's an education thing.

MR. PASSETTI: But you have to look first to

see what they're doing.

MR. STEINER. You have to look to catch them, you know what I mean.

MR. TINEO: It's also important to recognize hospitals that (unintelligible) commissions there a lot of time creates a lot of protocols that you have to follow. The part that we — that I run into a lot is the cardiology section and the non-radiology sections that a lot of people tend to — outpatient centers under Hospice of hospitals that are running on their own, which is not — there's no oversight other than just the physician that is reading the images, and the technologist is the one that have to do it.

But it's so busy because they have 20 patients lined up and they need to do the patient as fast as they can. And that's where we run into — what I see where we run into the problems a lot.

It's just there's no cohesiveness of all the areas in looking at radiation safety. I mean, I see it all, multiple times. I went to a cardiologist a few months ago because their readings of their radiation badges were astronomical.

Of course, you know, the first thing that they do is they don't wear the badges. I mean, that

stops, that stops the — that solves the problems.

So the problem is — again, it's a radiology person going up to cardiologist and tell him your radiation exposure is high. And I think they're not in tune with what radiation safety is about in a lot of these places.

And we should do, as a committee, more of enforcement and oversight, they have an oversight. I don't know, is there a regulation that those — that they need to be overseen by a physicist on a regular basis?

I mean, that should be part of it, that all these facilities, even they can inspect it, but there should be also a oversight by a physicist that comes in, looks at those departments and looks at the protocols.

Because right now, you know, the first thing I did when I received the letter, I took all the protocols and I sent it to all — to the physicist and just oversee, look at — another eye looking at it, from the physician perspective, from the physicist perspective and from the technologist perspective.

How many of the outpatient centers did that? How many people — so I think we need to make sure

that these stand alones in places are as radiation conscious as we are in the hospital setting. And also it was an eye opener to see that sometimes you ask the technologist, well, why did you do that. Well, the radiologist told me to or the physician told me to.

They need to understand, and we should do education on this, that they're part of the team. If they think something is wrong, they should not be pushing that button. I mean, if they feel like that's enough, that's too much radiation, they have as much right.

Just because a physician is parking in the ER, that they should not do something that is wrong. And I think sometimes we lose that aspect of it. It's just we are there just to do procedures, and we are not really looking at the safety of the patient. And that's where we lose some of it.

THE CHAIR: I don't know if you have any sort of enforcement capability, but even if you just let it be known that you're going to be looking at protocols and radiation exposures, that might have an effect.

MR. DIELMAN: That's the proactive aspect of it.

DR. SCHENKMAN: What about also, I mean, aside from CME credits, which are directed toward physicians, what about directing radiation safety towards technologists in their accreditation, you know, their updating, their education? Because maybe that's a big part of it too.

You know, a lot of this technology is new since they're out of school or changing, and so people don't keep up with it.

MR. FUTCH: What are you teaching in school?

MS. DROTAR: Absolutely. Do they remember? And I think what we had talked about before was that people that are directors or managers of departments haven't been through that, I don't understand the differences, so it's maybe not just the new technologist?

But one of the things that I've seen because now we have gone away from film screen, and we're into CR and DR, and we are talking lesser doses. But when you have training on new equipment, the training for the technologist is usually how to operate the equipment. It's not how the protocols are established in there or when you're looking at -- and each manufacturer has those different proprietary names for sensitivity or whatever the

range is, so that you know what your level of exposure is.

And each of those is different, but the technologist couldn't really explain that because it was something that was already set. And so if you have people that as we go from film screen to digital, that we're going and then into CT, which are the same components there, that people don't really understand what's happening with contrast and density as it applies to new technology. And that comes back to education again.

And maybe there might be a way to put into the requirements that, you know, that maybe there's one or two credits that you have to have for radiation safety or a couple of credits, if you're doing CT, that you need to have education and show continuing education in CT or MR because those CMEs are available.

And, you know, because we've got the 12 that we need and we always worry about professional development and maybe if there was — it was more technology based, which is what the CE has been for us that you would have, you know, if you're doing radiography, if you're doing CT, you know, if you're doing mammography is a whole separate

venue.

But the other thing is, too, that we have in place that the — that people who get the general radiographer license meet the requirements of the ARRT, and ARRT has been designated that people who are nuclear medicine trained or radiation therapy trained can then do the most primary exam for CT, and maybe that might be a mechanism that we could look into, that if you're dealing with (unintelligible) having met those requirements, you know, since we don't have the licensure in place, but if there's something in the rules that could be adjusted to that, so that that way we're looking at people having really been trained.

Because everything — and a lot of what's happening with CT right now — Tim mentioned that community colleges are implementing CT programs, but they're not really there and available, and a lot of it is on-the-job training. So, you know, where are they going to get the education, too?

But maybe if that component was in there for the ARRT and that they have met those criteria because then they have to do X number of exams in order to qualify for that, that it might be a limiting way to do that. And the next couple of

years, general radiographers or the radiographers as you apply for the ARRT, there's maybe a component in there for doing elective competencies on — with CT.

Right now they're looking at doing elective so that your — I think what we've seen is CT becoming part of that and that we need to be maybe a little proactive in looking at what we can fit in under those regulations.

MR. SEDDON: Actually, I have a question. So is it possible to have implements under the general radiation program (unintelligible) generic, and there's nothing specific for CT.

MR. FUTCH: Well, statute-wise, there's also been a operation in the machine part of the statute that says — in Don's statutes in Chapter 404, there's a very brief phrase and very long sentence that says we can require things with regard to operator — I forget the noun that's used.

MR STEINER. Competency.

MR. FUTCH: Yeah, something like that. It's not much in the way of statutory authority, but one could, one could, with the appropriate backing from the department, try it and see if it gets all the way through without being challenged.

I don't know what Don's feeling is on that.

MR. STEINER: We can do a lot with our radiation protection program because it just says the facilities will have one, and the department is responsible for making sure they use the equipment safely. So while it's tough to mandate without a rule that you'll do XYZ, you can send their radiation protection program back to them and say, I don't see where you address XYZ. So I can't tell you what to do, but you have to do something to address this issue. So, you know, we do have that opportunity.

MR. SEDDON: Because you have the model programs for like x-ray, mammography —

MR. STEINER: Have some — general. Because the rule required radiation protection program for offices and a lot of, not really radiation hazard like baggage industrial, chest x-ray, whatever. You know what I mean? There just wasn't a lot of dose.

MR. SEDDON: Maybe you can incorporate the information on notice 32 as a model RPP for a CT and maybe take some other suggestions here as well into that and look — if nothing else, it's a model people can follow.

MR. GUIDRY: I don't think you should underestimate how much mileage you can get out of that kind of thing. If your purpose — you have no regulatory mandate, but if your purpose is to try to start to get people thinking about this, addressing an issue that here today has been pretty much ignored, I think you should seriously look into that, because I think you have a lot of capability to get people addressing the issue by that method.

MR. STEINER: There is a reluctance to publish an information notice that makes policy for the department where you don't really have a rule to back it up, so that's why I was saying, while we do have a rule, it requires the radiation protection program. And it's relatively broad.

I look at it as akin to the materials section where they say, we can do anything we want. You know, the clause that says, you know, you need to do what's right. And so, I mean, there is some opportunity there. I don't disagree.

But in direct answer to the question about information notices, we have been — I'll not sugar coat it. We've been reluctant to publish significant numbers of information notices because

it's viewed by the public as regulatory, and we don't actually have a rule that requires, you know, a lot of — we do not have a rule that says — there are maximum doses for any type of examination.

You know, maybe we should, maybe we shouldn't. There's a lot of states that do not. It's not a part of the suggested state regulations. Some of the states have had problems because as the imaging dose came down with improved receptors, they were reluctant to jump to that imaging dose.

There was a dose on the imaging quality. The doses came down, they were reluctant to go there, because they were outside their min-max bounds. That sounds stupid, but they were really — they had some other issues.

So we'd be happy to look at recommendations from this committee related to, you know, radiation protection.

MR. DIELMAN: I want to raise the RPP issue. I think perhaps that is an appropriate way to go with questions on radiation safety. Everybody has had a real contribution here, I believe. I think this is a great group.

But there are a lot of things that I believe that you can do, that government can do, and this is

government, that can do without essentially making policy and asking questions and prompting following certain processes or following a standard of practice that already exists, I think is a good example of that. Some states have done that very successfully.

The RPP issue, though, I think to follow up, I think having an RPP on CT would be very appropriate. It allows those questions that you've addressed in the information notice, you know, to be raised once again, I think.

But I have a question on RPP. Over the years, I've seen — I can remember many years ago that we were — the inspectors were going around, and they were checking RPPs on an annual basis to see if they had been reviewed and signed. I see that still occasionally in my travels within Tampa Bay.

When I go outside this area, I don't see those being checked. I could give you some examples of places that haven't been checked for the last three years, or four. So I'm not sure, is that not being enforced at this point? It's a rhetorical question.

MR. STEINER: Supposedly they are being checked. You know, things happen. I went to

mis-administration, what they called them back then, for a therapy facility, and I asked them about their operating and safety procedures, and they said they didn't have one. I says, obviously, you don't know what you're talking about.

So I asked the physicist, where are their operating and safety procedures.

He says, we don't got any.

I said, we'll, you're a new physicist, and your specialty is in dose modeling and 3-D renderings of, you know, products and stuff.

And so I asked the physician, where's your radiation safety procedures, emergency procedures.

He says, I've been after the physicist to make those for years, right?

Well, they had been inspected for several years, and the first thing on there besides the RSO is do they have their procedures posted.

And I'm going, well, how did this happen. So we have good procedures for inspection. Sometimes they get glossed over. That's all I can say. That priority is not supposed to change from area to area.

THE CHAIR: You want to vote on some specific recommendations? You want to bring up yours?

DR. WILLIAMS: Sure. I move this organization endorse the Astro six point action plan for patient safety.

(So signified by aye.)

MS. DROTAR: Second.

THE CHAIR: Any discussion?

(No response.)

THE CHAIR: All in favor?

(So signified by aye).

THE CHAIR: How about the proposal to include Rad safety specific CMU require —

DR. SCHENKMAN: CME and CE —

THE CHAIR: What?

DR. SCHENKMAN: And CME for the physicians.

THE CHAIR: I guess we have to write a letter to the Board of Medicine suggesting that.

MS. BONANNO: Is it easier to do it on the technologist side —

THE CHAIR: Well, we can do the technologists first, and then we can —

MS. BONANNO: — and —

THE CHAIR: — so require specific CEU requirements for technologists and radiation safety. I guess machine protocols or —

DR. SCHENKMAN: I'll second that.

MR. STEINER: To me it would be a little better if you stated it, phrased something like doses for common exams or doses for exams done at a facility, because when you say radiation safety, is an x-ray (unintelligible)production overview and what's a (unintelligible)biological effect. I mean, they're not going to approach the safe operation of the equipment.

MR. FUTCH: Radiation doses and units for common exams.

THE CHAIR: Dose reduction strategies.

DR. SCHENKMAN: Okay. I'll second that one.

THE CHAIR: Any other discussion?

(No response.)

THE CHAIR: All in favor.

(So signified by aye.)

THE CHAIR: How about a proposal to include evaluation protocols and radiation exposures and any inspections —

MS. GILLEY: Yeah, as part of a review of the RPP.

MR. STEINER: Anyone second that?

MR. TINEO: Second.

MR. SEDDON: Question: So would you want that to be the actual inspector (unintelligible) or actually have the facility do their own or review

and have the inspector verify as part of the (unintelligible.)

MR. STEINER: To me they're two separate issues. The radiation protection programs should be reviewed by the machine program as appropriate and approved. The inspection process should be, do you have an up—to—date current radiation protection program.

Are you renewing — it's self—renewing. They're supposed to review it every year in January and say, this still reflects what's happening in my facility. Only they make changes to it. It's different.

So, you know, the inspection part of it, and having dose reductions strategies as part of the radiation protection program.

MR. SEDDON: So the inspector would not be actually (unintelligible) facility. They're verifying the facility.

MR. STEINER: Correct. Or you could recommend, you know, in selected cases such as maybe CT exams or something that they pull a couple of films, but then it's going to be tougher for them to evaluate unless we get some nationwide trend or statewide trend to evaluate —

MR. SEDDON: So my preference is that they were verifying the facilities are actually performing their own annual protocol review items.

MR. PASSETTI: Maybe the best way, Don, would be to draft up some model RPP programs for like CT facilities and let this group look at those and approve those. Make sure we are capturing what you think we should be looking at.

MR. DIELMAN: You could cover fluoroscopy under that circumstance.

MR. PASSETTI: You could do one for whatever, any one. Do we have a model RPP for therapy facilities?

MR. STEINER: Because we don't really have, you know, a lot of rule, what we have — well, I take that back. There's an information notice that talks about typical things that should be in a radiation therapy, but doesn't have language. It just says, address these items, so.

And that could be updated.

MR. TINEO: I think it should be important for us to guide some of these facilities, and we should have — I know the department pretty sure come up with a standard RPP for every single of these venues so that people are not over there just

guessing how to put it together, what to do, what to say. You know, at least the basic of what they should be looking at and approve, so.

MR. STEINER: I don't disagree 100 percent, but one of the reasons we did not do it that way, not only was because we didn't really have regulatory authority to make specific recommendations, so to speak, but that people do these like a radioactive material license. The physicist fills them out, they get them approved, they hand them to the facility, and they don't always know what's in them and they don't know how to operate under them.

So I give you, if I require that you follow my model for a CT scanner or a fluoroscope, they're going to pull it off the net, date, time stamp it, send it to me, make all these promises, and they don't know what they are talking about. Where before we were at least making them think about or hire a physicist to write it for them with the hopes that the physicist would explain it to them.

MR. PASSETTI: Like you said, that's what we do in the materials side right now, and you have to enforce that during the inspection. And if they're not following what they committed to —

MR. STEINER: We do now what they call a

pre-license inspection, which means when they deliver the license, the inspector goes over with them step by step, this is what's required of you and when we come back for an inspection, these are the records to document what (unintelligible)you agreed that you will do.

MR. TINEO: That's where I'm going. I think we need to be tougher in the machine side as we are in the material side because it's just getting to be too complicated out there.

MS. GILLEY: Is there a second to that?

THE CHAIR: So do we have a specific recommendation?

(No response.)

THE CHAIR: Why don't we say something like just that the RPPs include issues of protocols and dose reduction and patient imaging studies.

DR. SCHENKMAN: Updated. Updated. Use the word "updated."

MR. DIELMAN: Current.

MR. PASSETTI: What about if we do — would you like us to draft like an RPP for safety, fluoro and CT, those three areas and let you guys review those, see if they're appropriate?

MS. GILLEY: An action item for the next

meeting.

THE CHAIR: Propose RPPs for —

MR. PASSETTI: For those three areas?

THE CHAIR: those three areas.

MR. FRADY: Terry Frady, State of Florida, Bureau of Radiation Control. Among all of that, fluoro is an issue, and Don and I had the discussion, Debbie and I had it yesterday. Ray and I had it this morning.

There's people out doing their pain management, and I'm seeing really shocking exposure rates, you know, like cardiology. And so when we do this fluoro thing, and Don and I had talked about, if we create investigational levels like we have in nuclear medicine for inspection, I think that would create awareness with them to do one of two things: Take a step back or not wear the badge.

And I would like to see that as part of this when that happens is to have investigational levels for personal —

THE CHAIR: I think this is broad enough to include whatever you want to have in it.

MR. PASSETTI: Oh, well, so you're volunteering for the committee we are putting together to write those RPPs.

THE CHAIR: Any further discussion?

(No response.)

THE CHAIR: All in favor?

(So signified by aye.)

THE CHAIR: How about the recommendation that we recommend to the Board of Medicine that radiation dosimetry issues and medical imaging be required for CME for the state's physicians?

MR. TINEO: Second.

THE CHAIR: All in favor.

(So signified by aye.)

MR. PASSETTI: Vicki, how would we introduce something like that to the Board of Medicine?

MS. GRANT: A letter. Through Larry McPherson, and he would present it to the full board.

THE CHAIR: Any other issues that we want to? Do we have any leads on getting a cardiologist?

DR. ATHERTON: Tim brought up the fact again we are trying to get a cardiologist on the board, the panel, the council, and I wanted to know if there's any leads on finding a cardiologist for the advisory board.

MR. FUTCH: I'll tell you. There's four empty council positions. Two of them are lay people, and two of them are related to physician who employs a

basic (unintelligible) machine operator. I forget the other one. It's similarly related to that.

So there is no position for someone to be appointed. I'm sure there is like a Florida Cardiology Association. Florida ACC. Okay. We could certainly ask them, I think.

MR. PASSETTI: Maybe that's something the advisory council would like to recommend. We don't have a formal position we could appoint them to by statute. There isn't one created.

But in the past we have used — we have called it advisors, Libby Brateman, I don't know if you remember her. She used to be our diagnostic medical physicist advisor. We could do it that way, if you guys wanted certain type people to be advisors to this council, we could do it that way.

DR. SCHENKMAN: I think that would be important, because cardiology, there's so much use of fluoroscopy and radiation in cardiology.

THE CHAIR: I agree. We have to find a cardiologist willing to —

MR. TINEO: That cares about radiation safety.

UNIDENTIFIED SPEAKER: I know one man that would probably love to be on this advisory.

MR. FUTCH: Whatever college or association

there is first, and if we fail there, then —

THE CHAIR: Florida chapter of the ACC.

Any other issues before we move on — oh, we need a vote for that? (unintelligible) of a cardiology position.

THE CHAIR: We'll move on in the agenda.

MS. GILLEY: Well, the fun stuff. We are doing some good things. Not everything's bad.

(Presentation given by Ms. Gilley.)

MR. DIELMAN. In the transition, I have a quick question. I signed up for the program. I never got a response. So I presume I'm going to St. Petersburg anyhow.

MS. GILLEY: See me, and I'll get you the address.

MR. FUTCH: I wanted to mention. Dr. Janowitz is up for just a second. The website has gotten a fair amount of new material on it. We also, for those interested in the materials side, we created a new link off the materials page and off the bureau home page, what we are calling YRC items of interest, which are documents that YRC share with all your CR licensees. Which the licensees ought to know about but —

UNIDENTIFIED SPEAKER: They don't necessarily.

I won't say that. Anything you want to add about that?

MR. PASSETTI: No.

MR. FUTCH: We have one more scheduled talk, I think. And this is Don and Bill, use of portable and mobile x-ray machines. When do we lose folks? When do we have to get to airplanes? Take your time.

MR. PASSETTI: I'm going to turn this over to Don in just a second. I just wanted to kick it off. Under J-2, if you'd look at that, it's actually G-2, the third page, which is V-12, at the very top, paragraph C. Does everybody see that?

(Some respond yes.)

MR. PASSETTI: That is a rule we have that we would like to talk to you about. As it states here, it says: "Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary radiographic installation."

I don't know if you can see the problem with that rule, but we are having some difficulties. We don't typically inspect for this when we go out to do inspections. It's not something we typically

inspect for.

Right now we are having a big influx of insurance companies denying claims based on this rule. They're saying — it's not impractical for this patient to go over here instead of being x-rayed with a portable or mobile.

So they're denying claims. Now our attorney got involved because Don keeps getting someone to testify at — these insurance, of course, our attorney looked. He says, I don't like this rule, we need to change this rule. I kind of agree.

It's not really clear what's impractical and who decides, and all those questions go up. So Don's going to quickly go over the issue and wanted to see if you guys had suggestions on maybe changing or doing away with this particular rule.

(Presentation by Mr. Steiner.)

MS. DROTAR: Can you share what the attorney doesn't like?

MR. PASSETTI: Couple things. We're not inspecting for this rule. Some of the reasons we are not inspecting for it, it's not clear who decides it's impractical or not or the doctor who orders the x-ray or patient who decides it's impractical to go to a fixed facility. She feels

like if we are going to have this rule and enforce it, we need to be more specific and clarify what we really need.

MR. FUTCH: So to fix that, we could say, for example, before the word "impractical," where it is, comma, in the opinion of the registrant, impractical to the — to transfer the patient to a radiographic installation —

MR. STEINER: That would be bad though.

MR. FUTCH: I'm just throwing it out.

MR. TINEO: What you're seeing is, and I see where — and I'm talking from the perspective of the reg — more and more hospitals are being redesigned or rebuilt with private rooms, and the patients don't want to be inconvenienced. Not that they cannot be transferred but it's inconvenient to leave their room because there's multiple procedures being done at the same time, and the physician says just do a portable x-ray.

We don't charge for portable anymore. Nobody reimburses you for portable. Just reimburse you for x-ray. In fact, they don't even reimburse you for that — (unintelligible) — if you go that route, you might as well just do it for free.

But the question is we are trying to move the

patient the least amount of possibility to the department, and that's where you're seeing the influx of portable procedures being done. And in the hospital and then it just is to the radiologist whether or not they will accept that quality of radiograph, and if it's not acceptable, then we need to bring the patient down. And that is where we are, that's where we are —

MS. DROTAR: I think on the outside of the hospital because there are a lot of mobile companies in Florida and they go to nursing homes, they go to the jails, they go to prisons, and there's a necessity for those, for that to be done. They go to people's homes.

Would we be able to say where there is a written directive by a physician that it's an alternative method?

MR. PASSETTI: Where they actually prescribe a portable or mobile.

MR. DIELMAN: That's a good idea.

MR. PASSETTI: That puts it on them to decide whether it's impractical or not.

MR. STEINER: That's pretty much how we've been doing it in the past. We say, you know, we are not going to make the decision, you know, whether it's

medically necessary or not. That's for the physician to decide.

But if we find a physician that's ordering in nursing home all their patients portable, we would write a letter and say, look, you know, our regulations, (unintelligible) transferred to diagnostic (unintelligible) should be transferred to a diagnostic imaging facility, so that they get a quality exam for the dose that they receive.

So it doesn't mean convenient. It means you know what it says which is impractical and then as long as they're not abusing, right, their prescription, we are okay with that. We recognize that there is a legitimate and necessary need for mobile and portable exams.

That rule doesn't say that you can't do them period. It means, you know, let's be reasonable, you know, about this issue, which is, you know, what Bill is saying about us not really expecting.

We don't really go try and uncover misuse, but when the misuse is brought to us, we would typically write them a letter and say, look, Doc, let's fix this problem that we have, and usually they will.

You know, we haven't really had anybody that

says they wouldn't — except for now, these lawsuits, and now they're in the middle of litigation, so we are not corresponding with them right yet.

MR. TINEO: In that scenario, would you write the letter to the nursing home or write the letter to the physician that writes the order?

MR. STEINER: I would try, if I could get a hold of the physician, I'd write it to the physician. That's who I'd be talking to. I would not be above sending something to the nursing home and letting them know that there was a problem

And theoretically, if the physician refused to cooperate, we'll go to their licensing board.

MR. PASSETTI: And actually this rule is written for the registrant, not the physician or the facility.

MR. STEINER: It's true. The registrant is the x-ray company, so I have written letters to them too. I have written letters to the mobile companies, and when people call me every once in a while, they say, I'm thinking about starting a mobile x-ray company, and I say, well, that's great, to register your x-ray machine, have certified operators make sure every exam is

authorized by a physician.

The physician doesn't need to own the equipment. I say, oh, by the way, use of mobile portable equipment is prohibited for patients that can be moved to fixed facilities so don't think that you're going to make lots and lots of money going to nursing homes. There are needs for mobile equipment at nursing homes and patient's houses. If the physician orders it. We are not saying no; we are saying don't abuse mobile portable.

MR. FRADY: Right. The one thing I'd like to bring up. Our tax dollars at work by having ALF or nursing homes provide a rider to go with the patient to the x-ray place, and then the vehicle that transports them, which is about $68 to $75 dollars for that ride. Now, I'm not going to argue the point of (unintelligible) chest x-ray with a grid is as far better than fifty inch sitting in the bed.

Maybe if kind — I don't know how. You know, it's funny. I don't know what we have as far as , something where we recollection 3407. Other than the physicians probably working at the nursing home and not going to send them away anyway.

MR. STEINER: The deal really breaks down to

medical necessity and does that doctor that's ordering the exam understand the dose for the quality of the exam that they're receiving.

MR. FRADY: Usually next step, if they're going into pneumonia, he's sending them to the hospital.

MR. STEINER: You can make the argument of annual or routine physical chest x-ray shouldn't be taken.

If they're looking for pneumonia, they can hear with the scope. Back when I was an x-ray tech, which is ancient history, we did pre-admission chest of everybody that came in the hospital and did pre-surgery chest even if it's 12 hours before that, we did another x-ray on them, and they just had one in the last 12 hours. They knocked some of that stuff off, but I mean, that was common.

And things change, and, you know, what the medical — what are they really looking for. If they're looking for pneumonia, maybe they need a quality exam. If they are looking for fluid levels, maybe portable is good enough.

If they're in traction and stuff like what we have already suggested, I don't care about dragging the bed down to — they just want to verify the bones are still in line or whatever, what's the

status.

But when you say — I mean, I'll just say it, you know, I keep saying, don't sugar coat it. But when you got a patient that goes to see a chiropractor because they have been in a car accident and they come back every three to five days and get an x-ray of their spine with a portable machine, and then they don't even get the results of those x-rays for six weeks and they have been treating them the whole time, it doesn't take a rocket scientist to say you're misusing the equipment.

You know, actually you can say they didn't need the x-rays at all if they're treating before they get the results. You know what I mean? You're way out of the scope of feasibility here.

MS. DROTAR: It almost sounds like you already have, the insurance companies already (unintelligible), what they determine is misuse, and it's just more that by this law, what's written here that what we want to say is that the physician has that authority to determine by a written directive that the patient should have a portable x-ray.

MR. PASSETTI: To me, because we have gone and

asked physicians about this particular thing, and then said, well, I just ordered an x-ray. I didn't tell them whether it had to be stationary or portable. They just said, I just told this patient, go get a chest x-ray and they happened to go somewhere where they're using a portable or mobile thing.

So to me, it's simply who decides if it's impractical or not I think we need to spell out. Like you say, if it's through a written directive from a physician --

MR. SEDDON: I think also, the rule has been in existence for 35 years whatever, but the quality in most hospitals, the quality of portable x-rays isn't crystallized. Most facilities are (unintelligible). Most facilities use (unintelligible) to make sure. They're on -- most facilities have, if it's a DR portable, have ARC.

MR. STEINER: We're not talking about hospital-based.

MS. GILLEY: We never are.

MS. DROTAR: It's more about physicians offices or some place --

MR. STEINER: We are talking about a mobile company that shows up at a chiropractor's office in

particular and is taking x-rays. You know, one of the other things that we do is we say you cannot take mobile portable examinations unless you're a general radiographer because some of these problems with geometric imaging come up and realizing you have to change techniques and whatever, whatever.

And so we are saying in several places in our regulations that the use of portable is not a good idea. It's not an optimal idea. That is all we are trying to do here is say let's not abuse — we are not saying don't use them. We are saying let's not abuse the use of portable x-ray examinations.

Unfortunately, the insurance companies got on to this about a year and a half or three years ago, three years ago, and they decided, oh, boy, here's a reason to not pay. Well, they probably weren't looking at this issue for radiation protection.

In fact, I know they ain't. What I was describing, what they got is somebody taking lots of x-rays for no legitimate reason, you know, the services were rendered, and they had to pay.

And all of a sudden they say, oh, look, they shouldn't be doing this for this other reason, so let's not pay them. We got five ways of abuse. Let's use this reason to not pay them.

DR. ATHERTON: So I think we are in agreement we like the rule, but apparently, they want to change the wording.

MR. STEINER: I think we are saying — looking for some clarification in support of the committee.

MR. PASSETTI: Makes it more enforceable.

THE CHAIR: I think written guidance, written directive by a physician ordering the test is probably most appropriate.

MS. BONNANO: I agree.

MR. STEINER: After consideration of dose versus diagnostic quality —

MR. TINEO: Decisions are not even —

MR. STEINER: They should be — we are sitting at a table here for radiation protection. We have said 20 times today doctors shouldn't be ordering exams that they don't know what the doses are.

MS. BONNANO: We are talking internal medicine, and GPs, they're not going to have a clue.

MR. PASSETTI: But if you at least make them —

MR. STEINER: You can't do this unless it's special. You're going to have to sign it, and you've made a consideration of what the image quality is going to be.

UNIDENTIFIED SPEAKER: Make them think about it.

MR. PASSETTI: If they have to write a prescription for a portable mobile, they're going to think about it.

THE CHAIR: Maybe they should inquire, something like medically necessary sort of like when you write a brand prescription, you have to do that because it's easy enough to say portable.

But portable chest x-ray medical necessary.

MR. PASSETTI: We'll work on some language and bring it back to you guys.

MR. SEDDON: I wanted to raise a point that Don mentioned. You mentioned the letter from the FDA concerning the utilization of fluoroscopy or measurement of the 10 R per minute rule. We had some discussion in the past about that.

One issue has been raised from the vendors eventually that in order to meet the Florida requirement to be within compliance based upon the geometry set-up (unintelligible) they're having because the newer systems are all computerized detector. They're designed to be calibrated with the exposure (unintelligible) measure, so in order for them to get this to pass, the rule is to

actually lie to the system and so that it's (unintelligible) the system, very complex system involve (unintelligible). Not sure (unintelligible) qualities and patient dose and real situations.

So I'm not sure that has been raised with you, Don, or not. It's been raised with us when we come on facilities or come on vendors. We do all we can internally to restrict geometrize, how the equipment is used.

Sometimes you still have to have the vendor recalibrate the system to a different standard than what they're designing because they're following the FDA guides. So have we had that discussion with anyone?

MR. STEINER: Yeah, every week. Not so much facilities but with the manufacturing companies. The vendors are going, you know, our hands are tied, we can't do this, we can't do that, and what we do is we carefully explain to them that we are not upset with them and not upset with their calibration of the machine.

But the state of Florida has the regulation that requires that when he uses the fluoroscopy machine, it shouldn't exceed 10 R when it enters

the patient, and when you have a patient that has patient support, cannot get the input image intensifier up against the patient. You know, there's a three to five—inch gap in there.

And then if the facility has procedures or policies or some way to set that reproducible geometry up, that's how we'll measure. The regulations actually say worst case geometry, which is, we never meant to go there, you know what I mean. And we don't want to go there.

But if they got some type of procedure or policy that says this is the geometry we are going to use, then all we care is that the dose where it enters the patient doesn't exceed 10 R per minute at that configuration, so a lot of times what the vendors can actually do for you is —— not for you but for the facility is help them come up with a method to reproduce that geometry so we can inspect it in a reasonable case geometry.

Because the inspector's instruction is if they don't have those types of procedures, go ahead and put in worst case, let it fail, let the (unintelligible) facility correct it procedure—wise. In just the last month or so I've had a couple conversations, say, look, the equipment you're selling is getting very

sophisticated, and it's supposed to display dose to the patients on the machine.

And the only reason, the only way we can do that is to know our geometry, so we are plugging in that it's 70 CM, if you got 100 CM (unintelligible)SID system (unintelligible)SSD is 30, say you got 70 left, they're plugging that stuff in and they're saying — they intimated to me that they could do that for each exam type, that you could select that exam type, and it could give you the opportunity to change the source, to skin distance input into the dose system. And so says, well, that's great, get the reproducible geometry, figure out what the new source to skin distance is. Everybody good, happy as long as they can demonstrate to the inspector to set that up.

Maybe the equipment is going to help us fix this problem. But other than that, I made reference to it in the talking, the FDA on one hand says, we got this real problem. We need the state's help with those fluoro on the other hand, you can't inspect to your 10 R per minute state entrance limit because it looks different than what we —

MR. SEDDON: Because their guide is 30 CMs, yeah, for what they call —

MR. STEINER — not for what they call lateral fluoroscopes. Defined in FDA rule as 15 (unintelligible) centimeters from the center line. But the manufacturer said this thing was manufactured as ~~ACR~~ a c-arm. I say, well, that's great because that's not how it's being used. It's being used with a patient support device routinely, this configuration for heart catheterization, whatever they're doing.

And so, you know, like I said, we get these calls all the time, and we explain it to the vendor. Usually we have to go up the chain quite a ways and explain to them, we are not picking on you, and you certainly don't want to try to go to court and say we don't care about dose to patients and violations. To use federal rules, no, no, we don't want to do that.

Say, well, here's the fix. Okay. We'll work on that. It goes down, and then it's okay for a while, and then we got a new set of service guys come through and start the problem all over again.

MR. DIELMAN: For that end, just quickly. I hear in hospital systems, which you're in and I'm in, we hear constantly, it's either the vendor or it's the clinical engineering department, is there

any way or any — I know that you deal with (unintelligible.) Would you consider writing down or putting something in writing that we can distribute as to, you know, the intent that you have.

In other words, the solution that would be acceptable. Because you just stated it would be willing to write it down. I don't mean you personally. The department, you know, bureau, write it down, and then we could get it out there.

Because that would be helpful at least, because there's a lot of issues, other issues that play in there. You've got the vendor, you've got the clinical engineer involved and then you've got, you know, the bureau involved, and it's — there's not a good communication process taking place. It's always hearings.

MR. STEINER: Most of the time, the inspector, if he gets jumped will point them to the inspection procedures which are very, to me, straightforward. They want to play their trump card, which is "FDA Said" or "the manufacturer said". They want to argue with you. You know what I mean?

So after a while — but, yeah, we could do the

same thing. We could reiterate what's in our inspection procedures and say this is the — probably could put it on the agenda for next time, talk a little more in detail on what we're trying to accomplish.

DR. ATHERTON: Is there any way to run, when the machines are registered either fluoro or X machines, automatically triggers inspection or —

MR. STEINER: A good point, age of machines. I know some offices have things that are older than I am. There are some very old x-ray machines that perform very well. Then there is some cheaply manufactured stuff that didn't work good when it was brand-new, 15, 20 years old, and you can't get parts for them, and they should be taken away.

There is a state, I want to say New Jersey that says you can't use an x-ray machine that's over ten years old, something like that.

MR. STEINER: It ain't going to happen. But they are inspected. Medical equipment is inspected at least every two years. If they have a non-compliance, they're inspected the next year, and if they have no non-compliances, they go two years. So it doesn't matter how old are they are. Doesn't matter how old, they are going to get inspected

just like everything else.

So they're not slipping under the radar. Unlike Georgia, who says if equipment is pre-certification because FDA has no regulation, they have no regulation, and they don't inspect uncertified machines. Frequency of the inspection does vary.

The chiropractic DO, MD, on all that stuff and the hospital, it's the same frequency veterinary and educational, three years.

THE CHAIR: We'll go on. Any council member issues?

(No response.)

MR. FUTCH: October 5, October 19 possibilities. We can try and settle one today.

THE CHAIR: Any conflicts?

MR. LIVINGSTON: Let's say October 5 for now. We can send something out later. Would you like to go to Orlando next time? You tired of Tampa?

(Some say yes.)

MS. LIVINGSTON: So we'll shoot for Orlando next time.

In your package you all got your travel vouchers. Go ahead and send me the information with your receipts, and I'll take care of it all.

THE CHAIR: Motion to adjourn.

DR. SCHENKMAN: Second.

(Proceedings concluded at 3:00 p.m.)

CERTIFICATE OF REPORTER

STATE OF FLORIDA

COUNTY OF HILLSBOROUGH

I, KATHY L. GORRELL, a Notary Public in and for the State of Florida at Large, do hereby certify that the foregoing proceedings were taken before me in the cause, at the time and place, and in the presence of council as set out in the caption hereto, at Page 1 hereof; and that the foregoing typewritten transcript consisting of pages contained herein, inclusive, is a true record of the proceedings had at said session.

I FURTHER CERTIFY that I am neither an attorney or council of any of the parties in this cause, nor a relative or employee of any attorney or council employed by the parties hereto, nor financially interested in the event of said cause.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my seal this 25th day of May, 2010.

KATHY L. GORRELL, RPR
Notary Public
State of Florid