	STATE OF FLORIDA
1	DEPARTMENT OF HEALTH DIVISION OF ENVIRONMENTAL HEALTH
0	BUREAU OF RADIATION CONTROL
2	ADVISORY COUNCIL MEETING
3	HYATT REGENCY INTERNATIONAL AIRPORT
4	Orlando, Florida 32827
5	Tuesday, May 13, 2014
6	10:00 a.m 3:00 p.m.
7	MEMBERS PRESENT:
8	RANDY SCHENKMAN, MD, Chairman MARK S. SEDDON, Vice-Chairman, MP, DABR, DABMP
9	ARMAND COGNETTA, MD
10	ALBERTO TINEO, CNMT PATRICIA M. DYCUS, BS, RRA(R)(M), RDMS
11	TIMOTHY WILLIAMS, MD
11	WARREN JANOWITZ, MD, JD, FACC, FAHA TIM RICHARDSON, RT(R)
12	JEROME GUIDRY, P.E., Q.E.P.
13	WILLIAM (Bill) W. ATHERTON, DC, DACBR, CCSP KATHY DROTAR, M.Ed., RT. (R)(N)(T)
14	PAUL BURRESS, CHP
14	DEPARTMENT OF HEALTH BUREAU OF RADIATION CONTROL
15	STAFF:
16	JAMES FUTCH, Health Physicist Administrator BRENDA ANDREWS, Business Consultant
17	CINDY BECKER, Bureau Chief
17	YVETTE FORREST, Environmental Administrator JERRY BAI, Environmental Administrator
18	DEDADTMENT OF DEALTH MEDICAL OHALTHY CTARE DECENT.
19	<u>DEPARTMENT OF HEALTH MEDICAL QUALITY STAFF PRESENT:</u> PATRICK KENNEDY, Executive Director
20	GAIL CURRY, Regulatory Consultant
	MEMBER OF THE PUBLIC
21	KEITH NADASKAY
22	<u>DISCLAIMER:</u> Edits have been made to the original transcript provided by AMERICAN COURT REPORTING to
23	clarify and/or correct some inaudible statements, and
24	names of speakers.

1	
2	(Whereupon, the Chairman called the meeting
3	to order, after which the following occurred:)
4	* * * *
5	DR. SCHENKMAN: Okay. My name is Dr. Randy
	Schenkman. Most of you know me already. I'm
6	from Miami, a retired radiologist, and I've been
7	on this Board forever. But this is my first year
8	as chairperson. So can we go around the room and
9	everybody introduce themselves?
10	Would you like to start?
11	MR. BURRESS: Paul Burress from Florida
12	
13	State University and I'm representing health
14	physicist.
15	MS. DROTAR: Kathy Drotar. I am the
16	radiologic technologist therapy representative.
17	MR. SEDDON: Mark Seddon. I'm from Florida
	Hospital in Orlando and I represent medical
18	physicists.
19	MS. FORREST: My name is Yvette Forrest and
20	I represent the Bureau of Radiation Control,
21	radiation machine program.
22	MR. ATHERTON: Bill Atherton in Miami and I
23	represent the chiropractors.
24	represent the chiropractors.

25

n Miami and I MR. GUIDRY: Jerome Guidry. I'm the

> AMERICAN COURT REPORTING (850) 421-0058

environmental guy.

MS. ANDREWS: Brenda Andrews, radiation control.

MR. FUTCH: I'm James Futch, also radiation control Department of Health.

MS. BECKER: And I'm Cindy Becker, also radiation control, Department of Health. And I was going to get to introduce Dr. Armand Cognetta. I'd like to introduce you, who's our newest member. It was effective yesterday. He is representing our layperson status on the Board and he is a Board certified dermatologist. He's the founder of Dermatology Associates in Tallahassee; for those of you in Tallahassee, you would know that. He also is the program director for the Florida State University School of Dermatology that they have there. So, welcome.

DR. COGNETTA: Thank you.

MS. BECKER: Anything else you want to say?

DR. COGNETTA: No, thank you. Thanks everybody, for helping me get on board.

DR. SCHENKMAN: Welcome.

MR. FUTCH: We'll be hearing some more from Dr. Cognetta pretty soon.

MR. KENNEDY: Hi, I'm Patrick Kennedy. I'm

the new Executive Director of the Florida Board of Pharmacy, EMT, paramedic, and rad tech with the Department of Health, so I'm very happy to be here.

MS. CURRY: I'm Gail Curry, Department of Health Medical Quality Assurance. We do the licensing.

MR. TINEO: Alberto Tineo from Halifax Health.

MS. DYCUS: Patricia Dycus. I'm the representative for radiologist assistants.

MR. WILLIAMS: I'm Tim Williams for Oncologist, Boca Raton.

MR. JANOWITZ: Warren Janowitz, nuclear medicine, Miami.

MR. RICHARDSON: Tim Richardson. I represent the Florida Society of Radiologic Technologists, radiographer.

MR. BAI: Jerry Bai with the Bureau of Radiation Control, field operations.

MR. NADASKAY: I'm Keith Nadaskay. I wear many hats. I'm just here to kind of watch. I'm a proud Florida State grad. I work for Mosaic Fertilizer. I have a consulting company that I own and moonlight with and I'm also the Mayor of

the City of Wauchula, so I'm very busy but I'm just interested to see what the, what the discussion is today and really just here to observe.

DR. SCHENKMAN: Well, we welcome everybody and thank you all for being here to invest your time. I guess our first item on the agenda is the approval of the May $28^{\rm th}$, 2013, meeting Minutes.

MS. ANDREWS: Those Minutes were disseminated to you all back after the last May meeting, and everyone had an opportunity to look them over. I made edits to them to comply with the information that I was sent, and this is the copy that is the final copy. I think I sent you all a final version of it. I'm not sure. If I did not, I will be happy to do that when I get back.

MR. FUTCH: So you made all the changes?

MS. ANDREWS: All the changes were made according to the information that I was given from the Council members.

DR. SCHENKMAN: So do we have a motion to approve?

COUNCIL MEMBER: So moved.

DR. SCHENKMAN: Any discussion? No? All yeses? No's? Ayes. Okay.

Now the MQA update.

MS. CURRY: Like I said we're with licensing, so we do all the licensing of all radiologic technologists. And just trying to give you a rundown, since January 1st we have processed 769 radiologic technology applications doing those at 7- I'm sorry, 5.07 days. So from the time we get it in our office to the time we either make it deficient or set it to test or if it's an endorsement license then it takes us approximately five days, and that is also within a graduation time, also where we get a lot more applications.

Radiologic assistants. We've actually done two of those since the first of the year and those took us a little longer. We did those in about ten days. So we've done 771 applications since January 1st with all of those being processed within 30 days. On an average. Those 771 applications were processed in 5.08 days. That's it.

Anybody have any questions?

DR. SCHENKMAN: How does that compare to

previous years?

MS. CURRY: Last year we were down to about I think it was about 4.75 days, but we lost a position because we were so efficient, that we lost a position to nursing because their, their applications are just way, way more than what we receive. So we're doing that with actually three processors for the whole state, and we also do EMTs and paramedics. So, you know, our processors are very, very busy, very highly qualified, and they also answer questions from anyone that calls. So, you know, I think we do a phenomenal job with what we have, and our error rate is zero.

MR. FUTCH: Gail, you don't happen to know how many of the RA's there are now, do you?

MS. CURRY: I don't know. I didn't look
that up, but I think there's only like seven. We
had, we had some people apply but they weren't
qualified. So those are on the books as an
application, but they're not on the books as an
actual RA license.

MR. FUTCH: Were they, were they - do you remember why they went with the RPA's?

MS. CURRY: They were not ARRT certified as

RA's. They just thought they could apply because they were GR's and thought they could assist. So they never actually came to fruition.

MR. KENNEDY: James, that's something we can get for the next meeting if you'd like, kind of a breakdown of -

MR. FUTCH: Yeah, that might be interesting to see the running totals. I usually look at it once or twice a year for various purposes and I think we're around 27,000 radiographers, 3,500 or so basic machine operators, a little under 2,000 radiation therapists, and the nuclear medicine techs seem to be experiencing a little minor increase. They're like 2,200 or so which is an increase over the past several years for them.

MR. JANOWITZ: Have there been any nuclear medicine practitioner applications, do we have any processed -

MR. FUTCH: You know, I haven't even been asked about it.

MR. JANOWITZ: There are several programs that are there. I'm not sure they're graduated yet.

MS. CURRY: Practitioners?

MR. FUTCH: Yeah, they're like the RA on the

2

3

4

5 6

7

8

9

10

11

12 13

14

15

16

17

18

19

20

21

22

23

24

25

nuclear medicine side.

MS. CURRY: We have no experience setting up those yet.

MR. JANOWITZ: You probably will -

MS. CURRY: So that's something we need to - look into.

MR. KENNEDY: And even though we have headwind, so we, we, we downsized our staff, we do anticipate getting those numbers back down. That is a commitment across the Division of Medical Quality Assurance and all the health professions that we license. And, in fact, that's actually part of our evaluation goals is to get these numbers better and better, so you know, Gail and her staff really do an amazing job. Being new, I've really been impressed by how diligent the staff is at making sure that the applicants understand what is required of them and what it is that they may be missing and what they need to do to complete their application. But, you know, we can do better and we need to do as a division and a bureau a better job of supporting Gail and that staff, so hopefully we'll be back next time getting that one-third a day back and maybe more so.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

MR. FUTCH: Aren't you working on a new computer system upgrade?

MS. CURRY: Yes, that's going to go into effect in October. We did offer our suggestions, one of them being that we would like to see like the ARRT does a - the ARRT knows that they have just a check-off of the schools. schools can go into their website and just say, oh, yeah, this person graduated, this person graduated, so there's no paper work involved. That's what we would like to get to where everything is data, you know, database driven instead of, okay, you can apply online now but we still need you to fax us your ARRT card or your course completion, your HIV. So we're still getting some paper; we'd like to try and do away with that. We have done away with that with our basics, but not our GR's, NNT's and RTT's. They're still some paper that they have to send us.

MR. FUTCH: So that would be something for the program to do to communicate with you electronically, maybe when they graduate?

MS. CURRY: Yeah, we'd like - we'd like to see that happen.

MS. DROTAR: We already do that now. We have to send a letter on the day they graduate - MS. CURRY: Right.

MS. DROTAR: ... provide us with information so a little checkmark would be really nice.

MS. CURRY: Yes, I know you love that.

MS. DROTAR: I know.

MS. CURRY: We're working hard.

MR. FUTCH: You haven't asked for that before, have you, Kathy?

MS. DROTAR: Yes.

MS. CURRY: But, yes, there is some new data systems coming - it should be live and in action in October.

MR. FUTCH: And you guys are also going to have some protections against some of the issues that we were talking about before, you know, the licenses, extra protection against the license being issued, you know, without the modifier and things like that.

MS. CURRY: Yes.

MR. SEDDON: I have a question for Gail.

For medical physicist licensure, there was at one time an advisory council for medical physics. The

question's been raised concerning direction for supervision from some of the national organizations and so they're asking is that council still inactive?

MS. CURRY: You know, unfortunately, medical physicists got taken away from us.

MR. SEDDON: Right.

MS. CURRY: So it's now gone over to the chiropractic board. They have like seven different professions that they keep there, so unfortunately I can't really answer that question for you.

 $$\operatorname{MR}$.$ KENNEDY: But we can get you the answer at the -

MS. CURRY: Yeah. So just give me a little bit during the break and I'll find out if there's still a council for that.

MR. SEDDON: Right. I know they're all inactive that are currently on there, so they want to try to reinstitute that council and to try to clarify guidelines for supervision of physicists.

MR. KENNEDY: I think that's what's happening now with what the future might hold.

MR. SEDDON: It's a combination of both,

yeah, so we've had some debates the last couple of years about what we're allowed to do within Florida.

MR. FUTCH: I think if you go to the

Department of Health MQA licensure page for

medical physicists, the Council positions are

mostly vacant and they still for some reason list

Libby and also Agnacio is on there.

MR. SEDDON: Agnacio's just expired.

MR. FUTCH: Yeah. Okay.

MR. SEDDON: So just one person left and she hasn't met since, I think, like 10 years.

MR. FUTCH: Yeah. I think - Gail, what's the gentleman's name whose Patrick - is it Bill I want to say Little or something like that?

MS. CURRY: He's gone.

MR. FUTCH: Oh, he's gone? Okay.

MS. CURRY: Yeah. Allison -

MR. FUTCH: Allison's for Board of Medicine, right?

MS. CURRY: Adrian -

MR. SEDDON: Rogers.

MS. CURRY: Yeah. She started the same time Patrick did. They've only been on board about two weeks, so, you know, don't beat them up too

bad.

. .

. .

MR. SEDDON: Oh, right.

MS. CURRY: But, yeah, she's brand new, too.

MR. FUTCH: When she gets around to looking at her website which would probably be done by now, she's going to probably say here's the council and it's taken 'cause there's nobody up there now.

MS. CURRY: Yeah. I'm going to step out and ask - see if I can get you an answer for that.

Okay?

MR. SEDDON: Thank you.

MS. CURRY: Does anybody else have anything before I leave?

MS. DROTAR: Just background checks are becoming more of an issue. Is there - I know I talked to James briefly, where I could get more information to advise my students on that?

MS. CURRY: Actually, when they go online, Kathy, they go online and they check "Yes" to that criminal question, it tells them everything they need, every single thing they need. So if they send in part of it, they're going to get a letter that says we still need dispositions, we need court records, we need arrest reports, you

know. It's got a whole thing but if you go to the website it also lists it there.

MS. DROTAR: Yeah, I noticed it more in line to PRN.

MS. CURRY: Yeah. And those are done on a case by case basis, you know. We reference the statutes to be sure that they haven't done something that would exclude them completely, and if it's something that we're afraid, you know, they might have a drinking problem or they may have an alcohol - a drug problem, we're going to send them to PRN to be sure they're safe. And a lot of times PRN will put them on a two-year or a five-year contract so that they can monitor them. Now, they'll take them off that contract early if they're compliant, so - but - and exemptions are coming in, too, into play now.

If we license one of your students and they go out to a hospital and get a job, AHCA is going to come back and say, oh, we just ran a background check and you need an exemption to work. And so all they have to do is contact us 'cause they're probably going to contact you and say I need an exemption now. If we just approved them for licensure and nothing else comes up,

we're going to give them an exemption right away so they can work pretty quickly. They're going to have to send us the application from AHCA and the letter from AHCA and just ask for an exemption.

MS. DROTAR: Thank you.

MS. CURRY: Anything else? And you guys, you know, call me if you have any problems or questions or anything, just call and I'll be happy to track down whatever I can for you, whatever information you need, 'cause medical physicists did used to be with us. Although they aren't now, I can get you the contact person and the information.

MR. FUTCH: Kathy, you want to talk anymore about the incoming processing, how it's something that the students always understand, but our guiding principle is in our incoming licensure statute that basically says that we may not license somebody who committed an offense that would have been a violation of the discipline standards if it had been committed while they were certified. So everything kind of keys off that. So what we usually do is tell them to go look at the discipline standards which are in the

regulation 64E-3 and, you know, they're crimes against a person, crimes that relate to the practice or the ability to practice which is often where the - things like a series of DUIs or other drug related crimes come in, and that's when the - the Professional Recovery Network issues as a group of physicians who can evaluate someone and see if they are or are not addicted and safe to practice. But that's the way it generally works.

MS. DROTAR: And my concern was advising them before they come into the program kind of thing, and we give them all that information and have them do a pre-approval by ARRT, which is a help but it's still not licensing, so -

MR. FUTCH: That's the - yeah, I remember going back many years sometimes people would like to be able to get an answer from us ahead of time, and it's not something that we're really allowed to do at all 'til we get an application to act upon. So we're kind of in the situation of well, we can tell you these are the guidelines, but until you actually apply we can't give you a definitive yes or no. So, you know, we're not sure a person wants to go and spend

. .

\$20,000 and become a technologist then find out they can't practice in the State of Florida.

But one of the things they can do, at least if it's a radiographer, is apply to become a basic. The basic, as you know, doesn't require graduation from a formal program. So as long as the criminal history doesn't change from the time they applied as a basic, we can actually give them a definitive answer by licensing them as a basic - well, at least admitting them to the examination. Whether they pass or not is up to them.

MS. DROTAR: Yeah.

MR. FUTCH: But that's about the only concrete way you have of getting a definitive answer through the statutes the way they're set up.

MS. DROTAR: And that's fine, you know, it becomes their choice as a university you can't deny education, so it's kind of up to them. As long as we're advising correctly then I don't have any problem there. And we don't want people, some people to be licensed, so it's a good thing for the checks and balances. Thank you.

MR. FUTCH: Sure.

DR. SCHENKMAN: Okay. Anything else having to do with the MQA update?

MR. FUTCH: You never got a chance to tell us about where you came from.

MR. KENNEDY: Well, I come from the Agency for Health Care Administration where I was the administrator for data collection, quality assurance, and patient safety. So among other things my unit collected adverse incident reports from all licensed health care facilities. But most of my background, though, before that was with professional associations, among them the Florida Medical Association, American Heart Association, a number of different medical specialty societies. So I feel like I'm back with the professions, feels like coming home.

MR. FUTCH: And learning pharmacy.

MR. KENNEDY: And learning pharmacy rapidly, yes.

MR. FUTCH: (Inaudible) - at this point

MR. KENNEDY: Well, a little bit. I know the health care system pretty well and so it's more of a filling in gaps. I've lived next door to the executive director of the Florida Pharmacy

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Association for 17 years so, just little discussions, you know.

MR. FUTCH: Have the pain clinic things died down or is that still a major portion of the pharmacy (inaudible).

MR. KENNEDY: It's actually dying down and I know actually from my work with the governor's Council on Substance Abuse that we're seeing rapid rises in heroin use rates actually because we're doing such a good job with the pill mills. So that's a good thing, kind of, but now we're seeing an increase in the number of methadone clinics around the state. So it's a bit like squeezing a balloon, but if you go by the number of complaints we have from people who are not able to get their pain medication prescriptions filled then the supply is being managed much more aggressively. So I kind of walked into that.

But, of course, in Florida the big thing now - we quickly moved from there to compounding. Most of you probably remember the number of people who died last year from viral - bacterial meningitis from badly compounded drugs they were given, and we have spent - I say "we" meaning not me, but the Board and MQA have spent the last

24

25

year getting - locking down on that in state and happy to say that we just last week, the - the Florida Legislature passed legislation allowing us to clamp down on compounding pharmacies or compounding outsourcing facilities that are not exactly pharmacies. So anybody compounding and sending those compounded products to the State of Florida are now under our jurisdiction and we can send our inspectors to look at their facilities. So we're looking forward to extending our instate compounding - sterile compounding permit throughout the United States and I am happy to say it also includes both for human and veterinary use. There was a major issue two years ago with a number of Polo ponies from the Venezuelan National Polo Team were killed from an incorrectly - well, legal drugs that were produced illegally and dispensed improperly, which that's the trifecta, I think, you're taking a legal drug and you make it illegally if it were legal and then you dispense it improperly. So we're excited that we hopefully will be able to insure the safety of Floridians much more effectively through compounding now.

So the pill mills were again two to three

years ago, this was compounding, but the great thing about the State of Florida is I'm sure there's something else on the horizon, but we'll

DR. SCHENKMAN: Medical marijuana.

MR. KENNEDY: Undoubtedly, yes, but -

DR. SCHENKMAN: Is that going to follow you here, too?

MR. KENNEDY: Well, I'm happy to say that the Legislature in their wisdom did not provide for prescribing medical marijuana, so like in other states that it stays out of the pharmacist's chain so there will be - you'll - you'll be able to order it in Colorado and California they're called dispensaries. And because our law 465 is based around prescribing then you will not be able to go to a pharmacy. Pharmacies will not be carrying the marijuana. The marijuana will be obtained through a dispensary. As to what a dispensary is or how one accesses it -

MR. JANOWITZ: I know when this issue came up a couple of years ago, there was talk about these regular dispensing or compounding pharmacies, there was a question as to whether

2

3

4

5

6

7

8

9

10

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

the nuclear medicine preparation
radiopharmaceuticals would fall under those. Do
you know if that's been accepted or -

MR. KENNEDY: The definition of compounding in the bill is broad enough that we were joking about it that a peanut butter sandwich would be compounding. It's the combining of one substance with another substance to create a third substance, and it's that kind of broadness that we need to stay ahead of the people who want to be a little fast and loose with that. having been said, the preparation in compounding of substances within a physician's practice is licensed under 458 and 459 and is not the practice of pharmacy. So - and we have been observing a pretty bright line there. I know that there's potentially some areas where that's not entirely clear and they may have to discuss that, but as of right now I know that it provides for any type of sterile compounding. We haven't really taken up non-sterile compounding and as of right now if you're a compounding pharmacy or compounding outsourcing facility, then you're under our jurisdiction. And these facilities know who they are; actually, we know who they

are. We've asked around the nation, you know, who are you; if you want to send compounded products to the State of Florida, let us know who you are. And we did that in-state and we did find that a certain number of these organizations did not want to go through the permitting process.

MR. JANOWITZ: What about the independent radio pharmacies that supply all of the hospitals and medical practices?

MR. KENNEDY: If they're in the State of Florida, they're all permitted. If they're outside the State of Florida, they're already permitted. And again, the, the, the permitting process does not really provide for any additional regulation. It provides for you to tell us that you're a compounding pharmacy and that you display to us that you're already meeting the federal regulations for compounding. We also have our -rule in the State of Florida. We have to pass an administrative rule to finalize our in-state program.

The rule and the bill thankfully look the same. There are some limited and somewhat esoteric details there I'd be happy to share with

anyone that would like to know, but I - the deeper we get in now in my, in my, in my fourth week on the job, the less sure I become of my footing and the more I want to ask my Board attorney to advise me. So I -

MR. FUTCH: In six months you'll be asking the Board attorney to answer all the questions, then you'll really be - pretty soon no answers will be forthcoming at all.

MR. KENNEDY: But if anybody has any questions about compounding or any of those issues or any ancillary issues to pharmacy at all, I'm happy to answer your questions, and I've got cards so please come and I'll give you one of my cards.

MS. CURRY: Mark, I have some information for you. Sharon Gilford, and I have her written down here, is going to be your contact person and she said if you give her a call she'll give you all the details. I do know that there is still an active council. She said that the members that are inactive on the website are really still active, so - but she did say they all have to have a license. Right now there's three full council members. She did also say that the

_

attorney met with Libby and she didn't give me any details about what that conversation was or anything, but she said if you give her a call she'll be happy to talk to you.

MR. KENNEDY: Thank you.

DR. SCHENKMAN: Okay. So should we now move on to bureau update?

MS. BECKER: That's me. Okay. Well, I was hoping to be able to introduce you to the newest member of our division, our division director, and he's been here I guess several months now. Time goes by. But he could not make it; he had to go to his son's graduation which I think is pretty important. We'll let him out of this one. Maybe next time he'll be able to come. But his name is Dr. William Anderson. He's been CEO of several hospitals both in Florida and Alabama, so I don't know if any of you have heard his name but he's been in that capacity for a very long time at different hospitals. And we'll hope to see him next time.

The budget. The budget's kind of where we're looking to see what will happen to us this year. We never know. Last year about this time we had to give up two positions. We did have a

few vacancies, so we gave up one of our license evaluators in our RAD materials program. And the other one was health and safety specialist who did our maintenance down in our environmental lab, and those two did hurt but like Gail had said earlier, we just - I guess 'cause we're so efficient. So we're hoping we don't take a hit this year on positions, but we never know. We currently have about four vacancies, I think, but two are in the process of being filled. The other two are still in the process of being advertised.

The end of the year, all the budget stuff. Our end of the year, you know, is June 30th so we have a lot of staff working on tying up all the loose ends for the end of the year budget. We also have some rule issues which you'll hear James talk about later, so we're always dealing with those.

It's also the time of year for legislative proposals. Again, we have to get ready to put any of those together that we wish to try to get through. Well, last year as in other years, we always talk about increasing x-ray fees. They have not been increased in over 30 years now, and

as you know, that has not stopped - inflation has not stopped 30 years ago. So I don't know if we'll work on that again this year. We'll probably see how the climate is to see if that's something we need to try to push for again. As you know, that's very hard in the climate to get something like that through if the fee's increased.

We're also working - Crystal River, as you know, they're shut down, the power plant there, the nuclear power plant, and they're in the decommissioning phase. So we are working with NRC on what that means for us as far as surveillance and monitoring that we do around the nuclear power plants.

X-ray registration process, kind of ended for right now. The August through November time frame, Yvette can tell you more about that, but that will start up again about August and that takes a lot of time for their staff to go through that process. And it was actually faster this year. They improved the process and going at it.

Radioactive materials program is still doing licensing, of course. They're moving ahead with one less staff but they're doing well.

(850) 421-0058

They're actually having a fellow come from

Jamaica that wants to see how we run our program.

As you know, our radioactive material program

gets national recognition out there. We've

already had several different folks from the

Bahamas, France, Mexico - where else did the last

one - Canada. The Canadians came, too.

MR. KENNEDY: It's a country.

MS. BECKER: It's a country, yes. Our IMPEP it's called - Integrated Materials Performance Evaluation Program - looking at Jerry, he just did one in New York. It's the NRC language for the auditing that they bring and it's time for our audit of our RAD materials, our emergency response program. Not so much the x-ray but they're over us with the - with everything else we do. That will be in February and they will be here two weeks. They'll spend a week in our offices in Tallahassee and then they'll go out a week with Jerry's staff in the field and do some inspection accompaniments. So we're gearing up for that.

The Health Physics Society meeting was just a couple of weeks ago, April - April $15^{\rm th}$, $16^{\rm th}$, somewhere in there - $12^{\rm th}$, $13^{\rm th}$. That was very

successful. We had a training with them which we tried to do as much as we can to work with the society and we were able to train our staff on our newer detection equipment, so that was quite successful. And the biggest thing we were working on lately seems to be Office 365 in the cloud stuff and, oh boy, you don't even want to go there right now.

MR. FUTCH: Yeah, if you haven't gotten any e-mails or can't get any e-mails from us, that's because the whole department switched from servers that we have under our control to the Microsoft Subscription Solution, in the cloud, as they speak.

MS. BECKER: So none of us get lost in the clouds.

MR. FUTCH: Yes, so everything takes slightly longer now and we have connection problems, but, hey, it's progress, right?

MS. BECKER: That's progress. Did I miss anything? Yvette, Jerry, James, did I miss anything about the programs we're thinking?

MS. FORREST: No, I don't think so.

MS. BECKER: Does anybody have any specific questions? Okay. All right. Thank you, guys.

. .

DR. SCHENKMAN: Thank you. Okay. So now we're walking through the spectrum.

DR. COGNETTA: So I would like to comment just a chance meeting with Cindy led to my
discovery there was a radiation safety council
and I'm interested in radiation as it relates to
patients and how it's done correctly. I can't
stress how impressed I've been from day one how
people in this organization get back to you
immediately. The efficiency and the openness and
the inclusiveness - I would be sending an e-mail
out at 4:30 in the morning to Brenda and I'd get
something back, you know, before 5:00 and stuff
like that. So I appreciate the fact that I've
been invited to speak here and if I can get this
to come up -

It was working just a moment ago.

So this is a talk that I gave at the FSU
Department of Physics and College of Medicine
probably a year or two ago, and I shortened it
and I just wanted to give you some background.
You know, what is a dermatologist doing at a
radiation safety council meeting? And I am the
founder of Dermatology Associates. We have ten
dermatologists and a couple of plastic surgeons

and pathologists in our office. But, typically, what I do is MOHS surgery which is a method of removing skin cancer and skin cancer is - it's very much on the rise. But this is a typical skin cancer on an eyelid of a gentleman that we'll meet later. And what we do is we remove tissue, we analyze the tissue in our lab; we then match up where the positivity is in the tissue. These are frozen sections. We look at them under the microscope and within 20 minutes we can know exactly where this positivity is and go back in that exact area.

But dermatologists over the years have utilized the entire electromagnetic spectrum in terms of detection, treatment, and prevention of skin disease and I'd like to just - and I consider light and photon energy all radiation, so I think it might be helpful. So I'm going to start with the longer wavelengths and then work my way up to radiation and talk a little bit about how we use it. This, for example, is a microwave tissue processor, and in the past to get a biopsy back on permanent sections we would have to wait one or two days to put it through formally. We can now get results back in four

hours because this accelerates the tissue process.

And the next part of the spectrum is infrared, which we all are familiar with CO2 lasers and 1060 nanometers, and this is a typical workhorse CO2 laser that we use to treat warts, skin cancers, and other entities. And this is a good example of rhinophyma and then going after it with the laser and treat - you can literally with these lasers write your name on a piece of paper and burn the ink off and not burn the paper. That's how exact it is. This laser has been approved to do something called fractional laser where you put little tiny dots in the skin and it goes down and excites the collagen and tightens up people's skin. That's a cosmetic and we'll see this again in just a minute.

But infrared can also cause skin disease, and this is a condition called erythema ab igne. Everything in medicine is in Latin so it makes it sound better, but it's just ''redness from the fire''. But this is chronic - this is a person with chronic back pain who's had a heating pad on and this is an older lady that was sitting by the fire for many years and burned her legs. But as I

said, the entire spectrum of radiation can cause problems. And this is a gentleman I met probably eight or ten years ago from Marianna who moved back here, and for some reason he had multiple squamous cells on his legs. And here's a good example of somebody's erupted squamous cells that are coming up on his legs, and I kept wondering why would you get just squamous cells on your legs? And I kept asking, you know, have you ever been exposed to radiation? No, no. And then, lo and - and we did a scatter gram on it like we do on a lot of things and basically the guy had 41 squamous cells on his lower legs and with no known reason. He wasn't exposed to arsenic or anything like that.

Well, come to find out he was a - he ran a large fire crew and he went all over the United States and stood within two to three feet of the fire line at all times, and we wrote this up as a paper in our American Academy of Dermatology Journal.

And visible light. We've all heard of Mad King George and in retrospect he probably had porphyria and that's a disease that often happens when people are a little bit - become inbred.

But the porphyrias are a group of hereditary disorders that have to do with heme synthesis. I mean, making our hemoglobin. Some of them are acquired from lead and other things, from alcohol, but any diseases that represent excessive porphyrins are called porphyrias. And this is what we did for about two months in medical school - memorize all these different pathways going from aminolevulinic acid all the way down to hemoglobin, but some of the disease - here's hemoglobin down here - but in some of these disease states there's enzymes missing or blockage of these enzymes.

And this is a typical disease that we see with porphyria cutanea tarda which is the most common porphyria known. They get this blistering of the hands. They have - they're very photosensitive. They also get increased hair on the face, okay, and they get scarring from all this and they get this sort of almost a wolf-like appearance. So you can imagine in the Middle Ages these individuals might have been considered werewolves or vampires, and they were - they were all anemic because they didn't make enough hemoglobin. They couldn't go outside. Garlic is

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

one of the greatest inhibitors of protoporphyrin IX synthesis, so it causes a great spike in the disease.

It's, I think, to the credit of various specialties that we took this disease state and we went to using it to prevent disease. So this is aminolevulinic acid or blue light care stick (ph), and it's a precursor to porphyrins. any cells that are rapidly dividing, it gets taken up and it gets blocked at protoporphyrin IX. So we then put people under the light and they get a photosensitive reaction. And here's a good example of a before: a gentleman with multiple squamous cells and a lot of severe sun damage and after. Now, blue light as you know doesn't - it has more energy but doesn't penetrate very deeply. If you put a flashlight in your mouth, the red light comes through it and penetrates deeper. So we then looked to the Qbands which are a little bit further down the road but not as powerful, this end of the spectrum over here. And the red spectrum. And a company sent myself and two other derms to Amsterdam for a week to study red light porphyria. This is the red light district here.

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Anyway, it's a much more penetrating method of treating things and in Europe it's approved for basal cells and squamous cells. United States is just for pre-cancers, but we use it a lot for these.

And this is an individual with severe skin cancer problem. I remember running into him at one of our local Espositos, which is one of kind of home supply shops, and he's out getting tomato plants. I said to him, I said, I think I'm more worried about your skin than you are. You know, you're out planting vegetables and I'm trying to get the skin - but this is day four and this stuff caused a very, very blistering exudative reaction and it really cleans people up very nicely. And we just recently had started coupling it with, if you remember I showed you the fraxel wave. So we can punch holes with CO² lasers into the skin and then we can - this is the absorption spectrum with fluorescence at 180 minutes without the - without any pre-treatment, but if you pre-treat with that Fraxel laser you get a much increased - so we try to stack technologies and where we are in north Florida, the skin cancer ratio is extreme. I mean, we

take care of farmers and fishermen.

So here's just a couple of other lasers, the pulse dye yellow laser which is used for a lot of different vascular lesions. For example, this little child with a congenital hemangioma before and after; it does a very good job, it's a very safe laser. IPL is a very, very safe multispectral laser-like device that hits all different wavelengths. It kind of resurfaces patient's skin.

I'd like to talk a little bit about melanoma

because it's the biggest problem dermatologists have and - there's 300 million Americans. We have about 20 moles each, so there's about 54 billion nevi, 100 million melanomas a year. So for us to find a melanoma, it's like we have to look at 50,000 nevi per melanoma. So it's a needle in a haystack. And here's a very good - there's certain things that we can look for. That's a symmetric lesion. Here, this is asymmetric. This is well circumscribed. This one is very poorly circumscribed, the borders. This has one color, this has several different colors: black, brown, red. This is less than 6

millimeters, that's greater than 6 millimeters.

Around 1990, the Germans and Austrians came up
with a little device called the dermatoscope.

Actually, they used an operating microscope for
years and came up with these subjects. But it
allowed us to look below the skin's surface and
we could see features just like colposcopy or
other methods that we couldn't see with the naked
eye.

For example, here's a nevus that's round and very regular looking and with dermoscopy you see it has a fairly normal pattern. This is the same appearing lesion. This one has a very irregular pigment network and that one is a melanoma. And this is an example of a young girl that I have had the pleasure of taking care of for about 25 years. She has xeroderma pigmentosa. And actually this is another girl; this is a girl with multiple nevi. We have to find a needle in a haystack and this is, this is a melanoma on the arm that we could help with that.

Now, this is the girl I was talking about with xeroderma pigmentosa, and we look at this girl once a month. She's from Perry, Florida,

has no insurance. This little mole here we look at under the dermatoscopy that shows that it's a melanoma. Another mole here, that's a melanoma under dermatoscopy. Another mole right below it, another melanoma in situ there. And we wrote her up, and at the time we wrote this up in 2009 she had had 38 melanomas. Now she's had 62. The average depth is 0.15 which is reasonable. And we wrote this book in 1990 and it's The Color of Atlas of Dermatoscopy, and it's the first book on this subject. Myself and Harold Rabinowitz from down in South Florida have done a lot of work on this here in Florida.

We also wrote a rule on dermatoscopy where we were able to look at various features, asymmetry. This has no asymmetry. This has asymmetry; one more. This has two irregular borders; none; four irregular borders; eight irregular borders; various numbers of colors. This has five colors; this has three; this has two different structures. And we were able to then do various retrograde analysis and weigh all these different things and came up with an algorithm and anything over 5.45 was a melanoma; anything under 4.75 was not. As soon as we did

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

this, people started sending us - saying to us, well, we can do this with computers. And we said, you know, there's no way you can do this with a computer.

Well, lo and behold, MelaFind® came out after several different attempts and it's a multispectral analysis system that looks at moles. And we basically put it on the patient and - let's see here - and it basically sends out ten different wavelengths, collects the data, and by a proprietary algorithm, statistical algorithm, they can - it can analyze what is a melanoma and what isn't. And it looks at - goes from the blue wavelengths all the way down to below the infrared there and can actually tell us the depth of the melanoma. And I was the second author on this paper where out of 127 melanomas it found 125, and that's impressive because the best dermatologist in the world will probably find 70 or 80 percent. The key point is the majority of biopsies that are done are not necessary and that this may be a method of leveling the playing fields and allowing anybody to make a better diagnosis.

So a little more about ultraviolet.

24

25

Ultraviolet A is the most penetrating and the most damaging of all the ultra-violets. Ultraviolet B is what causes cancer. It is brought by the ozone layer. Ultraviolet C is in outer space, thank God, and doesn't bother us. But this is a teacher who sat facing the south. Her right side of her face facing the south for 30 years and you can see the difference. Her left side was exposed, the left and right. I think that's dramatic and this is a black light or infrared - or ultraviolet photo of a young girl with sun damage that is not really seen. This is a typical photosensitive disorder, lupus with the butterfly rash. This is a question this girl last Monday was at a party and doing something; anybody have any idea what she was doing?

DR. SCHENKMAN: Limes.

DR. COGNETTA: Huh? Oh, thank you very much,

Dr. Schenkman, that's very good. Yeah. So she this was your multiple choice, but it was lime.

And that's lime dermatitis or berloque
dermatitis. This is a psoralen type product;
this is bergamot which is in a lot of different

perfumes. Very good. And we use psoralens for various diseases. We put it on topically and treat vitiligo. We put it on people with psoriasis, so we use that wavelength, ultraviolet A, to get rid of that. And one of the things that the tanning bed industry has tried to tell us for years, which isn't true, is that ultraviolet - that tanning beds help get us vitamin D. It doesn't. You see there's an abrupt cutoff at 3:15 and its peak absorption is ultraviolet B.

Here's the ozone layer in 1979. It's pretty healthy. This purple shows that it's 110 units here and it's 92 in 2008, so we are burning holes in our layer, but to get to the next part of the talk here which is my final part - energy in electromagnetic radiation. I just want to show you a study that we did that I thought was intuitive and interesting, but about seven or eight years ago we started seeing - in one week, I saw seven or eight people that had multiple mid-line skin cancers and they're all in their 70s or 80s. I could not figure out; they had not had a history of radiation for acne which many patients have in Florida, and here's another one.

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

This, this - the last guy worked with CRTs early on in the computer industry. This guy was a - worked on a gunfire coordinant using a high end voltage CRT, an oscilloscope, in World War II.

This was a guy aboard a naval vessel and also had his head in a CRT or oscilloscope for many years.

And basically these screens are really just cathode rays and back in the early days of oscilloscopes there was no leading of the glass. So these patients got - they would sit there and look for hours in this little thing. They'd come out, they'd say their face felt a little bit red. And we wrote this up and 235 skin cancers in nine patients, midline face, and we got letters from all over the world, people, you know, saying how they - but, anyway, I did leave a little thing inside here on the history of radiation. I feel like the history of radiation is one of the most intriguing stories there ever has been, and we all know Dr. Röntgen discovered these accidentally using a cook's tube. He wrote the first article, he won the Nobel Prize in 1901.

In 1902, there were four cases reported by bridge dermatologists treating basal cell carcinoma, throat ulcers. This is an American in

3

4

5

6

7

8

9

10

of

11

12 13

14

15

16

17

18

19

20

21

22

23

24

25

Philadelphia dermatologist talking about it and our American Academy of Dermatology in 1903 there were already - they were already speaking on radiation in 1903 as rational indications for its And here's an example of a basal cell from 1902, before and after; and you can imagine the excitement this caused at that time when there was no surgery or really any good effective treatments for these.

This is Phillip McKee and he was the head

NYU Skin and Cancer in the 1920s. He wrote the first textbook on x-ray and radio and there have been a series written all the way through this century. And basically we all know a cathode ray to the difference with superficial x-rays, there's usually a beryllium window here and it's a multispectral energy pattern that comes out and - I'm not going to bore you with this. for a minute. I want to show you these real quickly. Now, these are the machines - these are the last machines made in the United States up until 1995, let's say, and these were built in 1962, and they work well. This is a typical basal cell on the rim of the nose, same guy the

LCD.

rim of the nose. This is three years after superficial radiation and this is three years after superficial radiation.

This is another small basal cell of the nose that was sent to me for MOHS surgery, and I felt it could be treated with radiation. We treated him - this is 12 years after.

The more modern machines obviously have

They have a lot of different safety factors. You dial in the amount that you want and it won't let you shoot over a certain amount of radiation, and you see everything on one screen where the old machines you used to have to watch the kilovoltage and the milliamps. And this is a woman with a large squamous cell carcinoma in situ on the forehead. This would have taken a large skin graft. This is fairly - this is desquamation day 14, this is two years out. This is a 102-year-old lady with a nodular basal cell on the tip of the nose. This is post-op day 14, this is 181 days out and she's still alive.

About seven or eight years ago, I decided to write up my last ten years - 1990 to 2000, of all the cases I did during that time with

22

23

24

25

radiation. There were 715 cases that we treated with superficial x-ray. It's the largest series of its time and there were about 631 basal cells, there were 860 squamous cells. There were - the most common location was the nose. recurrence rate, all recurrences was 2.6%. used very conservative recurrence. If something came back nine years and 11 months next to the umbra of the lesion, we counted it as a recurrence even though it was probably a new lesion. For basal cells, we had two percent - a two year 4.2% cap estimate which overestimates the recurrence rate. Every one of these lesions, I looked at this line. I knew how deep it was. I feel like after 25 years of MOHS I know how wide these lesions often are. Squamous cells have a little higher recurrence rate that's still acceptable and the average radiation is 31 years. So we have been doing superficial radiation for over a century. There have been a lot of new strides in the symmetry and technology.

The population of our state is rapidly growing. Almost all the patients we see are on Coumadin or have a pacemaker or some other medical problem. My son sent me this here. I

think it's kind of funny. This is the electromagnetic spectrum according to a comment, but anyway, here's radio waves, microwaves, toasters, infrared, regular visible light, ultraviolet light, Miller Light, all the way down the spectrum, and anyway, Dr. Mendenhall and I are close friends. We completed this book in 2013. We worked very closely together on a lot of difficult head and neck skin cancers and I am very honored to be here today. I hope I can contribute to this group in the future and work with everyone here. This is a beautiful canopy road in Tallahassee; I hope you all experience this. Thank you.

DR. SCHENKMAN: Does anybody have any questions for him?

MR. FUTCH: I have one. When we talked previously - had a previous discussion - I missed the last Council meeting about the training and educational requirements for physicians to use superficial - in general, to do radiation therapy from machine based sources - some fairly extensive requirements for physicians using materials to treat cancers, things like that. So that was kind of a genesis of this whole thing

and then we started getting in the bureau some calls from various places, even other states, asking about the newest form of the superficial machine which is produced by a company in Florida called Sensus. And then eventually we made the connection of you and you have some experience, and you had some dealings with the company.

What are your thoughts on how a person who wants to use one of these machines, what types of patients, and then the terms of the training of the experience of the physician. What would you - what would you say is optimal?

DR. COGNETTA: Well, I did include the paper in this handout if anybody cares to read it. We were very selective on - we treated five percent of patients who were referred to us from our surgery with radiation over that ten year period, maybe five or six percent, somewhere in there. That's a lot more than most MOHS surgeons do, I can tell you. There are very few people even offer the option of radiation therapy to patients who are elderly. And even though the cure rate is not as good with radiation therapy, it's better for some patients than, than, than four or six hours of MOHS surgery, which if I - if - so

23

24

25

looking at, you know, the way that we deal with tumor volume and tumor choice, you know, choosing different modalities is we actually sit all day looking at tumors under a microscope, and we can measure them. We can measure their depth, their volume, and basically we also - there's basal cells and there's basal cells from you know where. I mean, they're very aggressive basal cells of invasion that require MOHS surgery and radiation, and then there's very small nodular basal cells like a couple ones I showed you on the notes that literally melt away with radiation. So judgment is something you can't legislate or whatever, and I've gone out lecturing all over the country for many years on radiation and how I do it, and I think our results show that if you do it that way it's good. But you really can't tell people that, for example, I'm not a big believer in using radiation on the lower extremities or really anywhere below the neck, I think surgery is a better option almost always.

As far as training, I grew up in an era when we were trained to use radiation. We had two units in our - in our - at the first practice

24

25

I came to in Tallahassee had a Picker a Universal and a Grenz. So it was very natural for me, but MOHS surgery became so popular and so effective that basically most people - and so remunerative, that most people said well, let's do surgery. And the radiation oncologists, a lot of them, and I'm sure those here can speak to it, really got rid of their superficial units because they started using electrons. And this is a very, you know, compared to a lot of laser platforms that dermatologists use, and we have about 12 in our office, you know, the physics of this is, is, is not - is, is very comparable and in fact somewhat easier than a lot of them when you're looking at different, you know, durations and milliseconds of treatment. So how patients - how individuals learn to use this is variable. I've had people spend a week with me, quite a few, and spend time with me and read our textbook, and we give several courses every year. But it has been part of the dermatological material since the early 1900s. And it is now - I give the forum at the American Academy of Dermatology very year, it's a 2-1/2-hour forum, and it's well attended. all get our knowledge from, you know, our

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

American Academy of Dermatology and the State societies do it, also.

But what I'm interested in is making - is, you know, perhaps being a way to train, you know, your inspectors to, you know, I think we have a good method of documenting what we do and, you know, fail safes and ways to contact patients if they don't come back in, and things like that. There's a lot of logistics that go into radiation and positioning and stuff like that, so I've learned that over the years. So I don't really know how to answer your question about, you know, who should - who should, you know, how you train somebody, but it is a good question. But I think that your inspectors should be able to look at it and say, well, this is a good way to administer it and this isn't - and things are missing, so I hope I can help in that respect.

MR. FUTCH: We had the opportunity to watch Dr. Cognetta treat one patient and it was very informative to see the different aspects of the preparation and watch the reaction of his wife not too far away, and it was very impressive. I think the issue that was raised is, is there a national standard for recommended training and

experience? This is what always comes to us.

You know, we're a regulatory agency, so people say, well, should this be regulated and if so, how, and so forth and so on. I guess we're contacted by some other states that actually already have some training and experience requirements for the positions to use these kinds of devices.

MS. FORREST: Yes, I think we were contacted by a committee working in Council on Radiation program directors and they usually send us surveys about, you know, what are you doing in your state, here's what other states are doing. And they're trying to come up with national standards that they can recommend or suggest to your state programs. So that's always going to come up about, you know, what the qualifications are, the people that operate the unit of course, and then also what training and experience should one have to use the device. And so those are the kinds of questions that they're going to raise.

DR. JANOWITZ: Does the dermatology training program include radiation therapy?

DR. COGNETTA: They did when I went through it. That was 28 years ago. And they are now.

(850) 421-0058

24

25

They're starting to again now, but it's - as I said, dermatology went from a medical field to a surgical field and there was a time when radiation, I should add, before topical steroids and anti-inflammatory drugs, radiation was the only thing out there for various skin conditions. So it was used extensively and every dermatologist when I went into practice who - you know, in the early '80s that - any time had radiation units and had training and, you know, there was a lot more, but as those individuals died and you see these machines were last built in the '60s; and then the gentleman that developed the digital mammogram decided he was going to build a Phillips short contact machine again but digitally. And he built one. I bought one of those from Topex and then Sensus bought them from them. So there's been some training from industry, there's been some training from here in Florida Bob Nestor down in Miami has put together a one-day course on it here. We get a course from the academy and I'm asked to speak here and there, but I don't know if I answered your question, but it's not, you know, it's like nuclear medicine 20 years ago. It's different

than now.

1

2

3

4

5

6

7

8

9

10

10

11

12

13 14

15

16

17

18

19

20

21

22

23

24

25

DR. WILLIAMS: I've taught at several levels of this actually. Locally, it's the same here and nationally. I don't think that most dermatology programs have specific training in radiation oncology these days. At least, that's what we hear from ASTRO and I think if you look at the dermatology textbooks you'll find these 2000-page textbooks have five pages on radiation oncology. From our specialists point of view, the history isn't quite the same. I mean, I enjoyed seeing the pictures about the regimented x-ray spectrum and they're very impressive the things that you do and everybody can certainly see that there's a lot of value, you know, in multiple different wavelengths and different medical applications, but the niche that radiation oncology and dermatologic oncology to the extent that it's practiced involves ionizing radiation, which is a different biology, you know, from the visible spectrum, from the infrared spectrum, and the ultraviolet spectrum. I mean, these are - the biological effects of the radiation are substantially different they're completely different and the orthovoltage role

2

3

4

5

6

7

′

8

9

10

11

12

13

14

15

16

17

18

19

. •

20

21

22

23

24

25

right now as I survey it has three different aspects to it.

There's the isotope based which is Nucletron Varian basically, the meridian based devices, and we have one of those in our office and we use it in skin cancer as well in my office, and you and I are the same generation and both depend on it as well. And so I have no question at all about your capacity and expertise. That isn't the issue. But isotope based machines, they had 10 CFR 35 behind them, you know, that's nuclear regulatory stuff. State has really, you're in an agreement state or not agreement state, I mean, the rules are pretty clear about what the T&E is for an isotope based machine. I mean, you've got to be a radiational oncologist basically to use that machine. I think that's appropriate as an authorized user who uses all types of sealed and unsealed sources; you really have to be cognizant of not only the clinical side but also the physics side and the biological side.

And then there's the traditional orthovoltage machines, which are correct. We gave up our machine in 1997, I think, not because

we didn't like orthovoltage. We couldn't, we couldn't service it. It was a Siemens unit and, you know, they basically said we don't service that machine anymore, you know. So we didn't shift over to electrons because we loved electrons, we shifted over to electrons because we didn't have orthovoltage, you know. So our specialty, you know, sort of morphed over into the isotope based stuff, you know, before the orthovoltage stuff has now started to re-emerge and that's where the isotope based stuff sort of shifted over to the skin cancer world from the breast world and the GYN world and the prostate world, where it mostly resides.

But the traditional orthovoltage which is now coming back, you know, through Sensus among others, I think, and I'm not sure what your relationship is with them, but I think you have some type of relationship.

DR. COGNETTA: I do, yeah, I do. And so

I've been on the medical advisory board and I've

purchased stock in that way before they were

viable, and so I have been involved with them and

I helped train them. You know, I've not helped

train them, but I've been involved in training

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

individuals who are interested in being trained at no charge.

DR. WILLIAMS: I think it's great how the device works. I mean, it's a wonderful machine I think it's, you know, I've looked at it and not for this particular venue but the national stuff with ASTRO and there's no question that it's a high quality machine that will deliver successful orthovoltage therapy. And it's fairly straightforward, you know, it's basically just an RKV generator. And then we find ourselves with the e-brachytherapy which is sort of this middle ground of technology; the newer stuff. It sort of pre-dates the Sensus. You know, John Riecki (ph) is a good friend of mine. He is sort of the inventor of one device and I've been working with him for close to 15 years, I guess, since the original genesis of the idea. And it was - it was always intended as a radiation oncology device. Those rate very high with it and there's national controversy about where e-brachytherapy falls as far as the T&D requirements go. And next week I'm speaking at CRCPD. I don't know if you guys are going there or not, but I'll be there along with ASTRO staff to discuss this

situation.

And in this state, and correct me if I'm wrong, we have specific T&E language that says basically you have to be a certified radiation oncologist to use e-brachytherapy and not just orthovoltage. We thought that was the right thing to do. This advisory board debated it several years ago. It was carried through the legislative process and successfully became regulatory language in this state. Other states have tried to emulate it with mixed success. There is no national consensus as to where e-brachytherapy falls within T&E.

You are correct. Dermatologists have been using these things for years. The first radiation treatment I saw was a Grenz ray when I was a junior medical student at Augusta, you know, in the late '70s. And I thought, well, that's weird, you know. So it is, I think, a place - you know, I don't know where that place is, though. But you can see these pendulum swings in large practice patterns and based to some extent on technological development. And like you point out, they're based to some extent on, you know, sort of the, you know, the

23

24

25

experiences in the field on it and they're based to some extent on pecuniary aspects, you know, human nature being what it is, and having been involved in health care economics for over 20 years you see that in all specialties. I think that if Bill was in this room, I think he is probably the world's expert in management of radiation cancer, my guess is that Bill would say that this is an area that needs to be carefully considered from the standpoint of exactly where it takes brachy because with all due respect to your capabilities and expertise, you know, I'm just a local guy but there's a lot of stuff that goes on in the field both on the radiational oncology and the dermatology side which should not be done.

DR. COGNETTA: I'm in complete agreement with you. We see a lot of difficulty with electron beams, for example, scalp and (inaudible). On that where physics aren't done right (inaudible) radionecrosis from multiple cancers in these fields and everything, and as far as electron brachytherapy is concerned, it's in my opinion is nothing other than a short contact. You know, it's a miniaturized cathode-

24

25

it is not E-brachytherapy. It's just the thing and dermatologists have long agreed that, you know, it's not something we want to be doing in our office and it's the - the controversy I think has been because people have been teaming up with radiation oncologists and the bills have been \$25,000 to \$30,000 for a treatment, whereas our average bill is literally under \$500 for five fractions. So from a pecuniary aspect, I mean, people are taking this and are going to kind of capitalize on it, I do believe, but there are those of us that are doing it for I feel the right reason in the right way. And as the population ages, and health care economics as they are, can we afford to spend \$10,000 or \$12,000 for a basal cell with an electron beam versus a superficial radiation unit that'll do it for, you know, even with the complex physics and stuff, for a thousand or something like that.

So there - it has a place. I would very much like to work with the radiation oncologist. I have worked very much with Bill and Bill has been to my office many times and he's seen my results and everything, but can everybody do it correctly? Will they do it correctly? Probably

23

24

25

not. And it concerns me, also, because I invested in this company because I didn't want this technology to die, and that first machine I showed you was the end of the line. And so - and none of my studies had anything to do with Sensus whatsoever. Now, they used them to kind of promulgate this, but you know, the safe and judicious use of this modality is important, but as I was showing you, You can get in trouble with any laser I show you. You can get in trouble with any of your machines. I mean, there are problems everywhere. And dermatologists have a distinct set of knowledges about skin cancer; you guys have an incredible knowledge about the radiation and physics of it. Some of it is pragmatic and, you know, empirical what we do, but there's a lot of physics that we do understand. I was a physics major, so I'm not -I mean, any way we can move this forward as far as setting some type of standard forward, I'd be completely for it.

MR. FUTCH: Does anybody - let me back up for a second if I might. You know, we have a couple of statutes in Florida for this. Dr. Williams mentioned the part that comes from the

Nuclear Regulatory Commission, authority for the source-based side of radiation therapy and the E-brachytherapy regs that we wrote a few years back on the machine side.

You know, the Bureau, I think you guys will probably all admit is not exactly trying to beat people over the head with new regulations all the time. We try, and hopefully this comes through, we try and take a very reasoned slow consensusbased approach and really don't like coming up with - when it's needed, first of all decide whether it's needed, and if it is needed don't try and recreate the wheel. If there's some sort of a national standard, you know, we'd rather use that for the basis for regulation making in Florida.

And you may have noticed that the climate for regulation making in Florida is not exactly like it might be in some other parts of the country, medical marijuana abstaining from that. But, yeah, so anything to get a discussion going about this. Is there a need for doing something for that middle section that Dr. Williams was talking about before, and then what? You know, it's gotta be something that's supported 'cause

'

trust me, if it's not we'll be in court pretty quick and nothing will get adopted. That's my two-thirds. I don't know if you have anything else some of you want to say or you, Yvette, since it's your actual program.

MS. FORREST: We've been receiving a lot of questions about one particular unit in general. It's the SRT-100™ that seems to be a very popular superficial machine. We do receive or have received increased questions. Mainly what we're receiving is, are there any additional regs? What do I do with this? Is this something special I need to do?

The program office continues to field those questions until we really know the answer. I've enjoyed listening to both of you today. I'm excited to see, as they say, where this ball finally bounces but the program office will continue to receive these questions. And if the Council is interested, I can compile every six months or every year to just kind of give you an idea of what the program office is facing as this new technology develops and continues because it's not going away.

MR. FUTCH: I know I will be very interested

in hearing the outcome of this CRCPD meeting. It sounds like there's a committee and some, and some discussion that's going on, and that's always a good place for us to get suggested State regulations if there are going to be any or one standard for the country.

I'm curious also, Mark, have you seen one of these? Any thoughts on this particular area?

MR. SEDDON: We have older units which we have not used in a few years. I think Dr. Williams was saying one was still in one of our departments or it's an old unit, so we have not seen any of the newer ones at our facilities, at least within the radiation oncology department.

MR. FUTCH: Is there a - Dr. Williams, you mentioned a genesis for moving away from orthovoltage was the hardware. Now that this $SRT-100^{TM}$ - and I don't mean just to speak on the one particular product but it seems to be the Kleenex of the superficial world.

MS. FORREST: It's the most popular one that we're receiving questions on.

DR. COGNETTA: I think it's the only one.

There's another company, Guilmay in England, and they have a 250 kV and a 100 kV, but - what's

that?

BOARD MEMBER: Nobody's gonna use 250 kV.

DR. COGNETTA: Well, I'm just saying they use the two units, the 250 is the (inaudible) - but they do make another unit but there's no way to service them here in the United States, and they're not in my opinion well built.

MR. FUTCH: Well, I was curious if now that this technology is kind of re-emerging if there's any interest from the oncologist to do something with it.

DR. WILLIAMS: I don't know. ASTRO and ACR have a guideline which is in draft form. I can't share it because I'm part of the review committee for it. My understanding - I could be wrong about this - is that there was some type of a bridge between the AAD and ASTRO, but I'm not sure about that. You may know something that I don't.

DR. COGNETTA: There is something.

DR. WILLIAMS: Yeah, I'm not part of that.

So if it does, I don't know what traction it's got. There's an LCD if there's CMS then the State will try to get some of the control over some of the strange fractionation schemes that CMS -

First Coast Service Options were seeing up in

Jacksonville. That's been out for some number of
years actually and I think that Dr. Corcoran, the
CMD up there, was thinking about refining it
although he hasn't really made a decision on that
yet. So it has sort of an economical throttle on
some of the hypo, hyper, hypo-fractionated things
that were going out there.

MR. FUTCH: - Oh no, I can't imagine that would ever occur.

DR. WILLIAMS: Yeah, 60 skin fractions ... 30 a day.

MR. FUTCH: I know of one person doing that.

There's no one person and they're using some

archaic unit.

DR. WILLIAMS: Yeah, the only one I know - I think most people are doing 10 or 12.

MR. SEDDON: I think so. I think most people have some desire to field test -

DR. WILLIAMS: There's some literature for

it

But there is an LCD out there which technically says what you, you know, is appropriate for. So it's not like there's no language in place for it. And you know, so there are, there are

efforts that are out there but there's no comprehensive consensus driven, evidence based national program to pull this together. I just don't have - in today's climate, you know, national economic climate I just don't see that not only - and that's with any specialty. Those days if they ever existed are gone. So you won't get a clean answer from a national venue any time soon.

MS. FORREST: One can wish.

DR. WILLIAMS: Yeah.

MR. FUTCH: Have other states decided to do something or have regulations in place already?

Were they copying the NRC derived training and experience requirements for the positions performing it, or were they doing something else?

Does anybody know?

MS. FORREST: Not that it's been presented to the program office.

DR. WILLIAMS: There are efforts in other states. The general idea is that in the case of brachytherapy they shouldn't have the same beginning as isotope-based therapy. But you're basically talking about a scope of practice issue, not an NRC issue. And so, so that's a

bureaucratic-slash-legislative slog and state by state, so no specialist society has the resources to do something like that. Even ACR, you know, can't do a state by state, you know, comprehensive effort. And (inaudible) is a blue ocean organization, too, and they can take on anybody.

MR. SEDDON: So for these newer units located in the dermatologists' offices, are the operators the actual dermatologists or do they have therapists or some technologist type?

DR. COGNETTA: I can't speak for everybody, but I push the button every time myself for 28 years - for how many thousands of cases, and I check the set-up on everyone. I think a - and I don't know what the regulations are. I've been told by some people that a physician assistant can do that. I'm not certain. I don't have anybody do it but myself and - but certainly a radiation tech could do it, a radiation therapy tech could do it, but what is the-

MR. FUTCH: I was going to say, from the 468 licensure perspective, there's an exemption for licensed practitioners, which is defined as a person licensed to practice allopathic medicine,

23

24

25

osteopathic medicine, chiropractic medicine, podiatric medicine, et cetera, et cetera, et cetera. Everybody you can think of is a doctor, is a physician or someone who is, quote, "otherwise authorized by law to practice medicine, " and way back in 2000, the boards of medicine and boards of nursing determined that that language covered certain physician assistants and nurse practitioners in a very general sense. Now, the question was posed to them in the context of x-ray, diagnostic x-ray, and that's the only venue that I've ever seen. don't know, Jerry, it's the only one I've ever heard of. And what they said was that if the supervising physician was practicing and performing the same procedures, then the physician assistant or the nurse practitioner could perform those same procedures in themselves.

For a number of years, probably the first eight years after that determination was made, we understood it and enforced it in the context of the supervising physician having to be a radiologist oncologist, and then we ran into a facility that was using a PA and it was not being

underneath - the supervising physician was not a radiologist or an oncologist and we were corrected by the Board of Medicine that it was any physician who was performing those procedures. Okay. So, hopefully, there aren't any ophthalmologists performing radiation therapy; they don't have a PA that's doing, you know, radiation therapy. I don't know, but - Dr. Janowitz?

DR. JANOWITZ: Has the independent practice Bill for nurse practitioners passed?

MR. FUTCH: I'm sorry; say that again.

DR. JANOWITZ: There's a bill pending for independent practice, nurse practitioners -

MR. FUTCH: I don't think it did. I didn't really followed it. Patrick, do you remember how soon the nurses were going to be greatly expanded?

MR. KENNEDY: Yes, we had our hands full with a couple of issues ourselves. So, honestly, I don't know.

MR. FUTCH: I can't remember for sure. I don't think it did.

MR. KENNEDY: I haven't heard. Our management team meeting haven't been discussing

it what the requirements are.

DR. SCHENKMAN: But is it worth looking into

what some of the other states are discussing for this to see if they're a little bit further along?

MR. FUTCH: I think it's going to happen at the conference of radiation control program directors meeting, that Cindy goes to. And hooks up with that committee that was planned - .

DR. SCHENKMAN: Right, and then you bring it back to us and let us know what -

MS. BECKER: I don't know when their survey results are out. They were surveying all the state programs to put together their survey results, but it will be discussed, I know, at the meeting. So I will follow up.

MR. FUTCH: I know that - just one thing before we leave the topic of licensure statute. So in addition to the licensed practitioner who's exempt, of the licensed people in that statute which would be the basic radiographer and nuclear med tech, radiation therapy tech, all the specialty technologists which we now have and I'm going to talk about after lunch, and the

	radiologist assistant, the only one that has
1	radiation therapy in the scope is the radiation
2	therapy technologist. That's the only person who
3	can be doing the practice or making the exposure
4	besides the licensed Florida physician.
5	DR. WILLIAMS: So either the doctor has to
6	be
7	at the console or the RTT'S has to be at the
8	console?
9	MR. FUTCH: I don't really know how many
10	RTT'S are employed by dermatologists.
11	DR. WILLIAMS: I don't know. In some
12	states,
13	radiation techs can do it. In certain states, I
14	
15	know that -
16	COUNCIL MEMBER: They can do it in this
17	state if they were registered -
18	DR. WILLIAMS: Not radiation therapy techs
19	but radiation - just a regular x-ray. I mean, I
20	think they're - isn't there, so -
21	MR. FUTCH: There's probably very few
22	dermatology offices that have e-brachytherapy.
23	DR. COGNETTA: One point I would like to
24	make
∠4	is if people aren't doing it right, they don't

3

4

5

6

7

8

what

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

get good results, okay. And if they don't get good results, you'll hear about it and I so far have not seen or heard of any, you know, difficult - I mean, I've not - it hasn't been brought to my attention and I think that's, you know, if people are using it without using very good, you know, precise methods, you know -

DR. WILLIAMS: I agree with you. That's

TD is for, to make sure that people are doing the right thing, as opposed to the back door making them, you know, not doing right and then trying to regulate. And this body here is designed our job is to make recommendations.

MR. FUTCH: I think we've set a nice baseline discussion for moving forward.

Jerry, since you're here, have you heard of any PAs or nurse practitioners who are doing radiation therapy? Have you guys run across that?

MR. BAI: No. Almost every - and there aren't that many dermatologists who still do the superficial that I've seen. It used to be much, much more - 10, 15 years ago, but it's like, Dr. Cognetta, it's usually always the physician that

operates the equipment. We never normally see a technologist present. We've had some investigations where it wasn't a technologist or a physician because - yeah, otherwise, the only other superficial use of use that I've seen that the physician isn't operating the unit is mostly through an oncology center where they can actually have dedicated physicists or afford the technologist full time. At dermatology, that's basically all you would use them for is that one procedure for a technologist. So we don't see it at dermatology.

MR. FUTCH: How about in general, a PA or a nurse practitioner doing brachytherapy?

MR. BAI: That was the only case I've ever seen that, that one investigation that we did. I have never actually encountered that again.

MR. FUTCH: Dr. Williams, are you guys using PAs or nurse practitioners or do you know anyone in the community?

DR. WILLIAMS: (Shakes head no.)

MR. FUTCH: I kind of get the feeling from the blow-back that we got that it's mostly the PAs and the facilities where they're doing diagnostic x-rays, which is not to say tomorrow I

might have a different opinion.

DR. SCHENKMAN: Do you want to take a small break before we continue? Break for lunch.

MS. ANDREWS: It's 11:45 right now.

MR. FUTCH: Yeah, we told them between 12:00 and 12:30, so by the time we're over that will be about 12:00.

MS. ANDREWS: We have about 15 minutes before

we can break for lunch. Those of you who have brown envelopes in front of you; of course I've talked to some of you, that's your travel packets. It's pretty much the same routine as always. There are worksheets there that are partially filled out. If the information is not correct, that's for you to correct any, anything on there. Include receipts in your packets and you can either, if you have receipts now and you drove in and you know what your mileage is, you can give those to me now. Otherwise, if you have receipts that you need to send back to me, just - I'd rather you just put everything together and send it back all together at one time.

Remember not to fold the sheets with the signature part on there. I run those back

. •

through the computer with your final vouchers and sometimes if they're folded they don't go through quite as well.

You got your parking passes and anybody got any questions? It's pretty much the same stuff you all are used to.

MR. BURRESS: This is the authorization to travel?

MS. ANDREWS: That is your authorization to travel. That just needs to be signed.

MR. BURRESS: And this one we don't need to correct, right?

MS. ANDREWS: Do not correct that one.

That's an estimate anyway, so the figures are probably not exact. But that is the authorization for them to, you know, of the budget for travel. The only thing that does need to be signed is that one sheet with the signature part on there, and I do have a sticky there for you to sign that along with the authorization.

Like I said, the worksheets y'all can mark those up and make sure when you send them in to me it's correct and then I'll print out the finals. Any questions? Very simple stuff.

We are also - last time we met here the

14

15

16

17

18

19

20

21

22

23

24

25

Macaroni Grill was about the only place that could accommodate a large group at lunch, and James has kindly gone down there again and talked with them, and we have the menu. I don't know if you all want to see this or just wait 'til we get down there. So there's not really a choice again.

We have dictatorship here. Only the Macaroni Grill.

MR. FUTCH: It's a large airport with lots and lots of - actually, lots of different restaurants almost all of which are on their side. So unless you happen to have a boarding pass, you're not going to go there.

DR. FORREST: The only thing open last night on our side about 10:30 was Chick-fil-A.

That was it. And the line at Chick-fil-A, I felt so bad, there were only three staff members working. They had this expression on their face, like -

MS. ANDREWS: Yeah, but what about those people in line that were hungry?

MR. FUTCH: When we come back I'm going to talk about - I think I'm the afternoon session - we're going to bring you up to speed on some of

the licensure activities and the regulations, some of the things that have changed. I'll talk a little bit about nuclear medicine and PET CT. That's kind of become a little bit of an issue, a question, and then I have some scope of practice issues involving modified barium swallows and PICC lines, for the radiography folks in the room, some questions for you guys. But I think it's probably best to save all that until we come back, so unless anybody else has anything, why not just go ahead and break for lunch? What time are we coming back?

DR. SCHENKMAN: It says 1:30, but -

MR. FUTCH: Okay. It is a large group and it is Macaroni Grill, so probably 1:30 is a good idea if you can - if you happen to get bored and you're just hanging around, come back, we'll do it at 1:30, I guess, if that's okay with you guys.

DR. SCHENKMAN: Okay.

MS. ANDREWS: And remember those people who stayed overnight, if you did not get your parking validations make sure you get those from the check-in counter.

(Whereupon, a lunch break was taken.)

DR. SCHENKMAN: Welcome back to our afterlunch session. I'm turning it over to James.

MR. FUTCH: Thank you. And I know some of you guys have to get onto a plane at, like, 2:45, so I'll make this as brief as possible. We've got a couple of issues to cover. The first one is the status of our regulation Chapter 64E-3. As you recall, we got authority in the statute a couple of years back in July 2012 to add new types of licenses, we call them special technologists.

We worked from 2012, 2013, and June of last year we added computed tomography, mammography, and magnetic resonance imaging. Basically, they are all by endorsement and so there's no state exam pathway. Two of these are by endorsement of the ARRT credential, the CT and the - actually, all three of those are by endorsement of the ARRT. We adopted the scope of practice, so if anybody comes to me and says what is my scope of practice as a computed tomography technologist in Florida? We basically point to the ASRT's scope of practice which is up on the website.

And if you see - so here's the license types, CTMR and mammo, and then down here is the

scope of practice for the CRT, CT in 2001. Okay. So that was June of last year and on April 20th of this year we finally got the PET license type enacted in regulation. And, of course, the PET license type is by endorsement of the NMTCB PET credential and the scope of practice is the Society of Nuclear Medicine's - let me find it - positron emission tomography. Here it is down on the bottom. It is the scope of practice, positron emission tomography technology scope of practice, and performance standards which is from the Society of Nuclear Medicine and Molecular Imaging.

So, again, scope of practice right there.

And we have not yet - we still haven't set the database up, I think, to - have you heard back from Allison on that?

MS. CURRY: No. I know they're working on it, but -

MR. FUTCH: I don't expect a big rush of people to go bursting down the doors, anyway.

But in another week or two hopefully we'll have the data base set up so they can actually issue the license. And right now they're taking applications. The application is revised, it's

3

4

5

6 7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

up on the website in hard copy. So if anybody wants to apply for PET, they fill out the paper form and send it in. And when the database is ready they'll issue the license. But that should be happening pretty shortly.

Do you know if the other ones are available online yet or is that part of the coming in the future?

MS. CURRY: I think it's not online yet.

MR. FUTCH: Okay. So probably all for the time being should fill out a paper form. that's, I think, it for the regulations. was one other piece of legislation that passed this year, which was - kind of went by the common name of the Florida Veteran's Bill of Rights. It was actually a rather large omnibus bill that included lots and lots of different things that were very much desired and popular downtown that had nothing to do with any licensure that we do, but one thing that was included in the bill was that a veteran who has an honorable discharge and who applies to the Department within six months of that honorable discharge can apply for a license in basically whatever they hold a license in in any other state or territory of the United

3

4

5

6

7

8

9

10

10

11

12 13

14

15

. •

16

17

18

19

20

21

22

23

24

٥.

25

States. And that would be not just technologists, but that would be doctors and medical physicists and, of course, they're going to be barking up the wrong tree, I guess, with medical physicists because there are not that many states that do it.

And the criteria for us to evaluate them are slightly different from the rest of the normal pathways. We can - if I remember right, we can check the national practitioner databank and have to report discipline and they have to report criminal history, and we can deny based upon professional discipline that might pop up in the national practitioner databank or we can deny if any of the crimes are related to the practice. So that's - there was a little bit of blowback, I think, from some of the professions about that. Who knows, they may revisit that in the future. But I think by the time the Department had actually put its bill analysis together and I think the thing had been voted on and passed. So it was, it was, like I said, very popular. that's the only other piece of - can you guys think of anything else that passed that would affect technologists? Okay.

to

So this is the completion of - I guess it only took us two years to get the PET scope of practice. And, you know, the Society for Nuclear Medicine didn't actually have one, so we were, I guess, partially or wholly responsible for them getting a PET scope of practice.

MR. KENNEDY: James, just one thing to add

the veteran's bill, we had made a commitment, I believe, to the Governor's office that we will be licensing individuals which qualify under this new law within a day of their qualified application.

MR. FUTCH: Okay.

MR. KENNEDY: So that's - we have our work cut out for us.

MR. FUTCH: Yeah. Can you get a response from the National Practitioner Databank in a day?

MR. KENNEDY: Yes, as far as what I understand. And we are going to continue with the full licensure process behind that, but the -I don't think they call it the provisional license, but the initial licensure in Florida will come within one day. And that's like new criminal background screens and things like that

will take a little bit longer to come on line.

Any criminal background they have when they apply will be used, so we're going to feel our way through this but it's certainly a priority of the Legislature.

MR. FUTCH: Okay.

DR. SCHENKMAN: But you have the ability to revoke it?

MR. KENNEDY: Yes. Afterwards they, as I understand it, falls just completely under the Licensure and Practice Act relevant to that professional - profession.

MR. FUTCH: Okay. While I'm on this subject, I learned - very surprised - I had a call from a director of imaging center some place in Florida and apparently NMTCB has come up with its own CT license type, which according to their website they're going to be taking applications for that beginning June of this year. And the first exam for their new license type will be in November of I think it's 2014. And so they asked me if we would accept that for the CT credential in Florida and I think I gave them kind of one of those ''I'm not sure yet, I have to go talk to the Council' kind of things. But, you know, if you

go and look at the law I think probably the statutory basis is there to accept that credential, but one of the questions that I had was what is the scope of practice supposed to be for that credential?

I talked to NMTCB's staff up in Georgia, I guess it is, and I'm not - and then I talked to some of the folks who were part of their board or whatever their governing body is they talk about and I kind of got the feeling that they're sort of feeling their way through this, but the website says is that - well, one of the questions was, is this a CT licensed to do full diagnostic CT like in radiography or is this to do CT for PET CT or something in between? And there's kind of elements, I think, of both of those answers up on the website. So I think my preference would be just kind of stand back for a while and see how this thing flushes out, unless somebody feels strongly one way or the other.

MS. CURRY: So do you know what the CT requirement for that is going to be because you know we ran into that issue with that -

MR. FUTCH: Yeah, I remember, oh, yes, thank you. Institutional memory. Yeah, NMTCB had this

alternative eligibility, which I think is still there until 2015, an alternative eligibility for the basic nuclear medicine technologist allowed a person to have very minimal training requirements. You did not have to graduate from an actual educational program. You had to complete a certain number of hours. We ran into this one person who had made it all the way through their process and been licensed, and then of course we still ask for educational documents, as well as proof of licensure from whatever agency gave it to them, and she didn't have any.

And in the course of figuring out what had happened in that case, basically there is a document that they send out to the facility where the person worked, and I think somebody in human resources had filled it out and said she had done nuclear medicine technology, check the box for X number of hours per week, for X number of weeks per year, and met the hourly requirement, and that's how that person got a license. So I'll be glad when that pathway closes off.

MS. CURRY: Did, did we license her?

MR. FUTCH: No.

MS. CURRY: We didn't license her, did we,

because -

1 2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

MR. FUTCH: I can't remember. Yeah. don't think we did.

MS. CURRY: No, we didn't.

MR. FUTCH: Yeah, it's a little harder to pull a license back once you give it to somebody. So with regard to this CT category, their stated purpose on the website is that the ARRT requires a certain number of procedures in a certain number of areas be performed and be signed off on by someone who is certified in that area before they can sit for the exam. And, originally, they didn't have any sort of minimum didactic requirements for training at all. And I think next year or 2016 they're requiring 16 hours. This is ARRT. NMTCB position physicians seem to be they're gaining a certain number of hours of training, not a certain number of types of procedures that must be performed.

And the best I can tell you we're doing this because it's hard for nuclear medicine technologists to actually perform the procedures if they're not already licensed to do so and they're not doing it underneath the scope of a student exemption like they would be if they had

to in Florida. So by having a certain number of hours of training, I guess they feel like they're helping the nuclear medicine tech out, but again I don't know. We're not really sure how that's going to flush out.

Did anybody have any knowledge of this before

they heard me say it? Well, because I talked to you about it.

MS. FORREST: Yeah. I do, too, only because we had a technologist that was in nuclear medicine and she sat for the PET portion of the exam and then also got her clinical and got her ARRT CT license three years, so you've got her licensed for ARRT -

MR. FUTCH: Yeah, but that's the ARRT MS. DYCUS: And I think that we have a
second tech who is probably going to want to do
not the ARRT, but this. I think that I would
have to have a little bit more and to see what
they were requiring because I'll tell you what
we've run into even through the ARRT is
technologists not recognizing enough pathology
and enough to be able to say this, the
radiologist needs to look at before I let this

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

patient go and this kind of thing and doing a regular CT.

MR. FUTCH: One of the big issues for me is going to be our statute, when we talk about like we've adopted these scopes of practice. If NMTCB doesn't publish a scope of practice for CT, I'm not sure where they're going to get one from other than the one that's already out there from ASRT, which is one we already have, it's a scope of practice that was adopted for the pathway through ARRT, the ASRT's scope of practice for So it kind of boggles my mind to have a completely different test from an organization that I'm pretty sure is probably not going to write a scope of practice itself for CT and then rely upon the scope from the other organization who's got the test that it was built for. It's mind boggling. I don't - I'm not yet ready to say yes, let's do this.

DR. JANOWITZ: I suspect the SNMMI will come up with a scope of practice.

MR. FUTCH: That would be the normal thing.

DR. JANOWITZ: But then again many of them don't do CT, either.

MR. FUTCH: Yeah, see, you're coming up with

this scope of practice and doing something that's really not what you do in your - I mean, full diagnostic free standing CT -

MS. DYCUS: They're also building in an exclusion that you don't need to do any - you don't need to show us that you can do anything other than the PET portion, I mean, the PET CT.

MR. FUTCH: They have to clarify it further, but instead of 700 hours like it is for the PET, it's going to be, I think, 500 hours of training or on-the-job actual work in CT.

 $$\operatorname{DR}.\ Janowitz:$$ We did have one nuclear tech who took the ACR CT, not the ACR -

MR. FUTCH: ARRT.

DR. JANOWITZ: Right, and he passed that but he tried to get hired to do CT and no one would hire him.

MR. FUTCH: To do radiography and didn't have CT in the center and that didn't work out. But I wanted to make you aware of it and certainly if you hear this discussed, if you're part of this, if you know more than we do and find out feel free, give me a call. I'd like to not be surprised by the second half of the process.

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

DR. JANOWITZ: I'll try and find out next month.

MR. FUTCH: Yeah, it just feels too squishy, like it's really not quite fully come together even though there's a deadline and there's dates for the tests and applications and the rest of it. Okay. So that was, let's see, this guy.

I'd like to give you a little bit of anupdate on the PET CT issue. We have in 2004 the scope of practice, as you know, for a radiographer said that nuclear medicine procedures were prohibited. In 2004, the nuclear medicine technologists' procedure was written scope of practice, excuse me - was written in such a way so that it limited them only to dealing with administering radio isotopes and making measurements of radioactivity and nothing to do with x-ray. From '98 to some national meetings that we had with ASRT and Society for Nuclear Medicine, a consensus developed that to do PET CT, you know, you could basically start out as a radiographer or a nuclear med tech or a therapist and then learn the other parts of the modality, and then if you were appropriately trained and you meet competency testing

requirements, anybody could come from any pathway.

But in 2004 our statute was modified so that only the nuclear medicine technologist scope changed, and it changed to the way it is written today which basically says they can do a combined nuclear medicine CT procedure if they use the CT for certain limited purposes associated with that nuclear medicine procedure. And the scope of practice for the radiographer didn't change. It still said prohibited from doing nuclear medicine procedures.

Well, fast forward a number of years and it's, and it's - we've been involved in some questioning about whether or not - this is the core issue - whether or not PET CT is a nuclear medicine procedure. Now, for me that's a no brainer. It involves the injection of a radio isotope and it involves measurements made on nuclear medicine equipment to measure the uptake and various metabolic processes throughout the body. It uses x-ray in a different way from the way x-ray would be used in a full diagnostic CT. Specifically, for generating attenuation coefficients in the machine in place of the line

Ι

source that would normally be in the PET camera to do that. And therefore, there really isn't any question in my mind. But I'd like to get some discussion from you. Does anybody feel differently about that? I mean, if I walked up to anybody cold who works in, you know, obviously works in the area, is - if you say a nuclear medicine procedure, that's PET CT, is there much dispute about that point?

DR. WILLIAMS: We spoke earlier. I agree.

MR. FUTCH: Okay. As I often do, sometimes

call you guys ahead of time and ask you some of this stuff. Well, we ran into a facility that for many, many years who was using a radiographer to do everything in a PET CT procedure following the administration of the radio isotope, and they would pick up the person from - after the uptake period was over, and they would bring them into the - they would put them on the table, they would position them for both procedures, they would make the settings on the machine and put in the administration of the relevant parameters on the PET machine and when was the dose given, what were the dosage, pick the protocol for the person

and

both for the CT portion and the PET portion, run - be responsible for the patient while they were running through the scout CT, and then the non-diagnostic CT, and then for the longer time period it takes to do the acquisition of the positron data, put the images together, fuse them, and deliver them to the oncologist. And they did this for apparently many years and they're in something of hot water because of it, not necessarily with us but with Medicare billings and things like this.

So I actually got asked to - my opinion,

of course, I've been dealing with this for a long time so I freely gave it and found myself subpoenaed for a court trial. And it was - you know, I can say I testified in federal court now. But - and it really never came down to the question I thought that it would have come up to which was, well, the radiographer might be able to do a CT portion, but that was really never the issue. It was they did everything else. Of course, the lawyers for the defense act like this is some big mystery that PET CT is a nuclear medicine procedure. But I wanted to kind of put

_

•

that out there and see, you know, if I'm in the right place with this.

DR. WILLIAMS: Maybe I missed it and I apologize. Who injected the isotope?

MR. FUTCH: The nuclear medicine tech did.

DR. WILLIAMS: Where were they? They went somewhere else?

MR. FUTCH: They became the whistle blower.

DR. WILLIAMS: For the procedure.

MR. FUTCH: For the procedure, yeah, they went on to other patients. Yeah, I was trying to remember. I don't know how many people they were doing, but they had multiple radiographers. They really only had one system as far as I could tell, and I mean, from the testimony that was developed prior to my being involved in this. So the nuclear medicine tech would start out in the morning receiving the isotopes, would do the QA on the system, would pull up the dose, do the dose calibration, inject the patient, and then sometime after that point hand off to the radiographer who would carry through with everything else.

So that, that's where the whole thing ended up was, yeah, there's no question that's what

they were doing. Now, for me, there kind of seems to be some leftover thinking that, well, the only thing that really makes a nuclear medicine technologist is that they inject the isotope, and anybody can run this machine. And it's just silly, especially having sat with some folks.

MR. TINEO: But the nuclear med tech did the QA first thing in the morning?

MR. FUTCH: Right, right.

MR. TINEO: So that answers the question of who should be running the machine.

MR. FUTCH: Having sat in a non-nuclear med tech in training by any means, but having sat with several now watching them doing this, you know, if the radiographer is responsible for the patient that means they're responsible for something they weren't necessarily trained for. You're used to thinking of a machine emitting radiation when they turn it on and when they turn it off, not a person walking around being the source, having to think about exposure of themselves and other patients and, you know, if the patient as apparently happened in some facilities, has an accident on the table you have

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

a contamination issue, you have to deal with that. You have certain things you're looking for, I guess, in the - in imaging.

One of the technologists gave me an example of someone punching in the patient's weight incorrectly, which would then result in specific uptake values which were seriously skewed. And then rather than realizing that that was the problem looked at the picture and saw that everything was just awfully light, you know, nothing was being taken up very much, started playing with the intensity and cranked the intensity up so that it looked like the normal image and just totally blew everything apart for the oncologist trying to figure out what that image meant. Didn't communicate with him at all.

So for all these reasons, it's clear, you know, I think it's far more involved. And if you go look at NMTCB or ARRT's exam, they're requiring, you know, a whole section on operation of the nuclear medicine camera as well as contamination control, operating a survey meter, things of that nature. But what I would like to do is if everybody feels strongly enough, I'd like to ask for maybe a motion that says PET CT

3

4

5

6

7

8

9

10

11

12

13

14

15

16 17

18

19

20

21

22 23

24

25

is a nuclear medicine procedure and get a vote on that.

So we have a motion from somebody? Who's first? Dr. Williams or Dr. Janowitz? So, Dr. Williams made the motion, Dr. Janowitz seconded So basically the motion is the statement from Council is 'the PET CT is a nuclear medicine procedure', And if you would like to call for a vote?

> DR. SCHENKMAN: All in favor, say aye?1 COUNCIL: Aye. (unanimous)

DR. SCHENKMAN: Any opposed?

MR. FUTCH: Okay, good. Oh, I feel so much better now.

The last part of the day is I have a couple of, I guess we'd call them scope of practice questions. I'm going to pull it up here for a second. Okay. So this is what I got. You're going to like this. Can everybody read this? Make it a little bit bigger. Sorry. I'll let you guys read that first and then I'll -

Has everybody gotten at least down to the bottom? So this is apparently from the American

¹ Council voted unanimously that PET CT is a nuclear medicine procedure.

Speech Language Hearing Association. This little blurb down here, I think it's a little clearer if you read theirs. Okay. So the first question I got is, does anyone know how to do this? I mean, work with speech language pathologists? Okay. So anybody who's doing this, tell me how you're doing it in your facilities?

COUNCIL MEMBER: Each person the radiologist with the pathologists and the technologists.

MR. FUTCH: All right. So this is a fluoro procedure that involves taking down barium and watching it through the body.

MR. SEDDON: And I do want to say that my radiology group has strongly pushed this position against my best judgment - they actually may even be the ones who wrote this, the whole thing. It is - I'm familiar with the entirety of that last statement because they've given me everything and the key that I always bring up to them is the last sentence. "State legal and rigorous..." - the present radiologist - of the physician as well as the reimbursement. That's key. Make sure that you are being the regulatory standards. I know a lot of states are moving towards credentialing requirements or a state permit for

bit

physicians who perform fluoroscopy. So we're kind of moving in that direction overall. Now, the direction that some of the radiologist have indicated is that they're really not doing a whole lot during the case, and that's at least their interpretation of that.

They're really following the lead of the speech pathologist, so they're the ones who are really doing - telling what to do. They're just there to just sort of oversee and interpret if needed.

MR. FUTCH: I want to give you the little

from the law after this, but I want to hear from Pat.

MS. DYCUS: That was one of the things that radiologist assistants were going to be able to help radiologists out with is to be the one present to assist the radiologist; but again with the radiologist being there in the facility. I remember it seems like years ago there was a problem with mobile companies going out and doing these swallows at health care facilities, and there was some big thing with the third party payers not paying for it if a rad wasn't present

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

because they didn't want that kind of situation going on. I don't remember the specifics of that. I just remember it being an issue.

MR. FUTCH: Anybody else, personal experience

doing this at facilities? Okay. So for me, this is - you know, I'm thinking of this from the statute and regulation perspective and there's a couple of things here. First of all, in our licensing statute, the licensed practitioner they were talking about does not include the speech language pathologist. If they did, this wouldn't be a problem. But under the definition we've got it only includes people who are practicing allopathic medicine and osteopathic medicine and chiropractic medicine and podiatric medicine. And to the best of my knowledge - y'all correct me if I'm - as far as I know, that's not the speech language pathologist, although I guess they do have a fairly, you know, detailed educational pathway.

So we don't have - its fluoro. We don't have

a radiologist there. You know, we get very hinky about doing fluoroscopy with just the rad tech

there if there's not a physician to look at and view the procedure, and then to actually have - okay, so there's your questions. The first one is no and the second one, I think we've usually answered no, but then we have this and Yvette's law. This is the x-ray machine regulations, non-physician operated - well, we - that's another point about the speech language pathologist. They're actually getting it from both licensure statutes for the techs and also for the facility from this statement in the regulation that points back to the rad. It basically says, you've got to be a tech or somehow certified if you're going to operate the device itself. That's just the first question.

So further down here's what we have, "Individuals should not be exposed to the use of beams except for healing art purposes and unless such exposure has been authorized by a licensed practitioner." Now, I'm assuming in this case even though the radiologist is not there, there is a doctor somewhere that's authorized this procedure to be performed because the speech language pathologist cannot do it, as far as I can tell.

2

3

4

5

6

7

8

10

11 12

13

14

15

16

17

18

19

20

21

22

23

24

25

COUNCIL MEMBER: There should have been an order for that -

MR. FUTCH: Exactly, okay. So basically this

just speaks to who can order it in abeyance, and some other stuff that's not relevant to this thing.

Here's the last little criteria.

"A person shall not perform fluoro or otherwise expose a human to x-rays unless they meet the following...'' - okay, there's the first one again, licensed practitioner. That term is defined in the licensure statute for the techs. A board radiologist assistant so this would be Patty or someone like Patty doing it. Or a general radiographer. And the general radiographer, when they do it they have these three conditions that have to be met and they have to be trained and authorized in writing by the licensed practitioner to perform this specified imaging. Imaging doesn't - this is the key to me - imaging doesn't rely upon the radiographer to provide any diagnostic interpretation to determine suspicious areas or otherwise modify the scope of imaging, and it's

designed to prevent or reduce exposure to patients by pursuing proper positioning for the authorized radiographic imaging.

I don't know - you know, not being a tech and the rest of it, I'm not really sure how this applies out in the real world. What do you all think?

MR. TINEO: Well, the part that you don't see there is the billing part. If they're billing for a barium swallow, they have to meet those criteria, also, or who was the supervising physician and who was able to bill for it. I don't think a speech pathologist is - I have to check, I have to go back and check, but I'm pretty sure that they have to have the interpretation by the radiologist to do this.

MR SEDDON: An in-depth interpretation.

MS. DROTAR: And I think once you go by interpretation then I think you'd be capable of billing if you met these -

MR. FUTCH: So how do we, how do we get past - how do we get past B, call the doctor, there?

MS. FORREST: I don't see how you can because the physician - if the radiologist is in the room doing an interpretation, doing the study

and he can monitor the study and if he has a suggestion, I mean, normally this can be an addition to an upper GI series, which can cause issues of why they would even be doing the study to begin with. And without the radiologist in the room, I just don't see how any - you're going to call the patient back if you send him the disk and he's like, yeah, that needs to be addressed. I don't see how this could - the fluoro imaging or any of those things can be done without the radiologist in the room.

MS. DYCUS: But this is a modified swallow and generally all the ones I've ever done, the radiologist doesn't ask for anything different than what the speech pathologist wants.

MR. FUTCH: So you're saying, you're saying you can tell the radiographer do this procedure according to some sort of, you know, pre-arranged this is how we do it at our facility and these are the things we ask for, which would meet the requirement for A, I guess, and not rely upon the radiographer to basically fill in the role of the doctor looking at where they want to take a shot next in deciding that?

MS. DYCUS: Correct. I think with a little

additional training a fluoro tech or an RT with a little additional knowledge as a spokesperson for the radiologist could perform the same study that I've seen the radiologist perform for the speech pathologist.

DR. SCHENKMAN: If you're not getting the interpretation, how do you bill it?

MS. DYCUS: Well, we do get an interpretation. A radiologist interprets the images once they're sent over. Basically, the radiologist assistant or the RT with the additional training follows the pathologist - the speech pathologist's lead as far as the speech pathologist chooses to use thin barium or thick barium and if the patient doesn't tolerate the thin or the thick she doesn't go to thin. I mean, they make all those decisions even when the radiologist is there.

MR. SEDDON: Yes, that's the argument that some of my radiologists have made is - obviously you have a selection criteria on certain types of patients which you could have a - say you performed without the radiologist present based upon the severity of their condition, but you know, since the speech

_

•

our

pathologist is leading and directing the entire procedure in their mind they're kind of - they're there just to be there. They're not there - they're not doing anything.

MR. FUTCH: See, that's why this is such a formidable thing.

MS. DYCUS: The interpretation that the radiologist is making is pretty much for the letter of the law as far as being able to bill for something, an interpretation, but the true therapeutic or the true information is coming from the report that the speech pathologist does

MR. FUTCH: What this feels like to me is

law says the licensed practitioner - well, we're kind of extending what I - it's not directly - it gives a lot of information about this particular practice, but what it feels like is the law says you need a person who meets this definition of the licensed practitioner or you need a technologist. You don't have the person who meets the definition of a licensed practitioner performing the normal functions for this kind of a fluoro, and you're asking this other person

who's the speech language pathologist who knows all sorts of things about their own area of practice but is not a licensed practitioner to kind of fill in for some aspects of the licensed practitioner for the purposes of directing the radiographer on how to do fluoro or to do the fluoro.

MR. BURRESS: I just wonder if something goes

wrong if the person can't swallow right in many, many attempts if the fluoro time gets extended.

Can the general radiographer make the call the patient's got too much dose, or is that the role of the radiologist?

MS. DYCUS: I think any technologist should make that call as well a radiologist, and in California they are allowed to text their - I mean, there's a special fluoro license because they really limit in California. Radiant fluoro is very limited.

MS. DROTAR: It seems to me that the radiographer is the person that's responsible for the radiation safety of the patient and machine operation and that's the role that they're fulfilling which is scope of practice. The

speech pathologist is then overseeing what the patient's functionality is, which is theirs, and then the radiologist with the images provided to them after the fact is going to interpret and give the, give the verdict.

MR. FUTCH: Yeah, that's essentially that thing from the American Association was trying to set up.

MR. SEDDON: A lot of the practitioners in general, not just in this particular case but in general, they don't feel they're actually performing fluoroscopy, they kind of feel it's the technologist who's really doing it 'cause they don't really understand their equipment. I hear a lot from surgeons and other people who actually perform fluoroscopy.

MR. FUTCH: Does anybody have an issue with this as described by the - this thing that we're talking about up here originally?

DR. JANOWITZ: I don't do these and I'm not sure how they're done at our place, but you know, it seems to me that the technologist under the supervision of the radiologist can perform the fluoro. The radiologist should be available to review any sort of issue over the PAC whether

goes

he's in the room or not in the room. And I would also argue that this is a medical diagnosis, you know, whether or not the speech pathologist thinks it is or not. But they are doing a medical procedure to arrive at a diagnosis. So -

MR. FUTCH: In their proposed policy, it

to the - they're trying to segment it and saying that the radiologist assesses and comments on this swallowing function only and does not include

medical diagnoses, so I would have thought that would come from the radiologist.

DR. JANOWITZ: Radiology is primarily a (inaudible) but it does involve physiology as well. So the fact that there's a physiologic aspect to this doesn't mean that the radiologist is not interpreting it or qualified to do it.

MR. FUTCH: As described here, does anyone have an issue with any - do you feel like there's any safety violations occurring here, or do you think it's covered? I mean, it's one thing that the law says on how to twist ourselves around this and I'm not necessarily going to give an opinion.

MS. BURRESS: Who's actually doing the fluoro?

MR. FUTCH: The general radiographer.

DR. JANOWITZ: I guess an issue is is are they able to do fluoroscopy at that site without the presence of a radiologist, just a technologist?

MR. FUTCH: It just seems backward. I mean, it seems -

MS. FORREST: I think - I'm sorry, James.

MR. FUTCH: No, go ahead.

MS. FORREST: I hate to interrupt. I just feel like, well, in California they have a special fluoro, you know, licensing for it. So then that's probably acceptable because they've had additional fluoro training, but to administer fluoro without the presence of a radiologist I don't think as a general radiographer myself that I should be allowed to do that.

DR. SCHENKMAN: Especially if we don't have specific parameters of -

MS. FORREST: Of training.

DR. SCHENKMAN: Well, not just of training but of fluoro time and all the rest related to this study.

MS. FORREST: Because without that, any general radiographer that's not in a room is going, okay, you go in room seven and we've got a barium in there.

DR. SCHENKMAN: You have to really dose a patient.

MR. FUTCH: So your sense would be rely upon this, rely upon this and basically say no?

MS. FORREST: Yes, sir.

DR. SCHENKMAN: I think it's asking a lot from a general radiographer who doesn't have that kind of knowledge and training.

MS. FORREST: It opens them up and the patient.

MR. FUTCH: That was the answer you gave, your facility, nobody would like it?

MR. SEDDON: Yeah, they wouldn't like it because the radiologists - they, they were pursuing this route understanding that under 'A' they were training the RT's with additional training specific to the procedure and then there's no interpretation being performed after the fact and there's a radiologist on site. We never - you know, I just, you kn ow, I said the rule is the rule and that's our interpretation. I

think we even talked about it. 1 MR. FUTCH: Yeah, we did, we did. And who 2 knows if anybody tried to make a complaint and do 3 an investigation, I don't know where the lawyers 4 would come down on this one. 5 DR. ATHERTON: To me, it seems the speech 6 pathologist person is irrelevant if they're not 7 licensed. They're just looking -8 MR. FUTCH: Well, the funny thing is -9 DR. ATHERTON: So it should be just a normal 10 rad tech doing the fluoro procedure. 11 MR. FUTCH: Yeah, but the funny thing is 12 they're the ones who actually knows the most. 13 DR. ATHERTON: So either they need to be 14 licensed or the radiologist needs to -15 MR. FUTCH: If the speech language 16 pathologist was in the definition of licensed 17 practitioner, this would be fine, you know. 18 DR. SCHENKMAN: Or if we had like California 19 special certification for -20 MS. DROTAR: Specialty license. 21 MR. FUTCH: Right, right. So my 22 recommendation was to find a radiologist 23 assistant for this kind of a thing or, you know, 24 they could also - I didn't even want to say this, 25

but apparently they could find a PA probably,

too, who could - radiologist and do it. Don't

ask me what training they've got 'cause that's up

to the physician to decide. All right. Well,

listen, thank you for the discussion. I

appreciate it. We'll move on to the last one.

Are we doing okay on time?

DR. SCHENKMAN: Yes.

MR. FUTCH: Let me show you this one.

Probably opened this one twice. Oh, look, my
name's on this one. I'll show you this thing
that she's talking about in the second half. I
just want to read the paragraph first. It's a
non-X-ray system used to basically find the tip
of the catheter and put it in the right place.

And I'll let you read it. I like this statement
right here. Everybody in the room cringed. We
can't do that.

DR. SCHENKMAN: Why would they need a radiology tech to do this if they're not using any x-ray.

MR. FUTCH: Yeah, good question.

COUNCIL MEMBER: Did they even do it with an x-ray?

MR. FUTCH: Let me, let me show you the, let

me show you the device. It's this one. I got a couple of these about it. Okay. So basically it's sensing the tip, I guess it's emitting some sort of a current or it's got a magnet or something and they're locating it that way, apparently fairly accurately or else this would probably not be a viable thing to do. And then go over here. Sorry. So it says, "accuracy to within 1 centimeter," I guess that's good enough. "Displays the direction the catheter tip is pointing." "Helps reduce risks associated with blind catheter placement."

And let me show you one more thing. We've got the - everybody finished with this? Okay.

There is - this is the operator's manual, excuse me. Get to the pictures. So here's the instructions, that's what the whole device looks like. They make a big, they make a big deal about it's compatible with ultrasound. I'm sorry. Okay. Here you go. So I guess that's how you'd use it.

MR. RICHARDSON: Jim, this is an FDA approved device?

MR. FUTCH: That's what the lady who was asking the question said it was.

is

they

-

DR. JANOWITZ: Why is this an issue? This

not a radiologic procedure.

MS. DYCUS: Right.

MR. TINEO: Because it's a PICC line and

think it needs to be done in radiology.

MR. FUTCH: I think they're trying to maximize their use of personnel and they're doing it in, I guess, radiology, and so it's kind of a three-part question. Can you use the radiographer to place PICC lines at all? Is there some magical reason why we couldn't use them outside of radiology if they can do it? And then kind of flipping the question around the other way, is there a reason why you couldn't use the radiographer to do this on x-ray type things?

My usual answer for that is, you know, the statute doesn't provide any specific prohibition nor any specific language to cover such type devices or if they had the appropriate additional training and they were in compliance with the facility's policies and did it properly, then we're not going to discipline them for it, which is a big way of saying, you know, it's up to you.

So, yeah, the last one's not an issue for me, but who are doing PICCs in your facilities these days? Is it -

MS. DROTAR: It's within the ASRT scope of practice that a radiologic technologist can place a PICC line.

MR. FUTCH: When the radiologist assistant came along, this was one of the things they included. - are you doing these PICC lines? I'm sorry.

MS. DYCUS: I'm not doing them at my facility now, but I did do them before, but -MR. JANOWITZ: Radiographical.

MS. DYCUS: Right, radiographically, and I just - who's their supervisor? Who's supervising the RT?

MR. FUTCH: Well, it's going to be, you know.

> MS. DYCUS: If it's not - but I mean, if the radiologist isn't involved in it, he doesn't make a dictation on it because there's no images, right?

MR. FUTCH: Yeah. Don't forget; it doesn't have to be a radiologist. It could be any Florida licensed physician.

MR. BAI: Isn't the training for this
the same for RRT as it would be for a nurse, it's
manufacturer based training.

MR. FUTCH: For question three?

MR. BAI: No, I mean, just to be able to use this. I mean, if you're going to use the system, you're going to have manufacturer training to know how to use it.

MR. FUTCH: Well, if you're going to do normal PICC placements, you're going to do it under fluoroscopic guidance, right?

MS. FORREST: No, you don't have to have a fluoro.

MR. BAI: Not necessarily. You use ultrasound.

MR. FUTCH: Okay. But if you're going to use x-ray it's going to be fluoro. I'm just asking.

MS. FORREST: Yeah, and then once the PICC is in place, you know, the general radiographer will go in and we'll just do a regular x-ray to check for placement later on down the line, you know, for any number of reasons if we think maybe the catheter, you know, is not in the place that it needs to be without any migration.

	120 MR. FUTCH: In terms of the placement of it,
1	let's just forget about this non-X-ray system, in
2	terms of the placement of the catheter, is this
3	something that a radiographer is going to be
4	asked to do to assist the physician or to do in
5	
6	place of a physician?
7	MS. FORREST: Well, I'm reading that that
8	they want the - they want the x-ray tech to -
9	DR. SCHENKMAN: They want the technologist
10	to do -
11	MR. FUTCH: And you were saying in your
	facility they are doing this?
12	MS. DROTAR: There are a couple of
13	facilities where they do that, yes.
14	COUNCIL MEMBER: Are they certified to do
15	that?
16	MR. FUTCH: But without the physician being
17	there?
18	SEVERAL VOICES: (Unintelligible.)
19	MR. TINEO: Available -
20	MR. FUTCH: Okay.
21	MR. TINEO: But, yes.
22	MS. FORREST: Is that letter addressing
23	
24	specialist techs or is it general radiographer?
25	MR. FUTCH: That's in the context of

	radiographers. They didn't mention any
1	particular one.
2	MS. FORREST: Oh, because I think that would
3	be-
4	DR. SCHENKMAN: The techs that are doing it
5	are specially trained.
6	MS. FORREST: They are not general
7	radiographers. I look at that to say can a
8	general radiographer be trained to go in and do
9	this? Is anyone else looking at it that way or
10	am I upside down?
11	MS. DYCUS: No, you're right.
12	MS. FORREST: So I still think a specialist
13	tech, that would be the appropriate person to do
14	it, but a general radiographer, I don't believe
15	so.
16	MR. FUTCH: So if the specialist tech is
17	doing it, who's running the x-ray?
18	DR. SCHENKMAN: I would think the physician.
19	MS. DROTAR: It's the radiographer all the
20	
21	way.
22	MR. FUTCH: Yeah.
23	MR. TINEO: Most of them start with the
24	ultra
	sound. Ultrasound accesses the vein and then they

move the catheter in and then later on then they look for the physician. But that's what's happening. What's happening also is nursing is creating PICC teams, what it's called, and they put in PICC lines throughout the hospital. So what's happening is when they're knowing the right space, then they come down to radiology - to check for placement but that's just a back-up. What we find is PICC lines being placed incorrectly and then it's a mess and then you have to come back and clean them up.

DR. SCHENKMAN: I think a few of us have to go. Are you on that flight also?

MR. FUTCH: Okay, well - our former chair - Perhaps our vice-chair can take over for the rest of the meeting which is pretty much just kind of a few wrap-up things.

DR. JANOWITZ: I don't think they should be doing this.

MR. FUTCH: You don't think they should be doing which part of it?

DR. JANOWITZ: I don't think they should be doing it at all.

MR. FUTCH: Any one else want to venture forth a strong opinion while we're on this?

MS. DROTAR: That's within the scope of practice by our national standards that a radiographer that is trained in doing it is capable of doing it within the scope of practice. It's also within the standard of practice because there are several facilities in Florida that actually allow that to happen or allow the -

DR. SCHENKMAN: But those are specialty trained. That's the difference.

DR. JANOWITZ: Taking a x-ray and the radiologist is confirming placement, isn't that correct?

MS. DROTAR: I'm not sure on that end - yeah, somehow the radiologist is -

MS. FORREST: The radiologist is doing the confirmation.

SEVERAL VOICES: (Inaudible.)

DR. JANOWITZ: Without proper supervision, you put the entire onus on the technologist. I mean, suppose something goes wrong. Who are they going to sue, the radiologist? I mean -

MR. TINEO: Everybody.

MS. FORREST: The whole facility.

DR. JANOWITZ: Yeah. I would not want my tech inserting a line that I didn't know where it

was just because it was done - especially if it was done on the floor.

MS. FORREST: I don't think it should be a general radiographer. I think something - well, obviously, she said it's a specialty. I think that should be defined as a special procedures tech. I don't think we should cross that line where a general radiographer is allowed to do that.

DR. WILLIAMS: Do we even have that option?

This is an FDA approved non-radiological

procedure. So somebody -FDA said appropriate in

certain indications.

MR. FUTCH: For the questions three, I'm not terribly concerned, it's not using x-ray But for the first question which I think you guys are all speaking to is one - all right. Well, thank you so much.

DR. SCHENKMAN: Thank you all. We're sorry we have to leave a little earlier.

MR. FUTCH: That's all right.

DR. SCHENKMAN: Have a good day, everybody.

MR. FUTCH: All right. Well, that's it for my input.

MR. SEDDON: All right. Let's move on to

the last item of the day which will be old business. Any issues anyone has?

MR. FUTCH: I basically - I didn't really ask for a motion or anything on this one, but if you just want discussion, but it sounds like there's some consensus involving the radiographer with additional training, although quite frankly there's none out there that we require.

MR. SEDDON: I think it goes back to the previous, the previous issue in regards to the speech pathologist in the statute where it says, A, with additional training by the radiologist or the technologist. It's kind of the same - that's where it falls. That's how we're interpreting it.

MR. TINEO: But this is not an x-ray.

MR. FUTCH: There are at least two different issues in here. One is just the picc and the other one is this - in the normal method with x-ray. And the other question with this non-x-ray system. For me, the non-x-ray system is, you know, if you want to use the radiographer, okay, make sure they're appropriately trained. But it's not a licensure issue for me because it's the x-ray. So all of the comments you guys were

to

making before, I was taking them with regard to the first, the normal picc procedure.

MR. SEDDON: The first issue, not the third.

MR. FUTCH: And Dr. Janowitz seems to feel very strongly the other way, so.

MS. FORREST: I'll sit next to him next time.

MR. FUTCH: Does anyone else have an opinion they want to have recorded because we use this stuff later on in trying to answer other questions when they come in. Anybody else's thoughts? opinions?

MR. RICHARDSON: James, as an educator, I've always questioned letter A there. I would like

see objectives written. I would like to see it be very specific - what kind of training they've had, how is it going to be documented. It's a little scary how far legally we can go, according to what Kathy says, as far as our scope of practice. So basically it says we can do anything that we're trained to do. And I think that needs to be more specific.

DR. WILLIAMS: And I'm sorry I have to keep this going, but I have another question. Can we

2

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

control the scope of practice of a radiographer for non-radiographic procedures?

MR. FUTCH: I think so. I don't know if we'd

want to, but -

DR. WILLIAMS: But can we because that's the whole question here to my mind because this is not

a radiographic procedure. We're the advisory board for radiation protection and so I have a standing question, you know, as to whether we have the authority to even tell them what they can do. If we can tell a radiographer what they can and can't do radiographically and nonradiographically, then we do have standing. Ιf we can't tell them what they can do nonradiographically, then we don't have a dog in the fight, anyway, I think.

MR. FUTCH: Yeah. Here's the - here's where your - this is the Advisory Council authorizing section and this is the job of the council, and I think number three would probably cover what we're just talking about - making recommendations on matters relating to the practice, the performance of the duties, and radiation

protection.

1

2

here

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

DR. WILLIAMS: Isn't there a presumption

that that's for radiography?

MR. FUTCH: Well, you know, it's an interesting point that you raise because once you move beyond the x-ray what do you need - why are you even talking about a radiographer? You could pick the janitor up and do the same thing. That's one of the reasons that I usually answer this question the way I do, which is to say it's not provided for nor is it prohibited, it's other than what the statute talks about. But, you know, trust me, if they start doing - if they start doing phlebotomy and kill a patient some place, they're going to come back to us for discipline against the person.

MR. SEDDON: I think also we do make recommendations regarding MRI and that's just one of the most recent ones, you just said those earlier. So I guess there is non-radiation that we are affecting.

MR. FUTCH: Yeah, there is, there is.

DR. WILLIAMS: There's also a radiologic implication of that. Updated devices does not

require a radiologist to interpret.

MR. FUTCH: Okay. Again, I appreciate hearing all the different viewpoints 'cause it's useful to us when these kinds of things come in. But that's the last one I have, so -

MR. KENNEDY: James, as an old bureaucrat, I would say that that language pretty clearly does provide cover to comment on the practice of the radiologist assistant and radiological technology outside of strictly those modalities involving radiation. As an advisory council on radiation protection, I think that comments on what is safe for them to do, where that line is, and how far over that line that training allows them to go. So as a bit of a neophyte and fresh eyes on that, I think that's pretty clearly would allow -

Now, the farther you go away from that, I think that the weaker you get in terms of if there are things that they were doing that have nothing

I think as long as you stay within those things that are close to the other side of the line, that helps elucidate and shed light on where that

line is and how far it goes. 1 MR. FUTCH: Okay. I left off the last one, 2 but I always forget about number four - "make 3 recommendations to the to the Department 4 (inaudible) - conduct such procedures'. That's 5 fairly broad. 6 MR. KENNEDY: Has that been changed many 7 times? 8 MR. FUTCH: That's an old statute. 9 MR. KENNEDY: That's ancient history. 10 MR. FUTCH: Yeah, that's - let's see. 11 MR. KENNEDY: In '84? 12 MR. FUTCH: I'm looking for it, '95, '91, 13 '84 - yeah, '84. Okay. Any other thoughts on 14 this one before we move on to the other business? 15 MR. SEDDON: Is there any other business? 16 MR. FUTCH: Now's the time to bring forth 17 anything that's really been bugging you since May 18 of last year. Nothing? 19 MR. SEDDON: Well, I guess we'll look at 20 information for our next meeting. 21 MR. FUTCH: Dates, dates. October? 22 MS. ANDREWS: Are we still looking for 23 October? I didn't include calendars in your 24 packets this time, but I did print them out.

	I've chosen September, October and November. We
1	usually have it around October, but in October
2	the only thing we have in there is the $13^{ ext{th}}$.
3	Everything else seems open. We have the $7^{ m th}$, it's
4	a Tuesday, or we can do it on a Thursday if you
5	wanted to. There's the $14^{ m th}$, Tuesday, the $14^{ m th}$,
6	$21^{\rm st}$, and the $28^{\rm th}$ are the Tuesdays in October.
7	MR. FUTCH: So does anybody feel strongly
8	
9	about moving from October? Or is October good?
10	DR. WILLIAMS: October's good but I'll be
11	out of the country through the 12th.
12	MR. FUTCH: So the 14 th would be the first
13	date in October you'd be available?
14	DR. WILLIAMS: Right, but that's like the
15	second day I get back.
16	MS. DYCUS: Oh, that'll be fine. Just
	throwing it out there.
17	MS. ANDREWS: So the next one would be the
18	21 st .
19	MS. DYCUS: Would that give you a breather?
20	DR. WILLIAMS: That would be better for me,
21	but I'm not running the whole show.
22	MR. RICHARDSON: I'll be out of the country
23	until November 3 rd .
24	MS. ANDREWS: From what date to what date?
25	

	MR. RICHARDSON: I leave on the 10 of
1	October.
2	
3	MR. FUTCH: Anybody else want to pick it
4	from
5	then?
6	MS. DROTAR: I would like to be out of the
	country.
7	MS. ANDREWS: Can we go with you? Okay. So
8	who can make it on the $21^{ m st}$ at this point?
9	MR. KENNEDY: How about Thursday the $16^{ m th}$?
10	MS. ANDREWS: The $16^{ m th}$, would that be better
11	for everyone else?
12	SEVERAL VOICES: (Inaudible.)
13	MS. ANDREWS: Raise your hands up high for
14	
15	the 16 th . That looks good on this side.
16	So most people can make it on the 16 th . I
17	know you're out of the country. Can you make it
18	the 16 th ? You're questionable?
	DR. WILLIAMS: Yeah.
19	MS. ANDREWS: Okay, we're good. Okay.
20	MR. FUTCH: Dr. Williams, when you are
21	going?
22	DR. WILLIAMS: I leave on September the
23	30 th and come back October the 11 th .
24	MR FUTCH: So if we did just look at

September, 22^{nd} would be the Tuesday - the 23^{rd} 1 would be a Tuesday, 26th would be the Thursday. 2 Does that solve your problem? 3 DR. WILLIAMS: Yes. 4 MR. FUTCH: And that solves your problem 5 and your problem, right? 6 DR. WILLIAMS: Gastro is that week. 7 MR. FUTCH: All right. 8 DR. WILLIAMS: Normally I don't do these 9 things because I screw them up. I mean, Carole 10 can tell you the schedule if you want to just ask 11 her. That might be the easiest thing. 12 It's not just me, either, it's all of us. If 13 somebody else is away then I couldn't come. 14 MR. FUTCH: Gotcha. I'll get back to your 15 office and throw some dates across in an e-mail, 16 right, Brenda? 17 MS. ANDREWS: Yeah. So right now the 16th 18 looks the best for everybody. Okay. So we can 19 work on that. Okay. 20 MS. DROTAR: The 14^{th} through the 17^{th} . 21 MR. FUTCH: September? 22 MR. KENNEDY: The end of September. 23 MS. ANDREWS: September? 24 MR. KENNEDY: Yeah, the last week of 25

	September looks like -
1	MR. FUTCH: 23 or 25? Anybody have any
2	thoughts right now about conflicts on the 23 rd of
3	September or the 25 th ?
4	Jerome, does that help you out any? Okay.
5	MR. GUIDRY: I wish I met more with this
6	group than I do, but I'm certainly not going to
7	impose my schedule on this group.
8	MS. ANDREWS: The 23 rd . How does that look?
9	MS. DROTAR: Of September?
10	MS. DYCUS: Okay.
11	MS. ANDREWS: A show of hands? Okay. That
12	looks real good.
13	MR. FUTCH: We might work with that one.
14	MS. ANDREWS: Okay. So that's good, is that
15	like a first choice?
16	MR. FUTCH: What is that printed on - the
17	calendar?
18	MR. RICHARDSON: James, we found out at
19	lunch
20	that Jerome is quite a musician and I would move
21	that we have entertainment it during the next
22	meeting.
23	MR. FUTCH: What - which particular -
24	MR. GUIDRY: You aren't supposed to say

that. 1 MR. FUTCH: Since we're on the record, which 2 instrument is that? Do you want to tell us? 3 MS. DYCUS: Guitar. 4 MR. GUIDRY: Do I have to - I've been 5 playing 6 guitar and singing for about 45 years. 7 MR. FUTCH: Well, you'll have to open the 8 meeting -9 MR. KENNEDY: That's about how long it 10 takes. 11 MR. GUIDRY: I owe you one. 12 MS. ANDREWS: So do we want to look at the 13 26th then because we've got the 23rd in 14 September, which most people could make that, and 15 October 16th. Are we even still interested in 16 October? 17 MR. FUTCH: I think you've got everybody 18 for the 23^{rd} . 19 COUNCIL MEMBER: No, I can't make it. 20 MR. FUTCH: Oh, you can't. Sorry. 21 MR. TINEO: I will be at a chiropractic 22 conference that week. 23 MS. ANDREWS: The whole week? 24

MR. TINEO: Just the weekend.

	MS. ANDREWS: The 19 -
1	MR. TINEO: The $24^{ m th}$ through the $27^{ m th}$.
2	MS. ANDREWS: So you can come to the Council
3	meeting on the $23^{\rm rd}$ and then just keep going.
4	You have a whole week before that. So that
5	won't work for you?
6	MR. TINEO: Probably not but that's okay.
7	MS. ANDREWS: Okay. So we've got the
8	majority of the people that will be here then the
9	23 rd .
10	So do we want to settle on that date?
11	Decision made. Okay, 23 rd September is the date
12	for the next meeting.
13	MR. FUTCH: Okay. Thank you very much.
14	* * * *
15	(Whereupon, the meeting was adjourned at
16	3:00 p.m.)
17	
18	
19	
20	CERTIFICATE
21	THE STATE OF FLORIDA,)
22	COUNTY OF WAKULLA,)
23	I, Suzette A. Bragg, Court Reporter and
24	Notary Public. State of Florida at Large.

DO HEREBY CERTIFY that the above-entitled and numbered cause was heard as herein above set out; that I was authorized to and did transcribe the proceedings of said matter, and that the foregoing and annexed pages, numbered 1 through 131, inclusive, comprise a true and correct transcription of the proceedings in said cause.

I FURTHER CERTIFY that I am not related to or employed by any of the parties or their counsel, nor have I any financial interest in the outcome of this action.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my seal, this $^{\rm 28th}$ day of May, 2014.

SUZETTE A. BRAGG, Notary Public State of Florida at Large My Commission Expires: 2/21/2017