ADVISORY COUNCIL ON RADIATION PROTECTION

CERTIFIED TRANSCRIPT

Bureau of Radiation Control

Hampton Inn & Suites

Tampa Airport Avion Park Westshore

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Reported by
Rita G. Meyer, RDR, CRR, CRC
Realtime Reporter and Notary Public
State of Florida at Large

ADVISORY COUNCIL MEMBERS PRESENT:

Mark S. Seddon, M.P., DABR, DABMP (Vice-Chairman)
Kathleen Drotar, Ph.D., M.Ed., RT. (R)(N)(T)
Albert Tineo, MS, CNMT
Rebecca Coffey McFadden, RT(R)
Matthew Walser, PA-C, ATC
Nicholas Plaxton, M.D.
Adam Weaver, MS, CHP
Chantel Corbett, AS, CNMT, RT(N), RSO
Joseph Danek, CHP
Albert V. Armstrong, Jr., DPM, MCs, BSRS, C.W.S.

FLORIDA DEPARTMENT OF HEALTH STAFF

Cynthia Becker, Bureau of Radiation Control
James Futch, Bureau of Radiation Control
Brenda Andrews, Bureau of Radiation Control
Gail Curry, Bureau of Radiation Control
Kevin Kunder, Bureau of Radiation Control
Clark Eldredge, Bureau of Radiation Control

AGENDA

MORNING SESSION

AFTERNOON SESSION

MARK SEDDON: I'm Mark Seddon. I am Vice-Chair of the Advisory Council here today and Randy is unable to meet with us today, who's the current chair, so I'm stepping in for her. So if we can start out by going around and doing introductions around the table.

If this is your first time at the meeting, please feel free to elaborate and tell us a little bit about yourself.

So I don't know if we want to start down with --

JAMES FUTCH: Miss Brenda.

BRENDA ANDREWS: Okay. I'm Brenda Andrews and I work with the Bureau of Radiation Control. And I'm James' liaison for the Council as well as logistics for him.

GAIL CURRY: I'm Gail Curry, regulatory assistant consultant for Medical Quality Assurance, Radiologic Technology. Hello everyone.

ADAM WEAVER: I'm Adam Weaver. I work at the University of South Florida. I've been on the Council, I think this is my second go around, so --

MR. ARMSTRONG: My name is Albert Armstrong. I'm a podiatrist and professor at Barry University School of Podiatric Medicine. This is my first

meeting in a while, but I was on this one council several years ago. I served in the Air Force as a radiology technologist and then became a podiatrist. So that's my radiology background.

CLARK ELDRIDGE: I'm Clark Eldridge. I'm with the Department of Bureau of Radiation Control. I'm the Administrative Radiation Machine section.

KEVIN KUNDER: Kevin Kunder. I'm with the Bureau of Radiation Control and administrator for radioactive materials.

CHANTEL CORBETT: Chantel Corbett. I work with a company Fusion Physics, but I'm a nuclear medicine technologist representative.

MATTHEW WALSER: Matt Walser, University of Florida. I'm a physician assistant. I am the person who has never been certified as a radiologist, radiologic technologist or been a member of any closely related profession.

JAMES FUTCH: Sir, sir, where are your papers and can you prove that?

(Laughter)

MATTHEW WALSER: I have my papers.

JAMES FUTCH: Okay.

REBECCA McFADDEN: I love sitting by Matthew with introductions because he says that every single

time. That's awesome.

I'm Rebecca McFadden. I'm a certified radiologic technologist. I currently work with Orlando Health as a system administrator.

ALBERT TINEO: I'm Albert Tineo. I'm the hospital representative. I work at Halifax Health in Daytona Beach.

CINDY BECKER: Hi, I am Cindy Becker, Department of Health, Bureau of Radiation Control bureau Chief.

MARK SEDDON: And I'm Mark Seddon. I represent the medical physicists in the State of Florida. I'm currently RSO and chief assistant for the Advent Health Hospital Group.

JAMES FUTCH: I'm James Futch, also with Radiation Control. Administrator for the technology standards and CE section.

NICHOLAS PLAXTON: Good morning. I'm Nick Plaxton. I'm a nuclear medicine physician at Bay Pines VA.

JOSEPH DANEK: I'm Joe Danek. I'm a new member. Let me look at my notes to see who I am here.

I'm a retired consultant. I worked for Florida Power and Light NextEra Energy for over 35 years in

the nuclear division. I'm a certified health physicist. Got my Master's at the University of Florida.

I started out working at the Turkey Point nuclear plant and then I moved to the corporate office as the corporate health physicist and radiation protection manager for five nuclear sites. Turkey Point, St. Lucie and then as NextEra Energy, we had Seabrook in New Hampshire, Point Beach in Wisconsin and Duane Arnold in Iowa.

Among my many duties with Florida Power and Light, I was the radiological environmental monitoring program administrator for the environmental monitoring program for each site, which the state did a lot of the samplings for us.

And I'm a past president of the Florida Chapter of the Health Physics Society.

JAMES FUTCH: And with impeccable timing, our last member of the day. Introductions, Ms. -- Dr. Drotar, excuse me.

KATHLEEN DROTAR: Hi. Kathy Drotar, radiation therapy technologist, Board member, late, and representing Florida Society of Radiologic Technologists.

MARK SEDDON: All right. Thank you, Kathy.

And welcome, Joe, to your first meeting here.

So next order of business, we have approval of the minutes. So we have two large stacks of minutes here. Has anyone had a chance to review the minutes that Brenda has sent out?

Yes? All right. Do we have a motion to approve the previous minutes for the Advisory Council?

ALBERT TINEO: Motion to approve.

JAMES FUTCH: Do we have a second?

MATTHEW WALSER: Second.

MARK SEDDON: All in favor?

ALL: Aye.

MARK SEDDON: Any nays?

(No Response)

MARK SEDDON: No? All right. The minutes have been approved. Any discussions? No?

All right. So we'll move over to Cindy for our Bureau update.

CINDY BECKER: Oh, bureau updates. Well, good morning everybody. I'm glad that we're all actually together this time, although the virtual meeting I thought went fairly well in December. We got to talk about what we were doing during the Covid times and what our inspectors were doing.

As you know, I'm here kind of also representing Jorge Laguna, who's our environmental administrator for inspections, he could not make it here today, and John Williamson, our environmental administrator in Orlando for the environmental section.

So just an update for what they've been doing. A lot, as you know. One of the things for the inspectors, since you guys are out in the field and you see the inspectors, even more than I do typically, they have been doing inspections. They stopped for about one month and kind of regrouped and looked at what safety protocols they should put in place.

Basically, what they did is they would call the facility and say, what protocols are you using, and would follow suit with what they were doing. And they would do inspections after hours, anything they could to avoid being there with a group of patients and try to stay safe. And for the most part, I really think they did that. And they continued with inspections about a month after stopping.

During that stop period, they did a lot of training. They did online training. NRC even went with online training. Most folks did and some are still doing that. So they did the trainings. They

had meetings to discuss what they could do during this time that they were working from home remotely. They continued to do that. As you know, they still work from their homes.

So I think the inspection activities might have gotten behind a little. I think they're in the mode of catching up now. We've been really, really lucky lately. We had a few vacancies over the last year. And all of a sudden, we have these great and wonderful staff appearing and a lot of them started just last week; a few more this Friday. So we're almost at a full staff. And that's amazing. Knock on wood. So very rarely happens.

So I think the inspection activities are going well. John's shop has been quite busy. This last year, the PRND, the Preventative Radiological Nuclear Detection activities continued. You know, we had the Super Bowl in Florida. We had the races that were in Florida. They also did the St. Lucie nuclear power plant exercise. So things for them pretty much continued. They still had requests for sampling. There were still a few incidents happening out there.

Later today, you'll hear from Clark and from Kevin about some medical events and how those went

the last few months. So there was still a lot of activities for us going on. It didn't seem that different. I think most of us were still in the office collecting checks because, you know, we still do the old fashioned hand, here, mail in a check.

And just last week, we had the big conference, the Radiation Control Program Directors meeting. It was all virtual. Monday through Friday. Of course, we miss going in person to that. But some of the presentations were just fantastic. A lot of new modalities they talked about.

The most interesting one to me was and you guys know this, the ones that are in therapy. Flash proton therapy. A half a second treatment. Half a second fraction for maybe one to three fractions. Of course, you know, high dose, but that's just astounding to me.

So that's kind of our update. Other than that, it all keeps going with us. And you know where we are if you need anything. We're there.

So welcome again. We're going to have a great meeting. Good to see you all. Yay. All right.

MARK SEDDON: Thank you, Cindy.

CINDY BECKER: You're welcome.

MARK SEDDON: Any questions for Cindy?

(No Response)

MARK SEDDON: All right. Very good. Thank you.

Gail. Medical quality assurance update.

GAIL CURRY: Good morning, everyone. So nice to see everyone in person. I know last year was very trying for all of us. Especially those of us sitting at home looking at our four walls and never going outside our little domains. I'm very happy to be back around people.

JAMES FUTCH: I was going to say you had a very unusual experience because your whole division went home for --

GAIL CURRY: Yes. Our whole division was sent home. So we only had -- I only had two people in my whole office for a year. And one was our receptionist, who just didn't want to go home. I think he had a wife at home he didn't want to --

(Laughter)

GAIL CURRY: And -- he actually told us that. And, um, one other person that just wanted to stay and do our mail and things like that.

But, yeah, our whole division, supervisors, division directors, directors, everybody was working from home. And it actually worked out very well.

We kept our numbers down. Our number of applications and processing times were kept down to one to two days. Which is super, super good. Right now we are working at about three days because we're really heavy with graduation. I also do EMTs and paramedics and as you know, any time there's a pandemic or some emergency, you know, people want to help. So you see those types of numbers go up in those fields. So we're really getting slammed right now.

We do have a new executive director. Our former executive director, Anthony Spivey, has retired. I'll just introduce you a little bit to our new executive director. Her name is Christina McGinnis. She's our new executive director.

She joins the Department of Health from the Agency of Health Care Administration where she oversaw the medical and behavioral health policy section developing medical, behavioral and specialized coverage in limitations to improve health outcomes for over 4.2 million Florida Medicaid recipients.

During her time in office, she negotiated the Florida Medicaid statewide dental contracts and moved cost-saving health policy changes forward.

Christina McGinnis possesses over six years of program management and analysis experience in public health through roles with the Health Department, the Florida Department of Health and Florida Agency for Health Care Administration, including the supervision of up to 19 employees.

She review and analyzed, review and analyst of federal and state regulations, and making public presentations to multiple groups of stakeholders. Before then, she worked for 11 years as a dental assistant and dental office manager as well as obtained her Master's in Public Health degree from Florida State University.

Ms. McGinnis' knowledge, experience and educational background will be an asset to the chiropractic medicine, clinical laboratory personnel, optometry, nursing home administrators, physical, medical physicists, emergency medical technicians, paramedic and radiologic technology certification board office.

Christina enjoys crafting and baking, but most importantly, loves to spend time with her newborn baby boy and her husband.

So I will give you a few statistics.

JAMES FUTCH: So can I say one thing before you

move on?

GAIL CURRY: Sure.

JAMES FUTCH: Can you tell Christina really wanted to be here today? I think she gave you all her full entire bio.

GAIL CURRY: No, I did that. I did that.

JAMES FUTCH: Oh, you did that? I will say one thing that I did hear she told me when I first met her was she was also a dental radiographer, which seems appropriate for the person inside MQA now for the rest of it.

GAIL CURRY: Yes.

JAMES FUTCH: I was very interested in talking to you and the other folks.

In addition to Christine, there's been some other supervisory changes. You actually have staff who are working in the field when they got new managers, and the new managers' managers that they have never seen before --

GAIL CURRY: Yes.

JAMES FUTCH: -- for, like, half of a year.

GAIL CURRY: Yes. Right. We have a new executive director. I was the POA. I have stepped down to a supervisor position, so we have a new executive director, a new program operations

administrator. They already know me. But we do have another new supervisor. So all of our management positions changed during the pandemic.

We were doing Teams meetings, which we can see their faces. I conduct a Teams meeting with my people every Monday where we could see each other and talk and at least get that one-on-one kind of, you know, feeling keep going. We didn't have that for about six months, so it was very difficult to maintain some type of normalcy.

Once we got Teams, I made everybody turn their cameras on.

JAMES FUTCH: That's an important requirement.

GAIL CURRY: Yeah. Because, you know, nobody wants to show their face. I'm like, I don't care if you're in your pajamas, I just want to see your face. So that was a very big asset for us.

We also conducted a lot of meetings that way with IT and our executive management team. So Teams has been a really good IT component for us.

JAMES FUTCH: So you all -- so in our building in Tallahassee, just to fill a little bit in, the Bureau of Radiation Control is kind of like the meat in the MQA sandwich. The top floor is MQA, the bottom floor is MQA. Half of our -- we have 100,000

square feet of MQA between us. And you all were sent home in early March, right?

GAIL CURRY: Yes. We were sent home in early March.

JAMES FUTCH: And they didn't come back -- this building was almost completely empty until a week ago.

GAIL CURRY: Last Friday. Yeah. And we are still -- some of our people are still teleworking because they either haven't had their full vaccinations or they have some underlying medical issue that they really need to stay home for right now. You know, they've been very good about helping people that have medical issues that need to be at home.

We are getting a -- starting some time this week, we are implementing a new program called ELI. It will be out on the website and it's a chat system. So that if our applicants go to our website and they have a question, you know, how do I apply, where do I send my documents, how can I pay my fee? You know, those types of questions, scope of practice, anything that you can think of, those questions will be on ELI chat. If for some reason, they don't get the answer that they need from that

chat, then they can contact a live person. And that will be our processors that will answer those questions.

And I will let you know for the whole State of Florida, for EMTs, paramedics, radiologic technology, we have three processors who process every application that comes in. They do an outstanding job. So any time you guys feel like you want to give some kudos somewhere, throw some out that way because they could really use your encouragement. They work very, very hard.

Also, MQA has given some OPS hours to help us catch up on all of our applications and any outlying issues that we're having. We're receiving an awful lot of e-mail and an awful lot of documents that are coming in. So they have granted us 50 hours per office to give overtime.

With that being said, let me talk a little bit about some statistics for you.

I did ask for a report to be run because my reports were not generating numbers that I thought were true numbers. So I didn't get all of those reports back, but I'll give you what I have.

So as I said, we're working about three days to process an application due to the influx of

applications that we see coming in this time of year because of graduation.

So the number of licensed, as of last Friday, the number of licensed general radiographers was 23,755. Radiologic technologist assistants were 35. I do not have any numbers for our basic x-ray machine operators. I can tell you that basic x-ray machine operators podiatry, we have 52. We have 2,967 radiation therapy technologists; we have 9 PET and we have 3,965 nuclear medicine techs. That's what we have right now that are clear, active and can go to work if they're not already working.

I did not get mammographers or CT. If I get those a little bit later, I can throw you those numbers if you want them.

But I can tell you since July 1st, 2020 until May 19th of this year, we have licensed 1,720 general radiographers. We have licensed three additional radiation assistants and the others I don't have the answers for you.

I can give you a little bit about -- if you're interested in renewals, in May 31st, 2021, we had total number of processed renewals for that renewal cycle for those people, as you know, they all renew on their date of birth, was 669. So those total

numbers renewed last year were 56 percent. This year it's 71 percent. So we're seeing an increase in those numbers, which is good.

The radiologist assistants, we saw three renewals processed. That was at 60 percent last renewal cycle. This renewal cycle is 66 percent. So another increase.

In June of '21, we saw 425. Last renewal cycle was 36 percent. Now it's 44 percent. And radiologic assistants were three. Those were at a hundred percent last time and they're at fifty percent this time. But remember, we haven't reached June 31st yet. So hopefully that will also continue to at least be a hundred percent.

Right now, for July, which the renewal is open 90 days before the expiration date, so right now, for general radiographers, we're looking at 126 people who have already renewed and that's at 9.76 percent, which is up 14 percent so far. So I see that being an increase the closer we get to that July deadline.

With that being said, is there anybody that has any questions, concerns?

JAMES FUTCH: I have a comment I wanted to bring up. During Covid we had many, many, many,

many, many, many emergency orders --

GAIL CURRY: Yes.

JAMES FUTCH: -- from the Governor's office, from the State Surgeon General, and several of those emergency orders pertained to expiration date extensions for a variety of health care practitioners. And as you know, our inspection staff, when they go into a facility, one of the things they check is the current licensure of the rad tech staff, as well as some of the affiliated folks. And there may be quite a few licenses on display in your facilities which appear to be expired, because according to the paper and the date, they would've been expired but for the actions of these emergency orders.

So the very last one I saw took -- I think everyone who was a rad tech who was expiring from December onward, and pushed their expiration dates to June 30th, 2021. So this is something that we have to be aware of, Jorge's staff has to be aware of, my staff has to be aware of because the inspectors will call us, they were going to cite someone at a facility and they're not quite sure. I don't know if you had questions about that, Gail.

GAIL CURRY: We do. We get those questions.

JAMES FUTCH: Yeah.

GAIL CURRY: And of course, we put their nerves to rest by letting them know that, no, you haven't missed your renewal date. And trust me, most of them know that it's been extended. The majority of them know. So we don't get a huge amount of calls on that. Once in a while, we'll get a call that says, um, I'm over my expiration date, but did I hear that we have six months, like, until June? You know. Yes, you do. Don't worry. Just go out and renew your license.

So, again, our staff is very knowledgeable and has information to give our applicants and licensees when they call. So we try to stay on top of anything that's new, that's coming past us. A lot of executive orders were issued. A lot of emergency orders were issued. We really try to send those -- I send all those to my processors so they're aware because they answer calls. They are the ones who get the first call. I'm the one who gets them after they're angry. So they really try their hardest to be on top of the information.

MARK SEDDON: That's a good point because it's not just the inspectors. Actually, your hospital HR departments typically have automatic reminders and

suspension of pay if you don't renew your licenses by certain times, so those folks were, Alberto -- hospital administrators and their staff have to maybe education your HR department, you know, when those start, those reminders start popping up.

ALBERT TINEO: Yep.

MARK SEDDON: And you have to tell them there's an extension deadline. I think you guys have letters available.

GAIL CURRY: We do. We send e-mail blasts. We also send postcards.

And some of the reason they're not able to renew is because they had a hard time getting their CEs because as you know, a lot of them wait until the last minute. And then with Covid, there was no CEs being given live. So, you know, some people like to go live and if there wasn't, then they had to scramble to find some online, so that was a issue.

But you're right, those certificates that are by law mandated to be on the wall, say that they're expired. But if you know that an emergency order was issued, what I would've done was print out that and set it right there beside those certificates.

JAMES FUTCH: And then replace it when the next

one came in.

GAIL CURRY: Yeah. Or when that one goes away. But, yeah. I mean, you know, if they call, we always tell them, we advise them, the best thing to do is go ahead and renew. Don't worry about that extension. If you have your CEs and you can renew, please go ahead and do so and then that takes care of their whole issue. But you know, a lot of them want to wait.

Yes, sir?

ALBERT ARMSTRONG: I have a question.

GAIL CURRY: Sure.

ALBERT ARMSTRONG: Of those 52 general radiology podiatry people who renew, does that include the ones who certify that they have Florida Podiatric Medical Association or is that an --

GAIL CURRY: No. Those are separate.

ALBERT ARMSTRONG: Okay. Because we have 400 attendees.

GAIL CURRY: Right. Right. We used to also have podiatry in our office. They went to a different office. But, yes, James' group had the podiatry first.

JAMES FUTCH: For the basics.

GAIL CURRY: Yes, the basic x-ray machine

podiatrists. Then -- you know, which is from the knee down. Then podiatry came in and licensed their people and so that is a whole different profession. That is regulated under a different statute.

So, yes, there are much more of those licensed, but they're just podiatric x-ray.

ALBERT ARMSTRONG: Right. Right.

GAIL CURRY: Good question. Thank you.

JAMES FUTCH: So from a historical perspective, all of it originally was part of the statute that this section housed in 468 part four. And the numbers used to be -- and you were talking about basics. So the full basic was somewhere 3500 to 4500 years and years ago. And the basic machine operator podiatric was about, about ten percent of that. It was like 300 to, you know, somewhere in that neighborhood. And then when the statute was changed to allow the Board of Podiatric Medicine to issue its certified podiatric x-ray assistant, then the numbers started shifting.

Essentially, we have almost the same scope of practice for two different professions, both issued by different parts of the Florida Department of Health. One day, perhaps, a statute might be amended so that, you know, all of the podiatric

assistants will be only issued through the Board of Podiatric Medicine.

And there are some minor differences. For some reason, I believe your -- sorry, I'm pointing to Dr. Armstrong, the podiatric physician -- the statute there requires the person to identify the supervising podiatrist. Ours says they must be supervised by a podiatric physician but doesn't require them to name which one. Other than that, the educational background and which particular test they take, they're the same scope. One of the oddities of law.

ALBERT ARMSTRONG: Thank you.

JAMES FUTCH: Sure.

MARK SEDDON: Anymore questions for Gail?

KATHLEEN DROTAR: Just a comment. Since Gail has been back, it's been very obvious that Gail's back and has -- and is supervising again. At the last meeting, I mentioned the delay of graduate technologists getting their temporary licenses so they could work right away, and being like two, three months. It's now down to about a week. And not only that, but e-mails that we send in with the completion information for our graduates is being acknowledged that it's being received. So many

thanks.

GAIL CURRY: Thank you. Thank you.

MARK SEDDON: All right. Anymore questions for Gail?

(No Response)

MARK SEDDON: Actually, kind of tied to that, I know we talked about some structural changes with administrative on that side. Was there anything Cindy from the Bureau in general because of Covid or --

CINDY BECKER: No. I can't -- James, Kevin, Clark? No, not really.

JAMES FUTCH: Other than I think the inspectors were the most impacted and three quarters of that was because the facilities they were usually going into perhaps did not have a, have a need for them to be in there at that moment. They were focused on other things.

CLARK ELDREDGE: We actually took the entire March -- wait. April, May, June, basically, that quarter, and pretended like it didn't exist and pushed every facility inspection for machines, not materials, back a quarter. So the entire schedule was -- so people that were due in five years were now due in five years and a quarter, two years, two

years and a quarter; that type of thing.

MARK SEDDON: And did the facilities have restrictions on access because of Covid?

JAMES FUTCH: That was --

MARK SEDDON: I thought that would be --

JAMES FUTCH: That was a big part of it.

CLARK ELDRIDGE: That was --

JAMES FUTCH: Like I said, they were focused on, you know, Covid and keeping it out and treating the people who were there with it. And I don't, I don't think it, it was conducive to try and figure out when to bring the inspector in and where and which doorway and what protocols. How much PD are you wearing?

CLARK ELDRIDGE: We actually had one inspector who ended up, after we started, in the wrong wing at the hospital.

JAMES FUTCH: But the Bureau, as a whole -- I think we detailed this fairly thoroughly in December. The vast majority of us did not go home. The Orlando staff and the Tallahassee staff were doing things like working in the warehouses distributing gloves and all the other things that, that were needed. In some cases working on I-95, interviewing people from New York that wanted to

come to Florida.

CINDY BECKER: Wasn't that fun, Kevin?

MARK SEDDON: Expanding your skill set.

KEVIN KUNDER: Yes.

CINDY BECKER: Yeah, partially because we're in the Division of Emergency Preparedness and Community Support so the whole group gets activated in some shape or form. The call center or e-mail response.

JAMES FUTCH: Right. We have a bureau called the Bureau of Preparedness and Response, which we're used to not seeing at all because they are inside our division. The most involved and the most employed of any of us at any given point in time. But then there were people in the Bureau of Emergency Medical Operations, they've had some leadership changes and the person who is now one of the bureau chiefs, Steve McCoy, I don't think we saw him for most of last year until about a month ago.

CINDY BECKER: Right. Most of those two bureaus were deployed in some shape, you know. A lot of the Bureau of Emergency Medical Operations, a lot of them are EMTs and so they were out in the field. But, yeah, they did have changes.

The new Bureau chief, like you said, is Steve McCoy and the new Bureau chief for preparedness and

response has still not been selected. They have an acting, Jennifer Colter. Both of those Bureau Chiefs actually retired or just left, I'm not sure which, during Covid.

JAMES FUTCH: That puts a lot of demands on every aspect of work and home life, that's for sure.

CINDY BECKER: Yeah. So --

MARK SEDDON: Very good. Well, thank you.

Moving on, I know we have on the agenda, Council presentations, but James mentioned we wanted to jump over to the section rule updates for the different section chiefs. So I guess we'll start with Kevin.

KEVIN KUNDER: Okay. All right. Again, I'm Materials. Staffing changes for Materials, you have received, those have received the inspection letters. Usually we'll see Lee Thomas' name on things. He was our inspection coordinator and he decided in January he wanted to go home and be a stay-at-home husband, I think. So he left and he was replaced by Joyce McElroy.

She was an inspection reviewer for me and she won the position to take over for him so she's now the inspection coordinator.

That leaves open her position, which is

inspection reviewer. I am in the process of filling that with an internal transfer. No names as of yet to be published yet, but I have that one covered.

We lost a licensed evaluator to James' group to technology in January. I think I said that last time, too. But anyway --

(Laughter)

JAMES FUTCH: I think you say that every time you get the chance.

KEVIN KUNDER: Taking all my good ones here. Anyway, I got that position filled. Megan Thorpe. She's from the Tallahassee area. She's going to be coming on board this Friday. So she starts with us then. So that's the changes in the Radioactive Materials.

I just wanted to review where we were with the rule making process. As I talked about at other meetings here, in 2019, the NRC had their evaluation review. The IMPEP come through and they found that our program was behind with some of our rules and not being worded the same way as NRC wanted them or, you know, some other changes that needed to be made. So 2019, Cindy and I went to the management review board up in DC area. And by that time, when we went up there, we had already submitted our draft changes

to the NRC. So we were kind of jumping on that real quick, getting it done, but then, you know, they got back to us by that December and they had about 17 issues that they had sent us back that we had to address.

We've gone through; done all that stuff and we've sent them off, we sent it out to -- legal gets them after we get done with them. And from legal, it goes to OFARR, which is the Office of Fiscal Accountability and Regulatory Reform. They do their review on it. And then finally, April Fool's this year, April 1st, the Florida Administrative Register (FAR), we got published. It was basically an outline of the updates for the language that was required by the NRC.

We've been, since that time, doing language development. I think it is currently with Mike Stephens and with Brenda to do the strike through and underlining and get it all ready to go to division. It will go to division. From division to legal, from legal back to OFARR. And then from OFAR, it goes finally to JAPC, which is a Joint Administrative Procedures Committee. Hopefully that will take maybe six more months to happen.

The main things that are probably going to come

out of it, there's a lot of, you know, they want things -- we had stuff medical, institution, and outpatient facility or something like that and they wanted it changed to medical facility. Just shorten the whole thing. A lot of that type of stuff in there.

Probably the biggest changes will be in Part 6 of 64E-5. Training and experience will now allow board certificates and there's no more need for the end attestation. So as long as we have those. Unfortunately, we still need the attestation for the RSO position. So all the rest of them, we can just take the board certificate and that's it.

We're also putting in language, because that was required the first go around, we're putting in language for the Associate RSO. So the NRC has a position for an Associate RSO. So we're putting in the description, we're putting in the training and experience, and it's basically identical to the RSO. However, we're not going to get in the duties. That won't be further until the next rule development that we do, but we're at least getting in the language and what's required of it.

So that's kind of where we're at. So hopefully within the next six months, we'll have all that

done.

We've got a little bit delayed with legal last year due to the Covid.

MARK SEDDON: Quick question.

KEVIN KUNDER: Yes.

MARK SEDDON: So Associate RSOs, would that mean that offices are required to have an Associate RSO?

KEVIN KUNDER: No, no, no. Just that they are allowed it as an option.

MARK SEDDON: An option.

KEVIN KUNDER: Yeah, as an option.

CHANTEL CORBETT: They would actually be on the licenses.

MARK SEDDON: So just name the individual. So delegation of responsibility.

KEVIN KUNDER: Yes. An option.

MARK SEDDON: Makes sense.

KEVIN KUNDER: The last thing I got, which will probably dump into Clark's talk, is medical events.

So since our last meeting, we've only had one medical event for Materials and that just recently happened. It was an HDR. Vaginal HDR. Three fractions. On the second fraction, they used a longer guide tube. They connected a longer guide

tube. So unfortunately, the source rested just on the surface of the vaginal area.

So they had already put stuff into place where they actually had the tubes color coded, but when they went in, everybody went in, they looked and they did what they were supposed to do, but nobody verified what the length was. The radiation technologists go through and they do their measuring. Once they get it done, they measured it and -- the physicist never asked for it and they didn't do it as part of their time out. They went through and read what was there, but no one verified that that was not correct and they went ahead and treated. We're still under investigation of that right now, but that's the only thing that we've had since the last meeting.

MARK SEDDON: Quick question. Is that a specific offender do we know or --

KEVIN KUNDER: Um, what do you mean? Like --

MARK SEDDON: For the offender.

KEVIN KUNDER: I know which vendor it was.

MARK SEDDON: Okay.

KEVIN KUNDER: But I mean, the NRC did ask me. That was a question they did ask, because they're trying to look and see if it's coming out because

there's been some other ones elsewhere.

MARK SEDDON: I mean this is, I wouldn't say fairly common, but for HDR medical events, that's probably one of the more normal causes is wrong guide tube, using the cervix guide tube or just the wrong length, so I was just curious.

KEVIN KUNDER: This one here I just I thought it was even more so, because they actually color coded them.

MARK SEDDON: Yeah. That seems like it's a good way of doing it.

KEVIN KUNDER: They went and did that and I think the first day, the first fraction it was, the black one they were supposed to use and they ended up grabbing the green one and hooking up the green one.

MARK SEDDON: And they didn't have a time out procedure prior to initiation?

KEVIN KUNDER: Yes. It's under investigation.

MARK SEDDON: Okay. I'm sorry. Yeah.

KEVIN KUNDER: But, yeah.

ALBERT TINEO: Something failed.

KEVIN KUNDER: Yes.

MARK SEDDON: Something failed.

ALBERT TINEO: Something failed.

JAMES FUTCH: At least one something. Sometimes two.

KEVIN KUNDER: Yeah.

CHANTEL CORBETT: Just a quick question.

KEVIN KUNDER: Yes.

CHANTEL CORBETT: On the Board certifications, without the recent reform, I'm assuming that that's only the ones with the AU eligible stamp?

KEVIN KUNDER: Yes, I believe so.

CHANTEL CORBETT: Okay.

KEVIN KUNDER: I'll check and let you know.

Any other questions? It's all good. Thank you.

MARK SEDDON: Very good. Thank you.

JAMES FUTCH: Kevin, any new, new devices or uses of anything interesting on the horizon? I should probably ask the group.

KEVIN KUNDER: Yeah.

MARK SEDDON: He would be the one that will know.

CHANTEL CORBETT: There's more people using ammonia and that kind of thing now. So that's, you know, occasionally we'll get questions about new isotopes coming out, but the majority of them are diagnostic. You know, not therapy related or device

related. So they just fall under the normal categories already.

MARK SEDDON: I do know a lot of the potential trials coming out are over towards the therapy side rather than diagnostics. We're seeing that kind of a --

CHANTEL CORBETT: Yeah.

MARK SEDDON: -- we have, like, five or six on my desk to review for potential trials. So I think that's definitely a growth area we're seeing tremendous of down the road in the next ten years, you'll see a lot of radiotherapy, PSMAs and diagnostic type stuff.

So when, I guess when they come to the State, they present information to you, correct?

KEVIN KUNDER: We usually have to pull it from them, but, yes. A lot of times they don't let us know. They just come in and, and it's, you guys call in and asking us questions about them and having to go find the vendor and having them do a presentation for us. You know, kind of bring us up to speed on them.

MARK SEDDON: Because I know there's a lot of new technology coming out in the therapy world. GammaPod and ViewRay and some of those types of

things that are relatively new. So I'm not sure whose area it crosses over into, but, so you guys are involved with some of those. I know Spherotech did change, I think, their delivery device for the microspheres as well.

KEVIN KUNDER: I saw that.

MARK SEDDON: Do they have to go through any approvals with you?

KEVIN KUNDER: No. It's the same.

JAMES FUTCH: So one of the functions of the Council in the statute is to inform the Department of new technologies, new uses of technologies that you all see out in your facilities and in your professional societies and spheres of influence. And we have, some years back, brought some of the vendors to the Council to do a presentation on whatever the thingy is. That's a technical term, "thingy".

REBECCA McFADDEN: Thingy.

JAMES FUTCH: So I just wanted to remind everybody of that because we have the ability to, to do that. And would be happy to entertain that I think.

ALBERT ARMSTRONG: Has cone beam CT already been discussed with this group? High CAM, PET CAM?

JAMES FUTCH: I would defer to Clark. It's certainly terminology that I've heard before many times. I don't know that particular context for podiatric.

CLARK ELDRIDGE: We've been looking at it. This is actually one of the areas that we've requested legislation on a few times because the law current law, which specifies who's using what equipment, was set according to the equipment that was in place in 1980. And so, we have changes in energies and actual -- patient risk, you know, modalities that represent different risk/reward ratio. Not that they're all really good and high but, you know, that -- it does shift a little bit that were not present in other practices before. Such as previously, you know, people in podiatry and dental only used tubes up to about 70kV. Now they're using 120kV tubes. And that represents a different thing than the statutes were originally written for.

So we proposed twice now, updates. The first time they accepted part of our updates, but not the ones that actually opened up how we could expand or -- not expand is the right word. Shift the regulations a little bit to cover the fact that

we've got these different -- when you have a lot lower energy kV tubes being used in hospitals now. They're using --

JAMES FUTCH: Correct me if I'm wrong, but originally, it was based more upon the facility type in which it was used not necessarily the device that was used.

CLARK ELDRIDGE: It's the operator. The statutes are written around who's the operator because it's using, the operator -- no, it's actually the person handling it. It's a combination thereof. Sorry.

In some cases, it's the individual operating the machine; the other times, it's the facility, such as we have medical doctors and then we have educational institutions. So that's -- but it's more of the operator of the device, because that was a proxy for risk. And it's set for what that represented in 1980. Such as that kind of magic line somewhere around 80kV.

JAMES FUTCH: So contrast that with, with -- so Clark's talking about Chapter 404. So 468, part four, is where this group is housed. We were successful, a number of years ago, in legislative changes that allowed us to add additional modalities

of technology certification that were not present in 1978 when our statute began. So if we have a national registry that comes up with mammo and CT and PET and all the other things, as long as they're ionizing, we can add those to Florida certification by endorsement.

We have failed so far in non-ionizing realm. Most chiefly in the MR area, which we're usually asked, I thought you certified those people, too. Well, at one point, but then not.

But anyway, in terms of the hardware, if this is something that you have access to or think it would be of interest to the community as a whole, we can bring them here, put them on record with a court reporter, and have it documented for the future to rely upon in terms of what the device is supposed to do and achieve and safety factors and all the rest of it.

ALBERT ARMSTRONG: The reason I bring it up is because the Florida Podiatric Medical Association, they know I'm on this council and these PET CATs are starting to pop up. Folks are contacting me, asking me, you know, what, what the law is and, you know, how they get certified and I'm like, well, I'm not the person to ask yet.

JAMES FUTCH: This is -- I think Mark is familiar with this position since he's the representative for Florida AAPM. You get a lot of questions, don't you?

MARK SEDDON: Yeah. We get a lot of questions. Same, similar type of things like, you know, special situational equipment. That is, when it crosses over, like, ORMs, which are C-ARM/CTs right? It does both. And where does that fall as far as how do you test it, from a physicist perspective, and how does that fit with the regulations.

I'm not sure, Clark, how you guys handle the, like, ORMs, for example. They've been out there for a while.

CLARK ELDRIDGE: Yeah. We've still got some confusion still on our point. But, you know, primarily, since it's the actual, the CT part, of course, our primary concern is the -- since people normally aren't there next to the machine, it's the operator safety in the scatter.

MARK SEDDON: Right.

CLARK ELDRIDGE: Although we now have the statute that says you need to maintain it according to manufacturer or other national standards.

MARK SEDDON: Okay.

JAMES FUTCH: I think this is the nice aspect of having the Advisory Council composed as this one is. It's not, it's not a regulatory board, which has the same, essentially, powers and duties as an agency. It has to abide by all of the restrictions and requirements. I like to think after 30 some odd years of doing this, that we try and come out on the side of rationality and safety whenever possible. What we run across is that there's a patchwork of laws by which we all operate.

We talked about one of these before, Dr. Armstrong and I and Gail. We have two different parts of two different statutes, which appear to give almost exactly the same license to health care practitioners to do almost exactly the same thing. James Futch's view of the world, this doesn't make a whole lot of sense, but it's because there's two separate laws and sets of regulations that require these things. We can ask, we can suggest that perhaps that might be changed. We do so gently because it's against the law for us to lobby directly. For changes in the statute, we go through our chain of command and what comes out comes out.

But at least we have folks on this Council who are governed by the same laws of physics when it

comes to -- and biology when it comes to the interaction of radiation and human matter. So if we advise and think something ought to happen, we can -- I say we. I'm not a voting member. You guys are. You can have a chair and you can propose things and you can make recommendations. The Department can completely ignore them, but at least you made the recommendations. That might have some weight, at some point, to certain audiences.

Some groups actually have lobbyists who get paid to suggest things change in state laws.

MARK SEDDON: Yeah, that's true. So I think one of the comments made, Clark, was the operator, some sort of registration of the equipment. The operator -- so this is kind of -- I think I may have asked you this before. We have a lot of private schools and a lot of doctors' offices where the owner of the equipment differs from the operator of the equipment, whereas like a managed services types of situation. How do you guys like to approach those situations? Who do you prefer to be registering the equipment? The operators or the owners?

CLARK ELDRIDGE: It's generally the individual responsible for the radiation safety of the device.

The operation of the device. Now, we do see, when we have, say, a rental, a mobile fluoroscopic provider who's in one doctor's office one day and the next, next, next, we'll register the machine owner in this case because they're the ones who are actually -- they've got a rad tech going with it to operate the machine for the doctor. Even though the doctor's directing its operation, they're really responsible for the QA on the machine, the maintenance of the machine.

MARK SEDDON: Right.

CLARK ELDRIDGE: Although the doctors, themselves, still have to do their own radiation safety since they're radiation workers at that point, for their staff, et cetera.

When it's placed at a location for long-term use, clearly it's the facility that's got it. That is the one responsible for all the registration and --

CHANTEL CORBETT: But I think you mean like, the office, itself, the building is --

MARK SEDDON: Owned.

CHANTEL CORBETT: Owned by --

MARK SEDDON: Let's say.

CHANTEL CORBETT: One entity and then there's

another entity --

MARK SEDDON: They're renting it out, too.

CHANTEL CORBETT: -- that comes out and managing everything. The staffing, the running day-to-day of the building.

MARK SEDDON: Yes. To give you an example, there's a scenario now where the hospital system, they own an office with an x-ray unit installed in it. And yet, allow physician groups to rent it out, you know, a couple days a week.

CHANTEL CORBETT: Right. To come in and use the equipment.

MARK SEDDON: For their use and so the question is, I'm not sure if you guys have a situation like that.

CLARK ELDRIDGE: I haven't heard of this until now. So this is sort of -- what's the, what was the rental office company that got in financial trouble? They have a large building with a bunch of cubes and offices and people could rent it by the hour for office meetings and things. It was a hot spot for a while and then they fell out. But anyway, so it's almost like one of those, but it's a medical use.

MARK SEDDON: Right.

CHANTEL CORBETT: Then they even have ones that

are full-time management inside of another entity's building. So, you know, you have third-party management companies that come in and completely run the place, but they're not the ones that own the facility.

CLARK ELDRIDGE: Right. Actually, we've seen that one for --

CHANTEL CORBETT: The Stark laws came into effect and that killed a lot of the day by day, you know, rental kind of situation.

MARK SEDDON: Right.

CHANTEL CORBETT: We had a lot of that before that, but then once that came through, a lot of that ended, but I'm sure there's various ways for people to work around it if they really want to.

MARK SEDDON: Yeah. So I mean, I was just curious because I know, there are scenarios where, you know, we see more joint ventures where you have a collaborative support for, like, you have a hospital system going into a school system and running, like, a health clinic for them. You know, the school system owns the equipment, the hospital system is coming in providing the nursing staff and support team. Or actually, I guess, like mobile nuclear medicine cameras that go on site. Like

Digital Reaction, like those type companies.

CHANTEL CORBETT: Yeah. In that case, the mobile company, the mobile is the license.

MARK SEDDON: Right. They're licensed, so they provide the full --

CHANTEL CORBETT: Right.

MARK SEDDON: -- support.

ALBERT TINEO: The way I look at it is, whoever owns the equipment is the one that needs to register. Now, if you're managing the facility -- if I own the facility, if I manage it, then it's up to me to make sure that whoever has it is following the --

MARK SEDDON: Yeah, you would assume that the contract, right?

ALBERT TINEO: Yeah, that's where it gets tricky.

MARK SEDDON: That's where it gets tricky which I was curious whether you had to deal with that on the machine side. I think materials is pretty straightforward because it's pretty strict. I think it's on the machine side, we really see that more type of an arrangement.

ALBERT TINEO: Especially now with physicians becoming part of the system.

MARK SEDDON: Exactly. Physician-owned practices.

ALBERT TINEO: Yeah.

MARK SEDDON: Hospital-owned physician practices.

ALBERT TINEO: That's where it falls through the cracks sometimes. Somebody has an x-ray machine over here, nobody knew that, and the system bought that practice and nobody said anything to, and all of a sudden, it falls under the system.

CHANTEL CORBETT: Yeah. And last year was the first year I had an inspector give me a hard time on the materials side because we had a nuclear lab that two different entities wanted to run. So we had two consecutive RMLs for the same location, same camera, same hot lab. They were two different entities. So we were running two licenses in the same location. They were like, I don't think you can do this. I'm like, why can you not do this because the responsibility --

MARK SEDDON: Is on the individual.

CHANTEL CORBETT: -- on these days is this entity, on this day, it's this entity. It was a new thing for everybody. But we got it all done but it was definitely a more complicated explanation than

the normal.

MARK SEDDON: Okay. That's good.

ALBERT ARMSTRONG: Let me just explain how it's working with us, in our CT scanner with the PET CAT scanner. We're in Mercy Hospital, okay? But the university has got the clinic at Mercy Hospital, so it's the university that owns the machine, but I'm the only person that's qualified to run it. So that's our scenario.

So I just want to make sure that we're doing the right thing. We have federal accreditation. From the federal accrediting bodies, so we're okay there. I want to make sure that we're following what the State, you know, expects us to be doing.

MARK SEDDON: Right. So do you register the equipment or does the hospital? Owner of the equipment register it?

ALBERT ARMSTRONG: I register it on behalf of the university. So you see all the, the licenses that she was talking about says Barry University is authorized. They have two machines. Two radiation producing machines or something like that. And I'm the one who does the work --

MARK SEDDON: Right.

ALBERT ARMSTRONG: -- on behalf of the

university because I'm the only person that's qualified.

MARK SEDDON: Right. You're the individual and you're also the person responsible for radiation protection, the RPP.

ALBERT ARMSTRONG: Right.

CHANTEL CORBETT: So basically, in that scenario, if you're the only one that's qualified and you leave, and the machine is actually registered to the facility, it's still the facility's responsibility, I'm assuming, to change the person that, you know, the radiation protection.

ALBERT TINEO: That's where it gets, the management, whoever, has the contract, needs to make sure that somebody's hired to operate that.

ALBERT ARMSTRONG: Right.

JAMES FUTCH: You said the hospital owns it?

ALBERT ARMSTRONG: No. The university owns it. But the university's clinic is in the hospital.

JOSEPH DANEK: What hospital is it?

ALBERT ARMSTRONG: Mercy. Well, it's not actually the hospital. It's right next to the hospital. So it's the Mercy outpatient clinic.

MARK SEDDON: We see a lot of this type of convoluted ownership/agreements in current day. I'm

seeing a lot of it. My system keeps on expanding and coming up with new novel ways and I'm saying, I don't know if that makes a lot of sense. I'm uncomfortable with it.

JAMES FUTCH: Are you guys working off of -- I know it all seems very clear from the materials standpoint -- are you working off the same statute and two or three parts of the regulation or two different statutes that say slightly different things?

CHANTEL CORBETT: For what?

JAMES FUTCH: In terms of the ownership and who owns the material, who owns the machine.

CLARK ELDRIDGE: The x-ray statute really just says the registrant. It doesn't really look --

MARK SEDDON: Doesn't clarify.

CLARK ELDRIDGE: It doesn't clarify any of that.

JAMES FUTCH: So the materials, in 404, materials is kind of like the overarching, the way I think of it is the older, the older part of that. And then years later, they came along and kind of pushed the machine part in and actually put in some things to kind of cut off some aspects of 404, but do not apply to your, for example, P section, right?

CHANTEL CORBETT: Well, I mean, I know --

JAMES FUTCH: It's just an area to look at.

CHANTEL CORBETT: Yeah, I know we run into it a lot with the cardiology groups especially. You know, where this entity has the license but then the rule is if you change ownership more than 50 percent, you know, you have to get a new license. Well, then, it's 9 million people looking at each other in one room going, I don't know. Does that -- I mean, are we at, like, 49 percent or are we at 50 percent or are we 51 percent? So as a consultant, you look at them and say, I can't tell you that answer. You have to give me the information.

But it is harder and harder because of that. The hospital group will come in and buy them or, you know, they're one of a partner and then there's gray area of what that partnership means. Is it an ownership partnership.

MARK SEDDON: 50/50, then it's a big mess.

CHANTEL CORBETT: Yeah, it gets a little funky.

MARK SEDDON: Anymore questions for Kevin? I mean, Dr. Armstrong, did we answer --

ALBERT ARMSTRONG: I didn't mean to open up a can of worms.

MARK SEDDON: No. It's good. I think --

JAMES FUTCH: That's why we're here.

MARK SEDDON: This is a council for discussion.

JAMES FUTCH: We love worms.

MARK SEDDON: It's good to bring it to their attention because it's stuff that they've not been aware of that's actually going on out in the field. So that's the reason why we meet.

CLARK ELDRIDGE: The purpose of the Council is to dig for worms.

MARK SEDDON: Do we want to jump over to Clark?

JAMES FUTCH: Sure. We might need a very short break while we get set up hardware wise to show this part. Maybe about, what do you all think? Ten minutes, would that be good?

MARK SEDDON: Yeah, we can go ahead and break for ten minutes. Come back at 11:18.

(Proceedings recessed at 11:08 a.m.)

(Proceedings resumed at 11:27 a.m.)

MARK SEDDON: I think James -- sorry, Clark is going to go ahead and do a presentation for us.

CLARK ELDRIDGE: All right.

JAMES FUTCH: Three.

CLARK ELDRIDGE: So I'm Clark Eldridge, administrator for the radiation machine section. We'll start out with the medical events and that

current status.

So we've had four medical events so far this calendar year. Currently, our investigations are still following a Covid-safe protocol where we're reducing the number of folks that actually go into the facilities. We have one local inspector going to the facility and set up a remote connection using our equipment. And that also, that person is also there to insure who we're talking to is who we're talking to and that type of stuff.

And then the team, we're using Teams to -- Microsoft Teams to do the investigations remotely with the remote interview team in Tallahassee.

So in January, we had a wrong site. This was a surficial treatment for a lesion on the lower leg. In this case, the simulation was done three weeks prior to treatment. The marks had faded and this individual had numerous lesions on their legs. And so, there wasn't sufficient information transferred from the -- to the therapist so they could accurately identify it and they thought they picked the right one and it turned out it was wrong.

We had three other events in February. First was a wrong site. This was a wrong iso center for a T6, T4-T6 treatment. Four personnel reviewed the

images to check the alignment. Two therapists, a medical physicist and a doctor and they agreed on the wrong spot. And it was all due to the field of view of the imaging.

When you look at the spinal column and your field is a little narrow, you can't tell one vertebrae from another. So they ended up centering the treatment on T4 when it was supposed to be T5 and to treat 4 and 6.

February -- the next one in February involved another surficial treatment, but this is -- well, both of them were electron therapy. This is another electron therapy. In this case, the applicator cone was not placed on the machine prior to treatment. So with these electron beam therapies, there's a shield placed on the body, an applicator cone to kind of focus the beam and then the beam is hooked up to the -- the machine is attached to that and so you had a dispersion around the site from the radiation, from the -- it wasn't shielded by the applicator cone.

MARK SEDDON: Is that multiple infractions?

CLARK ELDRIDGE: I think just one. It only occurred on one fraction. They thought they'd done -- there were two people working on it and they

got sidetracked and walked out many room for, you know.

MARK SEDDON: Usually there's an interlock that -- on the most of them, they have, if you're missing the applicator, it will -- there's a forced interlock that will force you to have it on there.

CLARK ELDRIDGE: On there, so yeah. So that was --

MARK SEDDON: Had they done a deep dive on that? Like --

JAMES FUTCH: Somebody hit override maybe?

CLARK ELDRIDGE: Who knows. That was not discussed in the claim.

And then in February, wrong prostate patient. They messed up the time out, which is not an uncommon occurrence where you get your people out of order from the treatments on the screen and don't double, triple check their I.D. and end up providing the wrong treatment.

And ongoing issues, or other outstanding issue or incidents, there is -- we're currently working through a proton therapy -- I didn't talk about this last time. I checked to see, see it in the minutes.

This is a patient treated in 2018. They developed a C4 transverse cervical myelitis in 2020.

Investigation revealed there was a machine issue during the patient's treatment in 2018 that caused the patient to receive six seconds of unscanned posterior/anterior beam through the C4 area.

JAMES FUTCH: Is this the one where they -- they didn't realize the beam was --

CLARK ELDRIDGE: Nobody had a clue the beam was on.

JAMES FUTCH: It wasn't a treatment beam.

MARK SEDDON: In service.

CLARK ELDRIDGE: Right. Okay. So what occurred was there was a system error when the therapist attempted to initiate the treatment.

And this was apparently a common feature that this machine was throwing up errors and they would just push the button again and it would override and begin the treatment.

In this case, though, this was a proton beam, of course, so it's got a Cyclotron operator separate from the therapist and the Cyclotron operator put the machine in a diagnostic mode when he saw the error since apparently, it wasn't one of the common ones.

The therapist, on the second time they tried to initiate treatment, it opened up and let the

diagnostic beam out but did not initiate the treatment. So the beam -- and then it shut down.

So what had happened was previously, there had been a service upgrade. During this period, you put in overrides in the safety features. So there's actually a sensor at the beam stop delivery that actually measured the quality of the proton beam. Is it a treatment beam or some other type of beam? It only opens the shutter if it's a treatment beam. That override was written, was left in place from the previous service, and so it actually opened the shutter and let the beam out.

Then without knowing it, of course, the next -- a little while later, they had another service upgrade and this time the technicians came in, instated the safety overrides, did their stuff, removed the safety overrides, so it was a self-healing event that nobody knew occurred until the individual actually showed up two years later with a transverse cervical myelitis, and they had to go back and in and first they checked the therapy logs and saw nothing and then the vendor for the Cyclotron went through their logs and found this blip in the system, so to speak.

MARK SEDDON: So it's an equipment software

malfunction.

CLARK ELDRIDGE: Right. That's a good --

MARK SEDDON: Not a user error.

CLARK ELDRIDGE: Not a user error, other than it was obviously triggered by some sort of lack of communication of the status that we're still trying to figure out where that is.

JAMES FUTCH: Do they have a good grasp of what the service beam looked like from a radiation standpoint to see what the patient actually got?

CLARK ELDRIDGE: They've done some calculations and it was equal to or greater than the treatment dose straight through a pencil through the back, through the neck right where the --

MARK SEDDON: Right. And was this a single occurrence? I thought you said this was happening, a lot of errors popping up?

CLARK ELDRIDGE: This was -- this happened one time.

MARK SEDDON: Oh, one time.

CLARK ELDRIDGE: One time.

MARK SEDDON: One patient, one time.

CLARK ELDRIDGE: One patient, one time.

JOSEPH DANEK: Clark, a question for you. Typical medical event like the one you're talking

about right now, I guess it winds up reported to the NRC and it winds up -- I'm just trying to understand the reporting requirements and how everybody else within the State and within the country is aware of an event like this happening that uses, you know, similar equipment.

CLARK ELDRIDGE: This is a machine so there is nothing but the State to be reported to. Now, there are voluntary organizations that this facility is part of the Royals, which is a AAPM and ACR initiative to gather medical event reports and publish and educate them.

And we're, ourselves, are looking at whether or not, trying to finish this up and trying to see if we need to issue some sort of guidance that would actually focus on the communication between the Cyclotron operator and the therapist.

JAMES FUTCH: Where's FDA in this particular type of machine? Food and Drug Administration.

CLARK ELDRIDGE: Yeah, right, right. I'm not sure what you mean.

MARK SEDDON: Normally when you have an equipment malfunction, you report it to the FDA.

JAMES FUTCH: Or device experience network or any of the mechanisms for reporting things that went

wrong.

CLARK ELDRIDGE: I don't know the names -- we actually haven't put together a report on that yet for FDA, so --

MARK SEDDON: Yeah. Because normally, if you have an equipment failure or suspected equipment failure, sites will go ahead and self-report it to the FDA.

ALBERT TINEO: Right.

CLARK ELDRIDGE: They have not told us they have done that.

ALBERT TINEO: On the medical events, do you guys require them to submit a corrective action plan on how they're going to --

CLARK ELDRIDGE: Correct.

ALBERT TINEO: -- avoid it from happening again?

CLARK ELDRIDGE: Yes.

JAMES FUTCH: So we haven't talked about this this particular meeting, but we've talked about this extensively in previous meetings. I think some of you, one of the information notices touches on some of these criteria. I don't think Joe is familiar with that.

JOSEPH DANEK: Yeah.

JAMES FUTCH: There are extensive, detailed parts of 64E-5 which gives several criteria for reporting at different levels and different reasons.

MARK SEDDON: I would be curious, like, since you, you had that draft information notice for the medical event definition for wrong site. Taking that framework and applying it to the existing reported events, would they still meet the requirement of a medical reporting or do you guys look at that?

CLARK ELDRIDGE: This event?

MARK SEDDON: Not this one, but the previous four you mentioned.

CLARK ELDRIDGE: I mean, all the previous four were reported to us based on the criteria in the code.

MARK SEDDON: The existing criteria.

CLARK ELDRIDGE: The criteria. That's why we know about them. They reviewed the case and saw they met the criteria for a medical event and reported them to us.

MARK SEDDON: Right. I'm just curious for, as you make the clarification, medical event clarification, information notice, if that would, would that have changed their reporting at all?

CLARK ELDRIDGE: No. Because these were obviously wrong location --

MARK SEDDON: No. Okay.

CLARK ELDRIDGE: -- you know. None -- in these other cases -- well, in all these cases, there was the, um --

MARK SEDDON: The outside field dose is significantly higher.

CLARK ELDRIDGE: Right. Right. Like the leg, it was clearly the wrong lesion.

MARK SEDDON: Right.

CLARK ELDRIDGE: There was a focus, the target lesion was completely out of the treatment area.

MARK SEDDON: Yeah.

CLARK ELDRIDGE: And as far as the T4, there was, I think it was more of a, what you want to call it, not a doughnut but a lobes, the lobes were shifted.

MARK SEDDON: Right.

CLARK ELDRIDGE: So there was -- they actually treated the T4 properly, but then they got the other -- no, excuse me. I forget. They treated one side pretty well, but the other one was completely missed and they treated additional vertebrae.

MARK SEDDON: Yeah, because normally we see

from, from multiple -- for fractionated delivery doses, if there's a, like where you missed an applicator on a single fraction, based upon how many fractions there are total, generally that would not -- because the patient is still shielded, so there's still shielding on the patient. I guess it depends on where you're treating, what the fraction, number of fractions would be. But you may not see, necessarily, the -- to meet the criteria for excessive dose outside of field.

CLARK ELDRIDGE: Right. Right. If there was another scatter from the electron beam that it --

MARK SEDDON: Right.

CLARK ELDRIDGE: -- it dosed significantly outside. But if it wasn't an electron beam --

MARK SEDDON: Yeah.

CLARK ELDRIDGE: -- yeah, you could've had no --

MARK SEDDON: If someone forgets a bolus or something like, that that might happen. You wouldn't see a significant change in the profile to the target. And I know, like, at the national level, probably maybe me and Cindy talked about, we looked at changing medical events or abnormal occurrences, what's reportable, right? Was that

discussed last week?

CINDY BECKER: Yeah, it was. They did a presentation on how they collect the medical events from the different states. Now, some of what the discussion was, they wanted more diagnostic events reported, even though they may not meet the criteria of medical events because they're trying to see what really is happening out there in order to potentially, you know, look at how to change the definitions.

MARK SEDDON: Right.

CINDY BECKER: So there was that. And we do submit ours to the CRCPD committee that pulls those together.

MARK SEDDON: Okay. All right. Do they give you guys feedback when you submit to NCR or CRCPD?

CINDY BECKER: Give us feedback? I haven't seen much as to the way of feedback. Now, their summary of what they collected is pretty good feedback, and they do that annually at the meetings, but you can also, anytime you want, get a list of those.

MARK SEDDON: Okay.

CINDY BECKER: What's been submitted.

MARK SEDDON: Yeah, yeah, I've seen those. I

get those for our meetings.

CINDY BECKER: And then they had a whole discussion on the Royals.

MARK SEDDON: Right.

CINDY BECKER: And AAPM had a couple of different presentations that were good.

MARK SEDDON: Yeah. Yeah. I mean, there's a huge patient safety focus with the AAPM --

CINDY BECKER: Yeah.

MARK SEDDON: -- and the Royals in our society. It's a very effective tool to see what's the trend and what current trends are going forward.

CINDY BECKER: Right.

CLARK ELDRIDGE: Okay.

CINDY BECKER: I didn't really quite answer what your question was on that, but, I know that they've been looking at it. But you would probably hear it quicker than we would --

MARK SEDDON: Right.

CINDY BECKER: -- from AAPM. Melissa Martin gave a talk and she's always very good.

MARK SEDDON: Yep. She's great.

CINDY BECKER: And Kate Pagin (ph).

MARK SEDDON: Kate Lawson (ph).

CINDY BECKER: Yeah, she did a talk. Can you

get the transcripts from that, because we can get them.

MARK SEDDON: Um, I'm not sure. I haven't looked for it, so --

CINDY BECKER: Yeah.

MARK SEDDON: Thank you.

CLARK ELDRIDGE: We also had a reported, not a reported diagnostic or interventional event, fluoroscopy incident in March. A patient received over 19 Gy during a double angiogram interventional treatment. It was a complicated treatment. It was, you know, took much longer than was anticipated. And it was found that they -- the staff wasn't able to hear the audible radiation exposure warning. So, you know --

MARK SEDDON: How many times?

CLARK ELDRIDGE: Once you hit 5 Gy and every Gy thereafter, it's supposed to say, you know, alert. And they just worked right through it and either didn't hear it or ignored it or something. So apparently, it wasn't sufficient and that was one of their fixes to make sure that they could actually hear the warnings and adjust their practices to make sure, you know, to make appropriate decisions. Not that this was truly a medical event under our codes

because it was medically necessary. It was medically necessary.

MARK SEDDON: I guess that's a question because the sentinel event from one commission, so when you have excessive skin exposure for fluoro, it's not -- it doesn't fall under any of the current definitions for you guys.

CLARK ELDRIDGE: Right.

MARK SEDDON: So they reported it just as a, oops, tell us what to do?

CLARK ELDRIDGE: Yeah. There is a, there is a non -- there's a -- what am I trying to say? In the, in the dose area of our codes, the part three, where it's talks about general radiation safety and dose limits, there are limits there that are nonspecific, which are odd -- limits are supposed to report to the State any times these -- a member of any occupation or public or whatever exceeds these limits. And it's a very general statement. It explicitly excludes medical and it doesn't make sense since there are a lot of medical procedures that exceed that.

So in our discussions with this individual, our thought was, well, you could take a look at it as being if the medical procedure is greater than

the -- if this is a -- over the expected dose for medical procedure is a way to interpret it because obviously, the medical expected dose for medical procedure would be the floor of sort of what the -- you're measuring from. Because that was what was determined to be needed for that patient during this procedure. And if you exceed the limits that are in the part three by that amount, then you, you know, considered reportable. So there is a, sort of convoluted reporting requirement for excessive exposures in a medical event, in any sort of patient-centered event.

MARK SEDDON: Yeah. That's challenging, though. I'm not sure the other folks -- because it is interventional procedure directed by the physician determines it as medically necessary.

CLARK ELDRIDGE: At the time, although the issue in this is since the physician wasn't getting the feedback to make that decision during the procedure.

MARK SEDDON: Right. So he had a problem with the -- he wasn't aware.

CLARK ELDRIDGE: He wasn't aware, so that's really what this case was about or this issue was. They weren't aware they were exceeding the exposure.

They were preoccupied and so they couldn't make the decision -- they didn't have the information to make the decision that the dose was actually medically necessary.

MARK SEDDON: Right. Now, I mean, to be honest, I don't know of any current equipment out there that doesn't display time and cumulative air current. Are you guys aware of anything? I mean old, old stuff.

CHANTEL CORBETT: No. There's some old stuff out there.

MARK SEDDON: There's old, old stuff but --

ALBERT TINEO: Very rare, though.

CLARK ELDRIDGE: On the screen at the top corner, but if you're in the middle or something, you're not necessarily watching that and part of it I think is the audio alarm would have either been turned down or adjusted some way that they weren't hearing it.

MARK SEDDON: Yeah. They silence it.

CHANTEL CORBETT: I mean, in most of the IR cases, even with the older stuff that's not audible or whatever, you've got enough people in the room that one person is assigned to watch that, you know, and --

MARK SEDDON: Yeah.

CHANTEL CORBETT: -- be that verbal or nudge or whatever at the 5 Gy.

MARK SEDDON: The NCRP has a recommendation that once you get to 3 Gy, that every Gy is a notification to the operator that they have got 4Gy, 5Gy, 6Gy, and so on, so they can make the determination when they need to wrap it up if the intervention is not being successful. As I say, the physician has to know how long they've been working with that patient at that location to determine if they've exceeded skin dose considerations.

CHANTEL CORBETT: Yeah, because I mean, obviously, you know, you used to go by time but that's -- with the synay (ph) and everything runs these days, you can't go by time anymore. You have a very quick case that goes on very quickly.

MARK SEDDON: No.

CLARK ELDRIDGE: No.

NICHOLAS PLAXTON: Probably in some of these ORs, they have a, a lot of music blaring. So I don't know what was going on in this situation or if they looked into it.

CLARK ELDRIDGE: Their written statement just said they were unaware of the -- that they were not

receiving notifications of the --

MARK SEDDON: In the OR, I mean, there's alarms going off all the time. So they silence all the alarms.

NICHOLAS PLAXTON: Exactly.

CLARK ELDRIDGE: It could've been competing alarms for all we know; things like that.

ADAM WEAVER: Same frequency.

NICHOLAS PLAXTON: Maybe they can make it so, like, the imaging they're looking at starts strobing, you know what I mean? So like, it will be like, hey, what's wrong with this thing? And then when someone checks it, oh, you're over your dose limit. Because you couldn't shut it off because if you shut it off, then that could be a problem. But if you cause it to strobe a little bit.

CHANTEL CORBETT: Change the color of the screen.

NICHOLAS PLAXTON: Yeah. Change the color of the screen or something.

CLARK ELDRIDGE: Go from green to red.

NICHOLAS PLAXTON: Yeah. Go from yellow tint and then a red tint.

CHANTEL CORBETT: Right. Yellow, orange, red.

NICHOLAS PLAXTON: Yeah.

MARK SEDDON: Right. Of course, normally what they do, the physician operator will go ahead and reposition to change it to an angle so they can, again, you're worried about skin dose to certain locations.

NICHOLAS PLAXTON: Sure.

MARK SEDDON: It's just a change of angulation is enough to minimize that. Because A lot of times, we, from our facilities, that we have anything over 10 Gy, we do a deep dive calculation to determine what the actual applicable -- that's just telling you what the applicable machine was. It doesn't tell you what the actual patient's exposure was. They actually need to go and determine what that really was, was it a change of angulation, was it a biplane.

So I can see where, report like something where unattended, unknown exposure would make sense where, you know, I've heard those situations where like, they had a biplane and they thought they were using a single plane and didn't realize the lateral tubes actually engaged throughout their treatment, imaging the patient, things like that are, have occurred anecdotally happening around the country. So that would, I think, would be reportable to you guys as a

problem following that statute you mentioned, part three would make sense. It would be more challenging in this situation where they actually have complete control of the procedure by the physician.

CLARK ELDRIDGE: Right. And, yeah. I agree. We actually haven't been calling it medical or anything. Just an incident and a discussion because it really --

MARK SEDDON: Right.

CLARK ELDRIDGE: -- it was, you know, the medical necessary part of it is very important.

MARK SEDDON: Yeah.

CLARK ELDRIDGE: You know.

MARK SEDDON: Of course, they have to do, for FDA, they have to follow up with the patient for skin reactions, where appropriate follow up.

CLARK ELDRIDGE: Okay. Any other?

Okay. You all have three draft information notices that I was -- I apologize for not getting out to you earlier. I did not want to send them too early to people and then with the CRCPD meeting and whatnot, I didn't quite get them to James or Brenda in time to e-mail you all out. E-mail them out to you.

We could, if you all want to look over these, we can talk about these after lunch first thing or --

MARK SEDDON: Yeah.

CLARK ELDRIDGE: I can go on to my next stuff.

JAMES FUTCH: I think that makes sense. There's three pages of it you probably want to absorb a little bit.

CLARK ELDRIDGE: All right. So at this point, I have to turn my seat.

JAMES FUTCH: I'll be your back up.

CLARK ELDRIDGE: Okay. See what's happening. It hasn't woken up yet.

All right. This is the presentation I gave at the CRCPD meeting. I'm not going to actually do the full presentation. I'm just going to kind of talk about the points I made at it.

So this is about, I discussed our ongoing investigations to the non-compliant x-ray systems, which are basically dental handhelds. So the main thing is how, what -- in this case, what are we calling non-compliant? Basically, it's a machine that's never went through FDA approval. So there's no demonstration of compliance with the FDA radiological safety sections of Title 21 and the --

they've never gone to get the FDA approvals.

Let's see if I can -- I don't know. Maybe the, maybe -- I had to switch the thing around. Maybe it's not engaged properly. If you go ahead.

All right. So the Health Protection Agency this is in the UK, part of the UK radiation, Center for Radiation, they looked at one of these handhelds and, you know, what was that? What's the total dose there? Let's see. Where's the annual dose? There it is right there.

So they are saying 40 Sv to the hands for, if a dental hygienist was using this machine that they looked at, and they did five patients a day with four bitewings per patient for 50 weeks in a year, so -- which would be a full, that would be a full use of x-rays. That's on the, you know, they would be getting 40 Sv to the hands. So that's a lot of dose to the hands that would cause neurological damage and things like that.

So James?

JAMES FUTCH: Sorry.

CLARK ELDRIDGE: So the main key identifier on these machines is lack of labeling. Now, we've seen two types of machines come in. In this case, one can have absolutely none of the required FDA

labeling or any normal labeling such as what the power res. is, who the manufacturer is, serial numbers; that sort of stuff.

But the other key thing is the FDA compliance sticker that says this device is compliant with title, CFR21, Title 21, subpart (j). So what you have here is the actual unit that I'm going to show you in the front of the room and then the other one is a Vatech. Some of you may know Vatech is a Korean manufacturer has put a lot of machines through FDA approval, but they actually still have international models that haven't been approved for use in the U.S.A.

So where these folks finding these? They are going online. They're finding, they're actually showing up on several of your large online marketplace and auction sites and they look sort of like normal stuff. They make it sound get your really cheap handheld x-ray. That's the big deal. These things cost anywhere from 3 to 1500 bucks. When your FDA compliant unit start three times that and go up to, you know, so they might be $2,000 to $6,000.

JOSEPH DANEK: So it's not on the Amazon Prime site yet?

CLARK ELDRIDGE: Excuse me?

JOSEPH DANEK: It's not on the Amazon Prime site yet?

CLARK ELDRIDGE: I'm not allowed to say the names of the large, open manufacturers, but Mr. Joel Gray from Dycon is very good going to sites like that one and putting on there this is not an FDA compliant device in the sales. If you ever look up one and look through the descriptions, you might find his comments there.

So our response protocol has been to, you know, send them a -- the inspectors have been finding these and sending them a letter saying, our statute says you've got 90 days to come in compliance. We give them a suggested list, such as convert it to industrial. We tell them if you need to, you can take it to the FDA compliance and get it approved through FDA and then we file a report on what we found with FDA.

James? Next.

This is the list to date. I went over through these in detail during the meeting. But, you know, this BLX is a common moniker for these devices coming out of China. There's a range of numbers from, like, four to ten or something like that.

That none of them -- a number of businesses manufacturer a device under the same model name. The manufacturers, a lot of them have very similar names. And it's -- if you ever look at this, if you ever want to be -- I'm not sure if the word entertained is proper, you go to Alibaba and you search for x-ray machines and you look at their handheld machines and watch the demonstration videos. How they demonstrate the machine's working. And so the model will show it. We'll turn around and then they will put their hand in it and show you on the fluoroscopic image, they'll go, look at my hand and move it back and forth and they'll pull it out.

So, next.

So I went and described to these people, to the CRCPD members, participants, what responses we're getting back. We had one person send us this certificate of FDA compliance they get from the vendor. Which was some -- an engineered testing form that they might have submitted to FDA to demonstrate compliance, but it was just from the manufacturer. It wasn't actually FDA.

The vendor -- the registrant that had the Vatech, called up FDA and tried to convince them it

was a wonderful machine they had. Meanwhile, we had actually e-mailed Vatech in Korea and they e-mailed us back saying, no, that one was never submitted for FDA. That model is not one for the U.S. market.

And the distributor was rather indirect on it. Basically saying, we cannot trade products sold from our countries, but they wouldn't come out and say this wasn't -- the U.S. distributor wouldn't come out and say, oh, no, you can't -- that's not a U.S. model. They wouldn't actually say that, which is kind of funny. They did offer to sell them a whole new set to replace it.

James?

For getting rid of them, you know, we had the folks like, here's the vendor form we had submitted. Another guy disassembled his unit and sent us pictures as sort of proof of death. Here it is. I got rid of it. I took it apart.

And then, James, one more.

And then, as I'm writing this presentation, in comes another report from one of our inspectors where they found another unit that we haven't finalized. Ninety days isn't enough. We haven't finalized this case with them and how they're going to dispose of it and deal with it.

All right. So now, let's see if we can get the -- this will be fun since I will be doing the weatherman thing. I'll move it one way and it will go the other way on the screen, right?

So this is just kind of a generic, non-specific housing, right? You know, there's a power button here (indicating). This has an external power supply. So here's the power coupling. It's got this really kind of medium-weight plastic that's threaded to receive -- put it on a mount, put it on a tripod, something like that.

This is their source to skin distance cone. It's 100 cm and our code is 30, right? The FDA is 30.

Anyway, nice little foam plug in the housing. Open it up. And anybody here ever open up electronics anytime in their life, looked inside, you know? Things are built with hard points and screws to hold the pieces in place. You don't use rubber foam blocks to hold things, to align them.

We'll get this right. Okay. So rubber foam blocks to align them. If you don't know how it's going to -- you can't see it. So looking at this, this is the foam plug and the rings for the aperture is right here off center. So the whole -- so -- but

it is wrapped in lead. They do have an aluminum filter on it. It's held in by a screw and ring and that's threaded.

The only thing on this that is any sort of standard sort of quality construction is they do have threaded inserts to, thread inserts to receive the screws when you put the housing together.

David O'Hara, who works for me, is an electrical engineer and he took apart the power supply and he said it was really scary. The quality of the construction of that, but -- so this is, you know, the extent of the columniation, as in none. And the only backscatter shielding, which is basically two leakage shielding.

So that's why you don't want to buy your x-ray machine from a large online marketplace and auction site.

NICHOLAS PLAXTON: Do they have packing tape that holds it? It looks like there was packing tape.

CLARK ELDRIDGE: Yes. They basically rolled the whole thing in packing tape covering it, on top of it.

NICHOLAS PLAXTON: That holds it together.

ADAM WEAVER: To hold that filter in place.

NICHOLAS PLAXTON: Amazing.

CLARK ELDRIDGE: It's actually screwed in. There's a nice little screw set.

Who knows, maybe the screw -- I haven't thought about that. If I cut this, will the actually screw mount will come out? It's possible the screw mounting is being held in place by the packing tape.

ADAM WEAVER: They covered it so it wouldn't interact with the glue.

CLARK ELDRIDGE: As for the foam on the front, who knows.

ADAM WEAVER: Yeah.

CLARK ELDRIDGE: All right.

JAMES FUTCH: Do we have time for questions?

CLARK ELDRIDGE: Okay. I'm done until we --

JAMES FUTCH: Questions? Questions, anyone?

NICHOLAS PLAXTON: Where are we going for lunch?

JAMES FUTCH: I see what he said. The important part of the agenda, right? I think Brenda has some information if you're ready for that.

MARK SEDDON: Yeah. If there's no questions for Clark, I think you want to continue after lunch?

CLARK ELDRIDGE: Yeah.

MARK SEDDON: Okay.

CLARK ELDRIDGE: If most people want to go into it now, we can wait until after lunch.

MARK SEDDON: We should wait until after lunch. This might be a lengthy discussion.

BRENDA ANDREWS: Okay. So we made arrangements with the Hilton Garden Inn. It's just walk across the parking lot for lunch. And they're waiting for us. And we can order individually. They did not say that it was a minimized menu. So we'll see you when you get there.

JAMES FUTCH: So what time did we want to return, do we think?

BRENDA ANDREWS: We're scheduled to return at 1:30. It just depends on how fast they can serve us.

JAMES FUTCH: Hopefully by 1:30 they will have served us and we'll be done.

BRENDA ANDREWS: And also, your packets include your travel, for those of you who haven't looked through everything. There's three sheets in there. One is your authorization for you to sign and then two sheets in there with just a signature block. And both of those need to be signed. That's going to be your reimbursement once it's printed out. And if you don't have any receipts or anything that you

need to wait to give to me, you can go ahead and sign those before you leave today and put it in the envelope and give those to me.

CHANTEL CORBETT: Are they locking the room or no?

BRENDA ANDREWS: I'm sorry?

CHANTEL CORBETT: Are they locking this room?

BRENDA ANDREWS: I can check and see if they're going to.

CHANTEL CORBETT: I don't know if I should leave my laptop or not.

JAMES FUTCH: We usually try to have them lock the room.

MARK SEDDON: Yeah. Usually.

JAMES FUTCH: I'll hang out here, then you don't have to worry about it.

CHANTEL CORBETT: You're volunteering to starve yourself?

JAMES FUTCH: Yeah.

CHANTEL CORBETT: Let me ask.

CINDY BECKER: I'll go see if they'll lock it.

JAMES FUTCH: Shall we adjourn?

MARK SEDDON: So we can adjourn for lunch. We'll come back at 1:30.

(Proceedings recessed at 12:04 p.m.)

(Proceedings resumed at 1:33 p.m.)

MARK SEDDON: We can go ahead and get started. So back in session.

So we were in the middle of Clark's presentation, so we'll start back with up Clark, okay?

CLARK ELDRIDGE: All right. So in your packet, as I said before, we have three draft information notices for you all to review, comment, suggest.

MARK SEDDON: Any questions for Clark? I guess we'll go one by one. So the first one is what you kind of shared previously believed.

CLARK ELDRIDGE: I e-mailed you and I don't know that it was shared.

MARK SEDDON: So for the medical event definition for on site, I did present this at the Florida chapter meeting and with minimal to no comments or discussion about it. So unlike previous years where I've presented different versions, where there have been lots of comments, this one seem to be in pretty good agreement with it.

CLARK ELDRIDGE: Now, I'm not sure if National AAPM has something in the works or not, because I've got two people working on one of their committees or, excuse me, CRCPD committees where they've got

advisors on and they mentioned something. One of my folks repeated something to me that I'm not sure I have it right -- it sounded really good, but I'm not exactly sure what it was related to. I thought it was what part of the, was it a geometric miss or part of language for describing another situation or not.

So there may -- this may even go forward or if I get some clarification, I might come back with something different.

MARK SEDDON: Okay. I can reach out to my folks in AAPM and see if they're -- one of our physicists is actually involved with all the therapy safety committees with AAPM, so we can find out if there's something else can be worked out. I'm not aware of anything, but I'll doublecheck.

CLARK ELDRIDGE: As I say, they're working on some other -- they're working on a -- the CRCPD committee is trying to revisit --

MARK SEDDON: Revisit ten, right?

CLARK ELDRIDGE: The suggested regs on therapy and so they were discussing some of that. And I heard some language that, again, but this is --

MARK SEDDON: Secondhand.

CLARK ELDRIDGE: -- I just spoke to so-and-so;

this is what I heard, read me something, it sounds real good. Can you forward it to me? They didn't forward it to me and now they can't find it, so --

MARK SEDDON: Right. Yeah, I know they're revising that, the existing regulations, which I do believe it does have a piece with the clarification on this.

CLARK ELDRIDGE: Right. So they actually -- the version I saw, the draft that was forwarded to me later was actually almost the same language that's currently in our regs and they did not go into sort of the geometric miss, if that's kind of a phrase that's used to -- where the epicenter isn't quite lined up, but you still get most of the --

MARK SEDDON: So the, the debate is whether to define it strictly or to leave it up to the discretion of the, of the sites to determine whether it is a geometric miss or not, so I think that's kind of where, kind of the sticking point is. Some physicists who would like to have something like, as physicists want, give me a number, give me an action level. And other folks are like, well, there's no impact on the patient, so why are we worried about it? That's because the opposite side of the folks, so it's an error, but if there's no change in

treatment plan, then why are we splitting hairs. So I think it's both sides of the fence there.

I'll, I'll reach back out to my folks, too, and find out.

CLARK ELDRIDGE: Okay.

MARK SEDDON: Any comments on the first?

ALBERT TINEO: No.

MARK SEDDON: Anyone else? I know Dr. Williams is not here so, all right.

CLARK ELDRIDGE: All right. There used to be Information Notice Number 4 that was pulled quite -- I don't know how long ago it was pulled. I just know it was in effect when I started in 2016. It focused on interventional physicians and allowing them to have weighting factors. Our code doesn't restrict it to interventional physicians. It's anybody who, it's appropriate to use weighting factors for, can use them. So anybody in the, in an interventional setting, in the OR, wherever, where people are actually wearing personal shielding as a personal, personally on their body as supposed to personnel as in -- so we, we rewrote this.

They also were -- it also specifically mentioned a, a specific method for weighting factors, which again, our code doesn't support that

directly. So I generally took it, we generalized it; basically said whoever is appropriate to be covered by weighting factors, what's the appropriate method? Show us something that's peer reviewed and been adopted through AAPM, ACR, recognized by NCRP or ICRP, some other international or national, international standard setting or consensus body, that type of group, that has reviewed it and said, yes, this works. So that's the crux of this -- those weighting factors.

JOSEPH DANEK: I got a couple questions on it.

CLARK ELDRIDGE: Please, fire away.

JOSEPH DANEK: For clarification or whatever. Item C says, the method and calculation to be used in determining the weighting factor, which I understand. But when they do that, that also includes providing the weighting factor value, values that they are going to use, right?

CLARK ELDRIDGE: Right.

JOSEPH DANEK: I mean, 1.0 is going to be 0., whatever it is. That's part of it, so they have to provide you what those values are.

It says the method and calculation to be used in determining the weighting factor. I would think the actual weighting factor value would have to be

--

CLARK ELDRIDGE: Right. It should be, it should be -- you're right. Now that you mention that, the language should be something more along the line of, the weighting factor in the method and value for determining the effective dose or the method and --

JOSEPH DANEK: Yeah. Just maybe reword it a little bit. You want the method and calculation to be used.

CLARK ELDRIDGE: Right.

JOSEPH DANEK: And what is the weighting factor value, provide that as well so you know what that is.

And then Item E, that first sentence I'm trying to understand. The second sentence I understand, but the first sentence I'm trying to understand a little better. That's really mainly from the fact, a statement of personnel, a statement that personnel who have their doses calculated using this method, will be informed annually of the original dosimeter measurements. What does that mean, the original dosimeter?

CHANTEL CORBETT: The unweighted.

CLARK ELDRIDGE: The unweighted. The fact that

you've got one batch method, two batch method. Here's what the actual dosimeters read and here's where we put it through the calculation.

JOSEPH DANEK: Okay. So, you want to put unweighted in there or people understand original, parentheses unweighted, or you think it's understandable?

MARK SEDDON: Say unweighted. I mean, I understand what you're saying. Original is maybe slightly confusing.

CLARK ELDRIDGE: Okay. Yeah, okay. dosimetry readings --

CHANTEL CORBETT: The most clear would be unweighted.

MARK SEDDON: Unweighted.

JOSEPH DANEK: You can put in parentheses or something.

MARK SEDDON: The unweighted dosimetry measurement and --

ADAM WEAVER: I think original confuses people.

JOSEPH DANEK: It's confusing me a little. I wasn't quite sure.

CHANTEL CORBETT: So you just mentioned one batch method, two batch method. So, if you're doing a two-batch method in Landauer, for instance, the

batch company is applying this, is that considered under this to have to be a requested item?

CLARK ELDRIDGE: Yes.

CHANTEL CORBETT: Okay. Just clarifying.

CLARK ELDRIDGE: I mean, if you've got Landauer doing your weighting factors for you, you have to come to us before Landauer can apply them.

CHANTEL CORBETT: And if the facility has been doing this for years and years and years and you can't locate that permission request slash whatever.

CLARK ELDRIDGE: Just resubmit, do it again.

CHANTEL CORBETT: Okay.

MARK SEDDON: That was my question. The facility has been doing this for many years, they have maybe some old documentation from way back in the day.

CHANTEL CORBETT: Yeah.

MARK SEDDON: So, resubmit everything new.

CHANTEL CORBETT: Okay.

MARK SEDDON: This is a little more involved than what was previously, I think. So, one of the questions I had was B, a description of the personnel subject to the alternative. So you say personnel. So, you want to identify, like, job classes?

CLARK ELDRIDGE: Something like, yeah. Like, right. Is it everybody? I mean, it's all the people working in interventional radiology, you know, something to state that --

CHANTEL CORBETT: Everyone using fluoro.

CLARK ELDRIDGE: Fluoro.

MARK SEDDON: Everyone uses exposures primarily with a lead apron in place or something like that.

CLARK ELDRIDGE: Something like that. You have something that --

MARK SEDDON: It can be challenging sometimes to identify job classes.

ALBERT TINEO: Yeah.

CLARK ELDRIDGE: But we need some description of where they're working, what the condition is that's putting them in this situation.

MARK SEDDON: Okay. And then --

CHANTEL CORBETT: And those definitions, I guess, are going to be passed to the inspectors and then they're going to have to play the game of determining what those things mean? Yeah, that sounds a little onerous on inspectors.

MARK SEDDON: Well, I don't think -- inspectors haven't really been looking at this.

CLARK ELDRIDGE: Yeah. Inspectors are actually

supposed to be looking to make sure your, your RPP is up to date and been reviewed and all that, but they're not necessarily going to be interpreting everything in the RPP. They're just --

MARK SEDDON: Make sure it's present.

CLARK ELDRIDGE: They will make sure it's there.

CHANTEL CORBETT: I think my comment was if every facility submits their request is submitting their own description of who they're going to apply this to, it may get a little crazy because you may end up with 60 different versions of this job description or that to, you know, determine who's going to be able to use those.

MARK SEDDON: I understand. You're trying to keep it open ended to allow every facility to kind of use it rather than putting in --

CHANTEL CORBETT: Right. It benefits the facility. It just not necessarily benefits the inspectors.

MARK SEDDON: Right. I guess the --

CINDY BECKER: It used to be.

ADAM WEAVER: What if one facility does it one way and another facility does it a different way, as long as it's in the RPP, that still makes it hard

for the inspector to say, Facility A did a weighting factor for this, a weighting factor for Facility B has the same job function, but for some reason they're not --

MARK SEDDON: Right.

CHANTEL CORBETT: They're not applying it.

ADAM WEAVER: Yeah, they're not doing it or a different weighting factor, you don't like Landauer's method or whatever, or someone else's method. Or maybe they're not weighing lead aprons and they're in the whole --

CHANTEL CORBETT: Yeah, you've got some facilities where they're not going to have to do this, obviously.

MARK SEDDON: Yeah.

CHANTEL CORBETT: And others where they only do interventional, or you're going to do everybody in fluoro or everybody in x-ray.

ADAM WEAVER: Right.

CINDY BECKER: What about, Adam, remember when the inspectors used to go out, they used to ask for the approval letter from the x-ray.

CHANTEL CORBETT: I can't tell you the last --

CINDY BECKER: But that's right. It's been a long time ago.

ADAM WEAVER: Yeah.

CINDY BECKER: If you go back to the radiation protection program and it's approved, then that's what you could look for.

CHANTEL CORBETT: But the template radiation protection program is used by so many people.

CINDY BECKER: That's correct.

CHANTEL CORBETT: And it's not nearly that in depth, you know.

ADAM WEAVER: I don't think the templates, do they cover weighting factors?

CLARK ELDRIDGE: No, they don't.

CHANTEL CORBETT: No, they don't. Not at all.

ADAM WEAVER: I didn't think they did, so --

CLARK ELDRIDGE: There's actually nothing from them taking the standard radiation protection program and appending an addendum to that for the weighting factors. I mean, I don't think you have to come replace the whole template one.

ADAM WEAVER: I guess my question with Item D, you cannot use this retroactively, correct?

CLARK ELDRIDGE: That's always been the case.

ADAM WEAVER: Yeah. If you're doing it for an investigation and you think there was an overexposure, because Landauer or whatever the

employee did something different this time. What's retroactive?

MARK SEDDON: Yeah.

ADAM WEAVER: At what time point do you call it retroactive, I guess.

CHANTEL CORBETT: Yeah. And again, with the facilities literally, we've been doing this for double digit years going back with no documentation that we can currently find if you're going to resubmit, you know --

MARK SEDDON: Right.

CHANTEL CORBETT: The first question they're going to ask, are we going to get cited the next inspection now that they're looking for this, you know, if we've been doing this for twenty years.

MARK SEDDON: Is there a grandfather period?

CHANTEL CORBETT: Right. I mean, it's a true statement, though, I mean.

ALBERT TINEO: Yes.

CHANTEL CORBETT: You've got a lot of hospital facilities, you know, that have got, I don't know, 50 people who have gone through whatever that role is and there's no way --

CLARK ELDRIDGE: Right.

CHANTEL CORBETT: You've got the documentation

probably all the way back.

ALBERT TINEO: No way.

CLARK ELDRIDGE: No.

CHANTEL CORBETT: And we don't, you know, it's not to say that, obviously, we can submit this for every person out there, that's not a problem. But the first question they're going to ask is, on our next inspection, if they're starting to look for this and ask for this, are we going to get penalized for doing this without being able to find the documentation going back.

CLARK ELDRIDGE: I don't think there should be any problem with that if you make that --

ADAM WEAVER: Have you talked it over with the inspectors?

CLARK ELDRIDGE: Well, that would be part of the things we would educate inspectors now when we implement any new things.

ADAM WEAVER: Because I can see problems if they're doing two badge method and people switch badges around.

MARK SEDDON: That happens all the time.

CHANTEL CORBETT: That's why we use two badges because nobody can keep it straight.

ADAM WEAVER: That's right.

MARK SEDDON: They're both equal. Obviously, you weren't wearing one the other day.

CHANTEL CORBETT: Exactly.

CLARK ELDRIDGE: There was a recent case where they were using a two badge, and apparently, somebody picked up -- the badge was left on the apron and used that apron in a different procedure altogether.

CHANTEL CORBETT: Oh, yeah, yeah. Absolutely.

CLARK ELDRIDGE: They were using it to protect the patient or cover the patient and got -- it was --

CHANTEL CORBETT: Or they get left on when people test the lead every year.

CLARK ELDRIDGE: Yeah, exactly.

CHANTEL CORBETT: You try to catch it as much as you can, but --

MARK SEDDON: So we covered B kind of just -- I'm not sure if you want to do an example, for example, in the job description, just prime exposure is always, always involved with the lead apron in place or something of that nature to help guide the, the registrants.

And then for D, cannot be used retroactively. I don't know if you want to caveat that with like

a --

ADAM WEAVER: Some kind of --

CHANTEL CORBETT: I don't know if I want to put that in writing.

CLARK ELDRIDGE: It's the idea, yeah.

MARK SEDDON: Yeah.

CLARK ELDRIDGE: We may put that it could be for facilities that are renewing their --

MARK SEDDON: Right. Or maybe we ask everyone to renew their -- that could be somewhere here, you know, we're refreshing this and ask for all facilities who currently do submit their current practices and moving forward.

CLARK ELDRIDGE: Because we actually had that discussion with many facilities going through this for the last several years.

MARK SEDDON: Yes.

CLARK ELDRIDGE: It's been, we can't identify your current RPP on file. Please submit an updated RPP.

MARK SEDDON: Right.

CHANTEL CORBETT: I think that would be the cleanest way to do so.

MARK SEDDON: That makes sense.

ADAM WEAVER: Yeah, start all the same time

with enough warning to registrants.

CHANTEL CORBETT: Yeah.

ADAM WEAVER: This is going to happen, so be prepared to do it now.

CHANTEL CORBETT: Yeah. Because I mean, like, even with a cover letter to come back with your amendments for the RAM licenses, there's always a bold paragraph that says, like, the new guidance says you have to include the uses for each authorized user. Kind of the same thing, we can send out the letter, put a bold, you know, submit your current and then going forward, reminder that you're not allowed to use this unless you request a weighting factor or something like that.

MARK SEDDON: So, I also had a question about F. An individual works in multiple locations with exposure to multiple conditions. So I'm assuming you're talking about people working in multiple facilities.

CLARK ELDRIDGE: This is also the case -- I mean, this is probably very rare. But somebody who's working in interventional one day of the week and going and doing some other part of the other and how is that going to be or switches halfway through their --

CHANTEL CORBETT: Nuclear med, CT, I mean, it's not that uncommon anymore.

CLARK ELDRIDGE: Okay. But that's the problem is if they're using -- they can't necessarily only have one badge on them, right? I mean, they can't be using -- it almost is like, you have to be -- if you're doing CT one day, you've got one badge.

CHANTEL CORBETT: Oh, good lord, no. It's a badge for the facility. There's no way.

CLARK ELDRIDGE: No, that's the problem. How do we address the problem if somebody is going between modalities and all of a sudden, well, you're in the interventional room, where's this badge? Okay, that's going to be -- how do you -- how are we going to figure out what their dose is?

CHANTEL CORBETT: There's no way you're going to --

NICHOLAS PLAXTON: You're only supposed to use one badge. That's why you don't switch badges.

CHANTEL CORBETT: Right.

ADAM WEAVER: One badge per facility.

CLARK ELDRIDGE: Right.

ADAM WEAVER: People can be at multiple facilities, then you're going to have to do a summation.

CHANTEL CORBETT: Right.

CLARK ELDRIDGE: But I'm saying for some reason somebody is working, somebody is pulled into x-ray for a while to push images, they don't -- they're not wearing any shielding. They're not, they're just --

ADAM WEAVER: Right.

CLARK ELDRIDGE: The next day, they have to go -- normally they're working in interventional. I mean, this is probably a rare condition. I spoke with folks, our people never work if they're interventional, they don't work anywhere else in the hospital. They never work any other --

MARK SEDDON: I think that may go back to B where if you caveat that with, you know, for individuals, this is applicable to individuals whose exposure's primarily always with the lead apron in place. So that way it would capture interventional cardiologist physicians, radiologists or the, you know, CVTs who work only in those type of environments where they're always exposed with an apron on. That's where you can find the weighting factors because you have people --

CLARK ELDRIDGE: Right. But if somebody was to be in interventional for a month during the quarter

and then end up going to take --

MARK SEDDON: Right.

CLARK ELDRIDGE: -- work CT or in, regular radiography --

ADAM WEAVER: You don't get much from CT unless you got to be --

CLARK ELDRIDGE: The trick is -- you're not getting this from there, but at the same point, if for some reason they take their badge and apply a weighting factor to it, it's not properly representing what they actually were exposed to during that period because you're going to discount --

MARK SEDDON: It's a small fraction.

CLARK ELDRIDGE: Yeah.

MARK SEDDON: I think, I mean, so, okay. So here's a scenario. I've got physicians who work in multiple hospitals that I'm over and you want this weighting factor process specific to every registrant. So if they are wearing the same badge at multiple facilities, so how do you apply that across. You have to make sure every registrant has a weighting factor process approved so that they can go into that facility using that badge. How does that work?

CHANTEL CORBETT: So you're saying, like, they operate on one badge at, like, four different physical locations?

MARK SEDDON: Yeah, they're all on one license.

CLARK ELDRIDGE: They're all one, which isn't a problem.

CHANTEL CORBETT: To me, that's no different because how do you know which hospital the exposure came from, like, if you have a problem versus --

CLARK ELDRIDGE: That's true.

ADAM WEAVER: Different types of machines or different shielding. Somebody uses a light apron, someone uses a heavy apron. Because I've got a bad back, I'm not gonna --

MARK SEDDON: Right. Or someone, for example, who doesn't have, like, two different badges and then they work at one facility where they use weighting factors for their folks and then they go across the street and they don't.

CHANTEL CORBETT: Right. There's nine million issues.

MARK SEDDON: That scenario, too. That's an issue. I'm not sure, I wasn't sure that E, F was referring to that situation or -- you're referring to different modalities within the same facility.

CLARK ELDRIDGE: Same facility. Different modalities in the same facility is the intention there because when they're in different facilities, that's a problem for each facility and they're supposed to be summing over from the different facilities. And if you actually have --

MARK SEDDON: Right.

CLARK ELDRIDGE: -- a, in your group, you know, it's kind of a master overlord, so to speak --

MARK SEDDON: Yeah.

CLARK ELDRIDGE: -- who's coordinating that, then that's an acceptable RPP option that you're tracking it as a whole. And there is no --

MARK SEDDON: Right. Yeah, so we track over multiple facilities.

CLARK ELDRIDGE: Right. And that's just in your RPP. In fact, that's one -- a similar thing is dealing with what I'm -- we've had discussions with mobile providers and stuff about what kind of agreements do you have written out with your clients about how you're dealing with your radiation protection and stuff like that. So, did they understand all that. There's some written part of that. And so, you know, that's sort of the similar thing where you've got one -- you managing multiple

hospitals, people who are traveling between them. It's just -- it's understanding how the radiation protection is being done and how it's coordinated.

MARK SEDDON: Okay. Now, and then the second half of E where the individuals are signing a written statement. That's just the one time --

CHANTEL CORBETT: Annual, like the Form 5's, is that what that is?

MARK SEDDON: It says they understand there's several weighting factors being applied to their exposure.

CLARK ELDRIDGE: Um --

MARK SEDDON: So I guess again, going back to logistics, they have to have -- sign it for, if it's a physician who works in multiple facilities, they have to sign for every facility they're --

CHANTEL CORBETT: Badged at.

MARK SEDDON: Badged at, I assume.

CLARK ELDRIDGE: If they're separate badging. If it's one badging, then it's one process.

MARK SEDDON: And that's just one time.

CLARK ELDRIDGE: One time. I mean, we've had discussions whether it should be one time where there should be some reminders so they know that's part of the annual report.

MARK SEDDON: And I think it is -- Landauer, at least, you can see both.

ADAM WEAVER: Yeah, it's on the form. It's on the Form 5.

CHANTEL CORBETT: Yeah.

ADAM WEAVER: If you modified it --

MARK SEDDON: We don't use the other vendor.

ADAM WEAVER: If you use your own method --

ALBERT TINEO: They're all the same thing.

CHANTEL CORBETT: The problem with some of the vendors is that the Form 5's are not automatic so some of the clients don't want to pay that extra fee so they're manually writing out forms or something like that.

ALBERT TINEO: Right.

CHANTEL CORBETT: That would be have to be included in the reports if they do them manually.

MARK SEDDON: All right. Any other questions on, on this one?

ADAM WEAVER: I guess the only other question is the effective dose in the first part. Calculation of effective dose. We're really not changing the effective dose. I mean, you're just changing the overall dose. I mean, because you're -- I mean, because you're not, you're just

doing -- it's not a quality factor or a RVE or something of that nature where you're, you know, everything here is one. But now you're, you're changing the dose because of, you're saying someone's wearing an apron or not wearing an apron.

MARK SEDDON: Partial radiation, so you're changing the exposure.

ADAM WEAVER: Yeah. So you're really not -- I just, I just -- when you're using the effective dose terminology, it's not as I typically understand the definition.

CLARK ELDRIDGE: Yeah. Well, it's the way it's organized in the rule, so --

ADAM WEAVER: Right.

MARK SEDDON: Yeah.

ADAM WEAVER: Well, effective dose in the rule, I believe, usually in regards to, you know, organ weighting factors.

CLARK ELDRIDGE: Right. And so --

ADAM WEAVER: This isn't organ related to it, so that's why I'm just -- you need the word effective? Or reportable dose or -- I don't know. Just something to think about.

MARK SEDDON: Yeah. I think initially, that was what was in the previous language. That's

probably why it probably exists.

ADAM WEAVER: Yeah.

MARK SEDDON: Wasn't it -- I can't remember who was the physicist who came up with weighting factor you guys follow?

CINDY BECKER: Oh.

ADAM WEAVER: I mean --

JOSEPH DANEK: This wouldn't apply to organ -- the use of this?

ADAM WEAVER: No, it wouldn't apply. That's why.

CLARK ELDRIDGE: I mean, when you talk about whole external body, it is just one.

ADAM WEAVER: Right.

CLARK ELDRIDGE: It is effective, but as I say, the language, the way this was pulled out of the code, they referred to it as the whole body weighting factor of one in the code --

MARK SEDDON: Right.

CLARK ELDRIDGE: -- and using alternatives for that.

MARK SEDDON: I think even Landauer is EDE1, EDE2, that's what it's called, right? Using single or double.

CHANTEL CORBETT: Yeah, but they're opposite.

ADAM WEAVER: They're up to four options now.

CHANTEL CORBETT: Of course, they don't make it easy.

ADAM WEAVER: I believe, right?

MARK SEDDON: There's four options?

ADAM WEAVER: I think there's four options for Landauer.

CHANTEL CORBETT: Four? I don't use anything but the EDE 2000.

ADAM WEAVER: Yeah. Like a one badge method, two badge method and then there's other --

CHANTEL CORBETT: Yeah, I think they actually have, like, you can tell them a specific --

ADAM WEAVER: Yeah. Right.

CHANTEL CORBETT: -- weighting factor, right.

ADAM WEAVER: If you have it -- I mean, I don't know if you guys are using any of the ones where you just, you walk into the shield on a coat hanger, you know, with a giant --

MARK SEDDON: Yeah, yeah.

ADAM WEAVER: And some of those people --

CHANTEL CORBETT: Oh, yeah, and there is, like, zero dose.

ADAM WEAVER: Yeah. This may not, but that person may also go --

CHANTEL CORBETT: Right.

ADAM WEAVER: -- over to the next room where that's --

CHANTEL CORBETT: That's not there. The zero gravity is not there. Yeah.

ADAM WEAVER: Yeah.

JOSEPH DANEK: Maybe you might want to doublecheck the section. Just doublecheck the wording maybe.

ADAM WEAVER: I mean, if that's the word you're going to use, just based on definition, I think it's the definition that most people understand.

MARK SEDDON: Right.

ADAM WEAVER: You're just going to have to help the inspectors.

CHANTEL CORBETT: So the other question I guess is, since this is a draft, until this goes into effect, should they still submit the same information per their requests?

CLARK ELDRIDGE: That's what we've been asking for about a year and a half now. So --

ADAM WEAVER: Do you put this, or, like, when you send out the annual --

CHANTEL CORBETT: Renewals?

ADAM WEAVER: -- renewals or fees, do you also

say, update and submit your RPP?

CHANTEL CORBETT: When you say request, I haven't seen this request.

CLARK ELDRIDGE: No.

ADAM WEAVER: I want to know how you're communicating that to them.

CLARK ELDRIDGE: Basically on a slow case-by-case basis.

MARK SEDDON: People call up and say, where is the information that --

CLARK ELDRIDGE: We don't want to overload the individual who is responsible for this.

ADAM WEAVER: Okay. I'm wondering how you're getting them.

CHANTEL CORBETT: Yeah, it's not coming to the RSOs.

CLARK ELDRIDGE: No. Yes, we're trying to position ourself to be in a better position to actually do a bulk notification rather than the one by one that we have been doing as we come across these things as people requested weighting factors, we say this is the new methodology for requesting them.

MARK SEDDON: Okay. And this has been working well for you guys? I guess you guys have been using

this sort of format for your requests? Okay. Well, good.

CLARK ELDRIDGE: Not this exact language because we haven't had an exact piece of paper like this written down, but these are the elements we've included.

MARK SEDDON: Okay. All right.

ADAM WEAVER: I've just got one question for you. Does the AAPM have any documentation on --

MARK SEDDON: Use of the weighting factors?

ADAM WEAVER: Yeah, weighting factors and then adding them to the RPP?

MARK SEDDON: I mean --

ADAM WEAVER: Documentation of the weighting factors, whatever.

MARK SEDDON: So utilization of the weighting factors has been addressed years and years ago when it first came out, so we have all that research and recommendations. But it's almost become a -- Florida's one of the few states that actually has some of the additional steps involved with it and restrictions and a lot of the states, you know, they apply weighting factors. It's just up to the facility to contact --

CHANTEL CORBETT: Without a request, formal.

MARK SEDDON: The written request, that's it. It's pretty straightforward. So it varies from state to state somewhat. I know Florida has been early on it was only applicable to, like, international physicians --

CHANTEL CORBETT: Right.

MARK SEDDON: -- which was more restrictive than other states. So I don't think that the AAPM has got an actual statement on this. I believe they have some research documents and I can look through that and see if there's anything this there that refers to using weighting factors documentation.

ADAM WEAVER: I just think it would help the registrant to update his or her RPP.

CHANTEL CORBETT: Yeah. If there's --

ADAM WEAVER: Some kind of guidance out there.

CHANTEL CORBETT: -- documentation guidance.

MARK SEDDON: I think that's what the intention of this is.

CHANTEL CORBETT: Well, I mean, it says if you got it from another peer reviewed source. Now, I can tell you right now, one doctor will say, hey, I know him and he's my peer and he reviewed it. He said it's great, so here you go. I mean, like, it doesn't specify who the peer reviewer is in this

case, so that may be your other issue with that, but --

MARK SEDDON: You can always talk to the dosimetry vendors and ask them to send their processes that they use. But they have to have it all documented.

CHANTEL CORBETT: Yeah.

ADAM WEAVER: It's part of their accreditation. NAV Lab.

MARK SEDDON: Yeah. So I mean, that would be a pretty easy.

CHANTEL CORBETT: Yeah.

MARK SEDDON: Using them, using EDE1, EDE1, from Landauer.

CHANTEL CORBETT: Right. Yeah, that's easy.

MARK SEDDON: Yeah, instead of using one of the one offs that you're talking about.

ADAM WEAVER: Right. I know there's one offs. There's other methods out there.

MARK SEDDON: Yeah, there are other methods out there.

ADAM WEAVER: What kind of apron's you're wearing?

CLARK ELDRIDGE: Do we need another source? Do we need to say peer review journal?

CHANTEL CORBETT: Well, maybe just an example, an example of who those would be. You know, like, example, Landauer or AAPM or, you know --

MARK SEDDON: Right. That's true.

ADAM WEAVER: Maybe NAV Lab, too.

CHANTEL CORBETT: Yeah. Yeah. Some idea, so it's not as general.

ADAM WEAVER: I think there's also some kind of NCRP documentation for this, too.

MARK SEDDON: There is.

ADAM WEAVER: I don't remember how old it is.

MARK SEDDON: Again, all this is all from back --

ADAM WEAVER: Yeah, it's not new.

CLARK ELDRIDGE: No.

MARK SEDDON: We're trying to refresh it.

ADAM WEAVER: It's something that be looked at because there's so many different aprons out there. We don't have many lead-based aprons out anymore. That may change things versus the --

MARK SEDDON: No.

ADAM WEAVER: Versus, what are they using now?

CHANTEL CORBETT: I mean now they're even selling things, quote, unquote, "pregnant aprons", which are really not that much different from the

other.

MARK SEDDON: Pregnant apron?

CHANTEL CORBETT: Probably $200 more or something.

REBECCA McFADDEN: Add $200 to the cost.

MARK SEDDON: I've not seen that. Pregnant apron?

CHANTEL CORBETT: Yeah. I just had a hospital order some specifically. I'm like what? Yeah. It's just a double out.

MARK SEDDON: Okay. I got you.

CHANTEL CORBETT: They sold them. They're different enough where --

ADAM WEAVER: More ergonomically designed.

CHANTEL CORBETT: Yeah.

MARK SEDDON: It is nice with the newer aprons, that their disposal is much easier now without lead.

ADAM WEAVER: Oh, yeah. But some of them are tungsten based, which is a very expensive metal, and some of them are almost like a sand-based silica.

MARK SEDDON: Silica, yeah, that's right.

ADAM WEAVER: Right.

CHANTEL CORBETT: We digress.

MARK SEDDON: All right. Any other suggestions for Clark on Information Notice 4? That's a lot.

Sorry.

CLARK ELDRIDGE: No. The only problem is how long I have to wait for the minutes to catch them all because I don't think I got all the minutes down.

MARK SEDDON: Yeah, lots of comments. So we're looking forward to seeing that again. That's good. We're glad that's coming back because I think it's been absent for a while, so --

ADAM WEAVER: Yeah.

MARK SEDDON: And then Information Notice Number 108.

CLARK ELDRIDGE: TBD. Maybe I should have put TBD up there, huh?

All right. As many of you have heard, there have been extensive research and discussions of whether gonadal shielding is beneficial, useful, et cetera. As previously discussed in the meeting, the State, the language in our administrative code allows for, except for cases of which this would interfere with the diagnostic procedure. Which it provides the licensed practitioner significant latitude in determining the need. So this is a method and showing an example of, of latitude given and how it could be interpreted as not needing

gonadal shielding, referencing the statute that was adopted, two years now?

Talk about how the radiation machine should be operated at lowest exposure to achieve the intended purpose of the exposure. And one of the big things in the discussions on gonadal shielding was the fact with automatic exposure control, when you cover up the receptor, it increases the dose rate of the tube. So it accumulates the total -- a total amount of dose on receptor which was determined to give optimal imaging.

So instead of getting it spread out evenly across the detector, it's now concentrated in the areas that are exposed; therefore, the dose of that area goes up significantly. And with internal scatter of the body, you're not necessarily gaining a whole lot of dose reduction to the rest of the tissue, which would -- you know, it's not like you're eliminating the dose to the rest of the tissue because of the increase of the internal scatter to the body. So obviously in that case, gonadal shielding would not be of benefit to the patient.

So -- and that interferes, again, with the thing that you're trying to keep the tube and

operating as low as possible to get the medically necessary information.

MARK SEDDON: So is there any discussion on this notice that people read?

The only question I have -- I mean, I agree with it, obviously, but it refers a lot to the licensed practitioner has the authority to determine appropriate implementation. But a lot of places, the licensed practitioner is technically is not -- I mean, is there -- is the intention that they want a requirement for, like, an authorization from a licensed practitioner or is it just --

CLARK ELDRIDGE: The problem is that's what's -- what the current -- the intent is it's the physician or whatever, licensed practitioner is making these determinations on patient safety.

MARK SEDDON: Right.

CLARK ELDRIDGE: Now, if there is some other acceptable procedure within a hospital, a group for that, then that would be perfectly fine.

MARK SEDDON: Yeah. I assume like the hospital, the relationship you have with the hospital which has licensed practitioners on there agrees.

CLARK ELDRIDGE: Yeah. So in effect, you're

working -- that could be seen as collaborative practice at that point.

MARK SEDDON: Yeah.

CLARK ELDRIDGE: It's not like --

CHANTEL CORBETT: You can put it in your RPP --

(Laughter)

CINDY BECKER: No.

CHANTEL CORBETT: -- and you're done.

MARK SEDDON: Yeah.

Okay. Any --

ADAM WEAVER: Those RPPs are going to be long documents.

MARK SEDDON: Any other questions for Clark?

CHANTEL CORBETT: Maybe to increase his mailbox size.

ALBERT ARMSTRONG: Excuse me. I'm just kind confused to the meaning of this. So are we saying that, for example, if we're going to be x-raying the pelvis, for example, it's going to be up to the practitioner whether or not to use the shield. But if we're going to be x-raying the elbow or spine, we still shield.

CLARK ELDRIDGE: No. Because actually, this code says it's only when the gonads are actually in the direct beam. So if you're x-raying the elbow,

there's no requirement for gonadal shielding. Or the ankle or the big toe, because you're not putting -- unless you're really bad with the aim. If your field of view is that big, you need to work on your columniation practice. But, yes.

ALBERT ARMSTRONG: We're eliminating the shielding requirement for most of the body.

CLARK ELDRIDGE: No.

MARK SEDDON: Correct. For gonadal shielding.

ADAM WEAVER: Yeah.

CLARK ELDRIDGE: Gonadal shielding. Yeah. This is strictly the idea that gonads are -- that the historical concern of radio sensitivity of gonads which has been reevaluated with time. The fact that the efficiency in x-raying has increased as in less energy, better imagery.

MARK SEDDON: Right.

CLARK ELDRIDGE: Has reduced the risk, the understood risk to gonads; and therefore, do we need to really shield them in any radiologic, in any radiography practice.

ADAM WEAVER: And also the use of the shields could damage the product.

CLARK ELDRIDGE: The product, yeah.

ADAM WEAVER: I mean, like, I guess the biggest

one is the one that always get questions about, even if we don't have a dental facility yet, thankfully, or dental, but the dental office. Should we throw this weighted blanket on you when we're x-raying your mouth.

MARK SEDDON: So, yeah. So the dental PM and most of the ACR, most of the accrediting bodies have accepted that gonadal shielding is of no benefit, and potential adversity to the imaging of the pelvic area. So NCRP has jumped on this, everyone has judged on this as the acceptable recommendation way to go. Dental has not.

ADAM WEAVER: Right.

MARK SEDDON: They still have a recommendation to have patient shielding, gonadal shielding present when they do dental x-rays. So that's just a confusing step for parents of children and for folks who go to the dentist office, you're shielded in the dentist office, but they're not shielded when they go to the hospital. Actually, I had some slides for later on if we have time to go over this because we ruled this out effective last summer across all our facilities and how it's, how things have gone for us.

ALBERT ARMSTRONG: Okay. That's exactly, this

is exactly why I'm bringing this up is because if, in a podiatry, in the past, there have been podiatrists who didn't use a shield when x-raying a foot. And then the State of Florida gets a letter from the patient, saying, hey, the podiatrist didn't use a shield and took three different x-rays, you know. So usually, the response is, well, you know, you're not going to be exposed that much and it's not a problem. But the thing is, if we don't use it, letters go to the State.

MARK SEDDON: Right. And that's part of the --

ADAM WEAVER: Patients complain.

MARK SEDDON: There's a -- the way we handle it, I'm not sure other facilities have done this, we did an extensive educational program for all the technologists in our system with talking points that they can use with the patients and/or with their parents, family members who are concerned about whether, last week, or not last week, the last time I was here, someone put a lead apron on them. Now they don't. Why? And you try to explain that they can actually, you know, there's really no benefit. Your gonads are not more sensitive than any other part of your body so actually providing that shielding doesn't help and actually, it could

hinder, as Clark was saying, the actual capture of the exposure, itself.

Now, we do have it where if patients or family members are adamant that they want to have it still, I guess they will be provided with the caveat that the technologist is being conscientious about how they're imaging. But if it's in plane, they'll have to say no. We'll have to not perform the exam.

So I think there's, there's, there's actually the NCRP sent out a pamphlet with talking points you can reference, which comes from a -- so it wouldn't just be your practices doing this. It would be something that could be handed out to the patients at the time if there's any questions. So we -- that was this year that came out in January. Last summer we created our own handout to give to patients and family members to explain why we did that practice.

ALBERT ARMSTRONG: Yeah. The other reason I bring this up is I train the students. I train the students year after year after year, 60 students, so what should I be training them? You know, use the shield, you don't need to use the shield anymore? From my perspective, it's like --

MARK SEDDON: Kathy may.

ALBERT ARMSTRONG: Okay. Yeah, good.

KATHLEEN DROTAR: Okay. I brought with me the ARRT and the registry and the ASRT both have come out with statements about that. And we're still going to train people because it's part of radiation protection. If you're going to shield, you should know how to do it. That doesn't mean that you will do it in a facility. And AAPM, in their statement that came out, even said that the technologists at the time doing the exam, should be the one to determine whether or not shielding should be used and how it should be used effectively so that it doesn't increase that dose that goes to patient.

So knowing -- and part of that study, too, just to go back a little historically, is that there was a study done, I think it was like 500 different cases in a study in England showed that the shielding, there were -- the amount of repeats, because of the gonadal shielding, actually increased the dose to them, to those patients. And that by leaving the shielding off, the internal dose was only something like .008 mSv. That it wasn't substantial enough to, to think that there might be a repeat.

So it's to, overall, it's going to decrease the dose to the patient, which is in keeping with, you

know, principles of radiation protection. So it's a whole mind bend because after years of being taught, shield, shield, shield, and now it's like, oh, you don't have to do that anymore.

But I think we have to realize that we're in a world now with individual radiography that it's changed all of that. We don't have those huge doses that we had when we were -- when we had the single phase machines and film. And, you know, using a fraction of it. So that, you know, it's beneficial to the patient sometimes, but there's a lot of patient education that also needs to take place.

MARK SEDDON: Right. You know, so what, what the recommendation is, that came out in 2019 from the AAPM, as Kathy was saying, the educators are usually the ones who push back pretty hard because they've been advocating this for 20 years one way. Suddenly you're changing the story and it's just one of those things that it was an unwritten, a lot of places knew that gonadal shielding was not really of benefit, but because it's regulated, it was in place. And so it wasn't until, I think it was one of the current AAPM presidents said we need to change the regulations and not make this a requirement. It's a transition. So we've

transitioned from gonadal shielding is not required. You still use it if people -- because we're changing practices and changing the patients, but then at some point in the future, it may just be discontinued completely. But right now we're in that transition period from going away from the requirement to, it is not recommended. And then to the point where at some point, they say it's not required. Not allowed, I guess.

CHANTEL CORBETT: Yeah, and you run into the, you know, like this patient may go to two different facilities and they may do it two different ways.

MARK SEDDON: Right.

CHANTEL CORBETT: Especially at the beginning it was the same with iodine outpatient therapy. Initially, you had to be in the hospital and restricted and all this other stuff and now you can go home, you know, and it's two different worlds. But it's a process because some of those patients have come back and said, you know, I had this done X number of years ago and I was under all this restriction and now why I do this differently because it's the same, you know.

MARK SEDDON: Right. I will say --

CHANTEL CORBETT: Education.

MARK SEDDON: -- from our experience, we've had thousands of patients now without being shielded with gonadal shields. I think it's a small handful have raised concerns, generally parents, and then in each of the cases where they raise concerns, as long as they have, from a facility perspective, you have some kind of policy, procedure, that shows justification why you did it or explanation handout provided now by the NCRP, which is helpful.

CHANTEL CORBETT: Right.

MARK SEDDON: Because it's a regulatory --

CHANTEL CORBETT: Body.

MARK SEDDON: -- body. They don't think it's just you.

ADAM WEAVER: It's a national body.

CHANTEL CORBETT: They can Google it.

MARK SEDDON: I'm sure they can.

CHANTEL CORBETT: It makes everybody happy. It's sad, but true.

MARK SEDDON: So it's easier for them now to accept it. So that's kind of eliminating any serious concerns. I'm not sure what other folks --

ALBERT TINEO: There was not only the educators, but there was some old technologists that were pushing back, also. So those are the ones that

you have to spend a lot of time and educating and explaining --

KATHLEEN DROTAR: Yeah.

ALBERT TINEO: -- why. Because the apprehension from those technologists to the patients can be transmitted and that's when you get your complaints.

CHANTEL CORBETT: Right.

ALBERT TINEO: So then you get, why is this person complaining? I mean, they -- but it's sometimes it's that, you know. If they don't explain it well because you have old technologists that don't believe in it, and they're going to say, well, this is the way it is because this is a new policy of the hospital, then that's what you get. I mean, it's -- but if you have good technologists, good --

CHANTEL CORBETT: Communication.

ALBERT TINEO: -- communication going around, it should not be an issue, which is the same thing. We have, we changed some of those protocols.

MARK SEDDON: Yeah, you change protocols. A lot of this is education of the frontline staff because they're the ones that have to deal with the patients, right, and those are the ones to explain

we're changing the practice in the field.

ALBERT TINEO: But there was a lot of conversation, I mean, from -- I used to get calls, you know, from these people over here saying, this is wrong. Why are we doing that?

ALBERT ARMSTRONG: I'm an old technologist.

ALBERT TINEO: Yep. It happens.

MARK SEDDON: We had discussions on the Council when it first came up a year or so ago.

ALBERT TINEO: Oh, yeah.

JAMES FUTCH: This is, like, go around two or three, I think. I'm not sure which it is. You can still see we're not completely on the same page necessarily. Folks are still working their way through it.

ADAM WEAVER: Because it's still not universally accepted.

CHANTEL CORBETT: Right. It's still new.

ADAM WEAVER: Most medical providers may but the dental --

MARK SEDDON: Dental has not.

ADAM WEAVER: And chiropractic.

JAMES FUTCH: You can talk all you want to and the American public that has children, they're going to want certain things because they've come to

expect that. And it's radiation, as we all know, radiation is a whole different category of things.

CHANTEL CORBETT: Yeah. Similar things with the leaded gloves and IR, you put them in the beam.

MARK SEDDON: Yeah.

Very good. All right. Any other discussions on that? That's a good discussion, actually.

JAMES FUTCH: It's Clark.eldridge@fl.com.

(Laughter)

ADAM WEAVER: What else have you got for us?

CLARK ELDRIDGE: I think I will rest my case at this point.

MARK SEDDON: Oh, wow, we're actually moving along.

JAMES FUTCH: Yeah, moving along.

MARK SEDDON: So James.

JAMES FUTCH: So we have a couple things left. I have a small section update. Gail is handing out some information.

As you may recall, the -- well, let me talk about personnel first. I received a new staff person.

KEVIN KUNDER: You received, huh?

CHANTEL CORBETT: Traitor.

JAMES FUTCH: To my credit, to my credit.

ADAM WEAVER: It's the home office.

JAMES FUTCH: Contrary to popular belief, I did not recruit this particular one.

CHANTEL CORBETT: This particular one.

JAMES FUTCH: But Melissa Burns is now with our section. And we also have one other personnel change. Lynne Andreesen, who was with us for several years, has left with her Master's to become the program director at the Tallahassee Community College Rad Tech program.

ADAM WEAVER: Wow.

JAMES FUTCH: Which made her very happy. And it was very good to see her succeed in that way because it kind of all happened together. It was like, oh, you're now program director, okay. Big change. But she's a wonderful person and also, the person who tends to help us with recruiting new staff members to the Bureau of Radiation Control.

Speaking of which, another new staff member is Brittany Morrison, who is the continuing education coordinator now, taking over from Lynne, who took over from Kelly Nesmith earlier in 2020. And both Brittany and Melissa and other staff member on Clark's staff, Ginni Shaw, were actually from the same facility. I think from the same class of

radiologic technology a number of years ago. And also the facility where Lynne worked for many years. And all excellent staff members. We hope to see many more, well, at least while we're still running the show here, right? Which is another topic that will be changing.

So that's the personnel side of things. The biggest news I think that I have is, as you may recall from a previous meeting, the Bureau of Radiation Control, my program, the rad tech program is now recognize by ARRT as a CE, continuing education approver, and we have been for a long, long, long time, but they formalized it into something that felt like accreditation when we went through it in 2020. And we just completed our first annual report to the ARRT on our activities, whew, through that one. That was also a great deal of fun, lots and lots of statistics and looking at things six different ways to Sunday.

They have a very large document on CE standards that all of the approving organizations in the nation abide by in order to be accepted by one another. State agencies as well as non-state agencies; professional societies.

And one thing we discovered is, although we

have 650 approximately providers in Florida and literally, 5 to 7,000 courses in a given year that are approved, in the ARRTs way of thinking of such things when it comes to one annual report and whether or not you have properly audited the significant percentage of them, we are a first approver of a subset of those, ARRTs language for, for example, we have mini-courses which are ASRT approved which we accumulate CE in our system and apply it to the technologists so they can use ASRT CEs to get their Florida licenses. Many thousands of activities per month from ASRT.

They are -- we are a second approver for them. And the interesting aspect of that is, none of that counts for the annual report. So there's an awful lot of statistics that just changed dramatically when you go from this huge quantity to this much smaller quantity.

Then we have a slight difference in nomenclature when we talked to ARRT, whom we love dearly and all the staff there, with regard to what does it mean to audit, what does it mean to monitor. We had these discussions last year with our equivalents at ASRT where we were both kind of scratching our heads before ASRT went through the

same thing. We did it before they did.

So we've been through this once. We now have a pretty firm understanding of what we're supposed to be doing. And we did it correctly the first time and we'll do it even more correctly the second time and subsequently.

So in the ARRT world, we are essentially one hundred percent audited. In ARRTs way of thinking, audit means asking the technologists to provide the certification documents, the certificates that you have attested that you actually had when you renewed your license or maybe asking the provider.

In our world, before we renew a license for the 12 hours of CE, we require the provider to send us proof of that class completion and to a small percentage of folks who renew close enough in time to renewal so there isn't time for that to happen, the providers have 30 days to supply that to us. The technologists, themselves, must supply the class certificate proof to the department.

So in ARRTs world, in some sense, that means we do one hundred percent audit, which is good, because we're only supposed to do ten percent. But in other aspects of what they want, in terms of physically going and looking at sign-in procedures and

documentation in a live proceeding, or following up afterwards and reviews of core satisfaction surveys and things of this nature, we still have another body of statistics where we do that.

Anyway, long story short, all three of us, Kelly and I and Brittany, I think our brains were just total slag at the end of this particular process trying to get everything right.

One aspect of this is that ever changing CE consensus document requires us to change some things. And in Florida, of course, we're a state agency, so often that means we have to change things in regulations. So what you, what you had passed out I think in front of you is, is four pieces of paper. And in actuality, the very first one is a summary of those kind of areas where we need to change the regulations in summary bullet form. And then the next three pages is a, is a very preliminary draft of what the regulatory language to implement those changes looks like.

I'm just going to go over the bulleted points. You're more than welcome to take the actual draft. I emphasize the word draft language with you and provide any comments or feedback. If you don't have it right now, then certainly give me a call or give

us a call or, you know.

So the first thing is I grouped them in the area of post-test changes for self-study activities. So self-study activities have to have a post test. In this case, the one aspect that we did not have was a limitation on the number of post-test attempts that the provider was going to allow the class participant to take in order to say that they had retained the material. ARRT and all the RCEEMs have a three post-attempt limit or will soon. This is supposed to be implemented in January of 2022.

We probably will not immediate that deadline with our regulatory timeframe, as I see smiles from Kevin and Clark. That often takes us, I think six months would be a good regulatory transit time for us. We've had some before that have taken a year, maybe more.

But -- so that's the first one. Curiously enough, this is a, this is a difference from where we used to be. The time to complete the post test is an opportunity to learn; and therefore, should be included in the time required and allowed for the CE activity. Previously, many years ago, we actually did this and then ARRT changed their policies, we said, no, that's not allowed. And we've come 180

degrees around now to back to the beginning so that we're going to change it back again.

Maybe I should just put like a little coin flip in that part of the regulations. Whatever you feel like today. No, just kidding.

The next one is entirely, well, mostly due to the CQR type requirements, where folks are now doing relicensure and continuing education activities, are very targeted towards those requirements in very, very, very small time allotments or very small chunks. So textbooks and e-books when we deal with them, typically, in the previous regulations, we would approve a textbook as a course or an e-book as a course. And in the ARRT world, we're now subdividing those into chapters. Not smaller than chapters; not subsets of chapters, but chapters. And, and that's what the bullet two is about. And, of course, it will require a post test because it's a self-study activity.

Three is completion of CE activities. No partial credits of CEs awarded for partial completion of an activity. I don't think this comes up too often, but this is, this is another change to. If, for example, it's a live course and the learning parts of the activity have all been

completed, apparently there's some caveat to this that says you can, in fact, still award full credit for this. So it will be interesting to hear how this one flushes out through the regulatory process.

Psychomotor. I couldn't wait to work that word into something. From this point on, I'll refer to it as hands-on component of an activity. Didactic and hands-on components of CE activity have the same per unit of time value, ARRT's words -- we'll probably end up with something a little different -- and credit will be awarded in the same manner. So this is a mechanism by which the hands-on component, not just the didactic component of a CE activity is allowed to contribute to the overall CE awarded.

And then certificates of completion and achievement, activities which we approve, which are already approved category, ARRT credit, must state this on the Florida certificate as well. I think this is just kind of helping out the folks in the other, other communities who may see the certificate later on that we, we approved it.

CHANTEL CORBETT: That's just saying if it already has been approved by ARRT, Category A, you're good.

JAMES FUTCH: Yes, it's got to say that on the

Florida certificate. I guess in some way, shape or form, that was, even though the activity may have been approved, it wasn't appearing on the Florida certificate or the RCEEMS certificates from other places.

CHANTEL CORBETT: ARRT or A Plus credit?

KATHLEEN DROTAR: But they're not approved by ARRT. That category. I'm sorry.

JAMES FUTCH: That's okay.

CHANTEL CORBETT: She was just saying the ARRT doesn't have to approve anything.

JAMES FUTCH: Right.

KATHLEEN DROTAR: It's going through RCEEMS.

JAMES FUTCH: It shouldn't be. Right. So the ARRT consensus standards that the groups are using to approve this, we'll say Category A. I was trying to shorten things up.

KATHLEEN DROTAR: Yeah. I hear you.

CHANTEL CORBETT: We'll just say approve.

JAMES FUTCH: Let's see. The last one. Okay. This one, I haven't seen this in practice yet and my mind is kind of wondering how this is all going to fit on the certificate, but the learning objectives, when we approve a course, we already have a set of stated learning objectives that comes in with the

paperwork. And for a hands-on activity, the learning objectives must be stated on the certificate of achievement. Like I said, I don't know exactly how that's gonna work out, but maybe Kathy does.

KATHLEEN DROTAR: Well, I was just going to pose that because we just did four credits on Saturday.

JAMES FUTCH: Yeah.

KATHLEEN DROTAR: And the certificate we were going to give was that they attended those, but then we would have to have -- so I'm wondering would it be the objectives for that, for that seminar or the objectives for each of the activities.

JAMES FUTCH: And the short answer is right now I don't know.

CHANTEL CORBETT: Put them all on there.

KATHLEEN DROTAR: Not for 2022.

JAMES FUTCH: Whenever we start out with these ARRT consensus document kinds of topics, we bat it around the staff for a while. Sometimes we come and ask the other staff, like Kevin, some of the other technologists, what do you think? How does this work? Kelly's the resource, because she's seen lots of different kinds of things over the years. So

we'll come to a certain set of questions and then we'll bounce it off ARRT and it will churn up there for a while and I imagine they're probably reaching out, too, and sometimes they'll come back and say, oh, that's not quite what we meant, you know. We meant this, which is close to what you're talking about.

I think, because we were the first ones to go through the whole approval process and one of the first, if not the first, to go through the first report process, we found a lot of things that were in their documentation that they had told us they were fixing. That they were correcting. So I don't know if, if that will get fleshed out and make more sense because it seems like kind of a broad range of things that would be on a certificate, itself.

CHANTEL CORBETT: So on this, it looks like it just says the hands-on activity learning objectives.

JAMES FUTCH: Exactly.

CHANTEL CORBETT: It's not the actual lecture part, it doesn't look like, on that wording.

JAMES FUTCH: That was the difference at least --

KATHLEEN DROTAR: In addition to --

JAMES FUTCH: -- between what we do currently

and what they're talking about.

CHANTEL CORBETT: Right.

JAMES FUTCH: What their new objective is. They were focused on hands-on activities.

CHANTEL CORBETT: Right. I know some of the physician, you know, certificates that we get, instead of being the traditional, you know, landscape, they turn it portrait, and then just do the normal -- it's like a half certificate, like the old version, and then the bottom portion was like objectives and things, so that may be an option.

JAMES FUTCH: Yeah.

KATHLEEN DROTAR: James?

JAMES FUTCH: Yes, ma'am?

KATHLEEN DROTAR: When I submitted to ASRT online, they did have -- we did have to put objectives for the seminar first and then as we added the other, the activities in, then they each had their own separate ones. But there were -- that we were required to put something. Maybe that's what that might be.

JAMES FUTCH: Okay. So that's it for the ARRT-related matters. The personnel matters.

I do have, I do have one request to take back with you. We've talked about it a little bit with

one or two of you. We have a whole set of licensees on, when you go to check somebody, verify a license online. Last year, the year before, pretty much every single active type of health care practitioner license was added to sort of like, for example, radiologic technologist, you'll now see radiologist technologist out-of-state telehealth provider. And that happened, as far as I can tell, for all the different kinds of licenses there are.

If you actually go and look and see who's licensed as a out of -- whatever ones say out-of-state telehealth provider, whatever the practice is, almost none of them have anybody actively licensed in those. But the law was changed to allow Florida licensure for folks who are based elsewhere who want to become Florida out-of-state telehealth providers. We actually do have one person listed in the rad tech section, but I think he's a fellow who kind of ended up in the wrong place because he looks like his educational background is an osteopathic physician with radiologist type training. I think he was supposed to go some place else.

There are, however, something like 1767 licensed out-of-state telehealth medical doctors.

So my question essentially is, if in your facility, you have run across anyone who has a technician-type license like a rad tech, who or maybe the facility or somebody is trying to sell you something, that would use a out-of-state telehealth provider at the technician level, how is that working? How is that proposed to work? And I'm not talking about folks who, for example, the doctor can review, you know, a chart or a radiograph, you know, on the other side of the planet theoretically, and give you an impression from it. But in the classes of folks who would be setting up and positioning a patient and all of rest of that. I'm not necessarily looking for an answer right now, but what's out there. Let me know if you, if you see this.

REBECCA McFADDEN: So are you referring to a technologist who has a Florida license going to another state?

JAMES FUTCH: No. No.

CHANTEL CORBETT: Opposite.

REBECCA McFADDEN: Or opposite.

JAMES FUTCH: Opposite. A technologist who has a New York license, who has a -- not a physical license in Florida, but a Florida rad tech out-of-state telehealth provider license. And I

don't mean just rad tech.

CHANTEL CORBETT: The tech is not physically in Florida.

JAMES FUTCH: They can't be.

REBECCA McFADDEN: But are they ARRT registered?

JAMES FUTCH: It doesn't matter.

REBECCA McFADDEN: Because you can be state licensed without an active ARRT.

JAMES FUTCH: They can be -- yes. So the method of out-of-state licensure is agnostic. It could be ARRT, it could be a state license or any the number of things. And I asked the question because we're -- well, it would be, it would be good to see an example of what is envisioned in that. I have not yet seen one.

MARK SEDDON: So I could share that, I know for the one vendor for MR at least, there's such a thing called virtual cockpit where you can have an off-site technologist operating the scanner remotely. You used to have the on-site technologist doing the positioning, but a more advanced technologist is actually performing the actual, itself, because they know -- the other half of the advanced console, post processing for a lot of the

3D specs stuff for, they're just more advanced in the training.

So in the MR world that exists, and I think I heard that's coming down in the CT world as well.

JAMES FUTCH: I heard the same thing about CT. So we're kind of putting our, you guys aware and maybe put your feelers out and see what, what comes back with regard to that. If it happens to be a CT.

CHANTEL CORBETT: MR makes it easy since they're not licensing.

MARK SEDDON: Yeah, MR, but CT --

JAMES FUTCH: I mean, I can't really -- what we're afraid of is that someone might think, okay. You can use the out-of-state person to initiate the exposure and then you use someone else. Now, if someone else is also a Florida licensed technologist for this modality, okay.

CHANTEL CORBETT: Correct. Your worry is like they're going to bring a transporter in to position the patient.

JAMES FUTCH: Medical assistant or something like this and that kind of stuff.

MARK SEDDON: I think we had that discussion with PET mammography. You guys remember that? Where you had -- because it's technically PET, but

the position's like mammography and so, your techs were not comfortable positioning the patients. They were having a mammographer come in to position the patients and that came a whole huge scope of practice.

JAMES FUTCH: Yeah. At least in those areas, we can kind of think of, yes, you're out here with this license, but there's someone else here who's actually licensed for the hands-on portion.

MARK SEDDON: I think what we --

JAMES FUTCH: Some kind of communication.

MARK SEDDON: I remember the direction was the mammographer cannot -- they can guide the PET technology, but they can't actually position the patient. Because to position the patient is considered part of the study.

CHANTEL CORBETT: Part of the study.

MARK SEDDON: Part of the study. So that's what they have to adhere to.

JAMES FUTCH: Anyway, so I just want to throw that out. Unless there's more questions for me, I think there are actually some slides to get to --

MARK SEDDON: Okay. Yeah.

JAMES FUTCH: -- for you. If that's okay.

MARK SEDDON: If you want. Yeah, I put

together some slides for Council business. We can do it.

JAMES FUTCH: Yeah, we can do it. I'll be your tech person, okay.

MARK SEDDON: Okay. I guess for any other council business, anybody have anything they want to bring up?

(No Response)

MARK SEDDON: All right. James asked me to put together some slides.

JAMES FUTCH: We had some discussions --

MARK SEDDON: Go ahead.

JAMES FUTCH: -- about some things earlier in the year. Whoops, sorry. Can you guys see it okay?

MARK SEDDON: Yeah.

KATHLEEN DROTAR: Mm-hmm.

MARK SEDDON: So it was a discussion that came up -- slide down a little bit -- concerning MRI conditional cardiac implanted electronic devices, because there's some newer stuff that's out there. And so a question came to James from a facility about whether these are in practice or in place, in use.

So if you want to go to the next slide.

So in the last few years, we have pacemakers

and defibrillators are capable of being scanned in the MR suite, but they have to be placed into a safe mode or they have to be programmed properly.

ADAM WEAVER: Programmed.

MARK SEDDON: So the programming it as a scheduling issue. So usually, we generally have a manufacturers rep. come on site to do the programming. So we've been working with the different vendors. They, especially Covid, when perhaps we were limited to access to facilities and for traveling around, we were working with different vendors to go ahead and pilot out some of the different products they have.

So Biotronik was the first one we did. They have an auto detect system that will actually two weeks before the patient is scheduled to have the MRI study, they can put the device into an auto protect mode and it will go ahead -- and you can switch slides.

I think the next one talks about -- yeah, Biotronik. So it will go ahead and detect when the sensor in the pacer is within a 10 mT magnetic field. Once it hits that, it will automatically jump into safe mode. And so --

JAMES FUTCH: Sorry.

CHANTEL CORBETT: Is there an outward way to verify?

MARK SEDDON: No. There's no outward way of verifying it. Basically, what happens is the activation is still done by the representative, but it's done at the direction of the physician within the physician's office. So it's done, you know, at any points with the 14 weeks -- 14 days prior. And then once the scan is done, after the MRI scan is done, then it will go back into normal mode.

So it's sort of an auto detect when it's within the magnetic field and then be a safe field once it's completed, it will no longer be in that type of situation.

So we started at one facility last summer and it's been working fine and now all the Biotronik pacemakers are to be initiated at the physician's office and then auto detect when it comes on site to be scanned.

So the next one we've been working with is Medtronic. So theirs is a different type of system. It's called a CareLink Express. I think this is the one James was called about.

JAMES FUTCH: Yeah.

MARK SEDDON: Basically, the equipment to

program the device is on site. So it's actually within the MR suite or at the MR suite. And so, it allows for a remote support to walk the technologist or nurse through programming and making the program change to place it into a safe mode.

So we have a handheld wand that you hold up against the pacer, the little device; a tablet which controls it.

Typically, they'll go ahead and Facetime with the, the representative remotely and then they can go ahead and program the device, scan the patient. When they're done, they go back and reprogram the device. All under the supervision of the representative virtually.

So this is -- have you ever had a logistical challenge? You can go to the next slide.

I have a summary. Yeah, so this is kind of work flow. So you have to have an order from the physician. And so that they go ahead and place the -- that they want the device placed into a certain, certain setting to a certain mode. The, the nurse or the technologist will go ahead and program the device under the supervision of the remote rep. And the remote rep. will review the written order that they provide to us to make sure

that the -- they know how the setting should be. And they're basically watching the entire process as we're doing -- watching the screen, and they're watching, you know, the technologist or the nurse perform the change.

There's a print out once the device has made the changes so you have a record of what has been done to the pacer. They do the scan. And when it's done, you have to go back in and reinitiate and revert back to the original settings.

So we still have been doing this under the pilot. Go to the next slide. And, sorry, this is the order form.

So this is an example of -- the physician is the one who actually creates the order for the change of settings. Normally it's default settings, but if they have specific settings they want to do for the rate, how to set the pacemaker, they can go ahead and determine that specifically. So the, the rep. and the past rep. would be on site to do this, but now the rep. is sort of guiding the nurse or technologist to go ahead and do so.

Next slide.

CHANTEL CORBETT: And that order is coming from the ordering.

MARK SEDDON: From the ordering physician.

CHANTEL CORBETT: Their cardiologist?

MARK SEDDON: Our cardiologist. Our physician who is the one, who's ordering the pace, right? So the cardiologist is the one who manages the pacemaker and determines how they want the pacemaker to be functioning.

CHANTEL CORBETT: Right.

MARK SEDDON: Or set the app. This is the next one.

So our experience with Medtronic has been we have had the rep. Because we're still piloting it. We've had the rep. on site for every time we're doing this. So even though we're doing it remotely, we still have the rep. there to make sure it's being done, physically present, because as we had talked through, there is potential for connectivity issues right, because you're in an MRI suite when you shield it, and so having the ability to actually dial out and talk to somebody via Facetime or some type of remote device is challenging.

CHANTEL CORBETT: So they're not changing the settings until they're already in the MR suite?

MARK SEDDON: When they show up at the MR suite for the scan, that's when they get the settings

changed.

JAMES FUTCH: It's very different from Biotech.

MARK SEDDON: Right. The Biotech -- Biotronik, they set theirs into an auto detect mode.

CHANTEL CORBETT: Right.

MARK SEDDON: They program it so that they turn on the auto detect mode. When the person enters the MR magnet, itself, it will detect the magnetic field, enter protection mode and it will allow the patient to be scanned without damaging the pacemaker.

CHANTEL CORBETT: Right. I just wasn't sure if there was a reason not do this, like, in an exam room outside of the MR suite and not --

MARK SEDDON: Yeah. So for Medtronic, it has to be done 30 minutes prior. So it's about 30 minutes prior, because they have to do interrogation of the patient. There's some logistical steps to go through and so that's why we -- we're probably in two places. One with the nurse doing the program change and one with the technologist doing the program change. Again, in both cases, the representative who would normally do it is doing it with them, but remotely.

CHANTEL CORBETT: Right.

MARK SEDDON: But the problem is, you know, does that connection fail. So what do you do in that type of situation.

So the reason why, for all, all of us, the big reason besides Covid is, scheduling can be a challenge because right now, whenever you have pacemaker patients for MRI, they have to be scheduled like 9 to 5, Monday through Friday only. They have to be scheduled in advance because you have to make sure there's a representative available to come on site to be there to actually be present. And as we all know in the hospital world, you know the MRI schedule is never on time, so you're always delayed, delayed, and so, just a lot of logistical problems. So having remote access, you can actually scan those patients at different hours, and then have ability to have remote support to make those changes.

The third study we're going to start up is with Boston Scientific. Theirs is called Latitude. It's very similar to the Medtronic work flow with remote access. You have the equipment left on site. Their remote is actually through the actual program, itself. You can actually go ahead and talk to the, to the individual there through the device, itself.

And the individuals, they're actually seeing on their end, what the programmer, the device is doing to the, to the pacemaker.

So the one nice thing about them is that when it goes to MR protect mode for their, it has the auto protection time out. So rather than at the end having to go back and turn off that change or make the change back, it will automatically, after three hours, after you set that up, it will automatically turn off. So you don't have to worry about going back in and having a rep. available again after the study to, to go ahead and turn it off.

So, so those are three things that out there. They've been available. I think Covid really kind of put the fire under the vendors to go ahead and push this pretty hard. St. Jude or Abbott, the other vendor out there with pacemakers, they also have a version, we'll probably do a pilot with them later on, so this is something out there. The Biotronik version is the easiest because it's less labor intensive. It saves a lot of time in scheduling, but the other vendor products that are out there, are something is coming down the pipe.

So anyone have any questions on that?

ADAM WEAVER: Does the patient know what kind

of pacemaker is --

MARK SEDDON: Yeah. The, yeah, the patients are very aware of it because they constantly have to -- they constantly have to be consulting with the representative because they're in the doctor's office. So it's, again, there's a lot of representative contact with the pacemaker within the physician's office. It's just when they actually come to be scanned for the MRI scan, then there's a coordination of the rep. to come on site to go ahead and do that.

JAMES FUTCH: That's what I was saying we're always being available for being a resource on this because we, we were contacted by a completely different hospital system who didn't really have a problem. It was more of an internal communication problem, I think. And we ended up redirecting them I think to their internal medical physics support and marketing development team. I don't know if they ever contacted you, but we offered you to talk to -- the medical physicists --

MARK SEDDON: Yeah, I mean usually, like for us, our MR safety committee, there's been a big push in the past -- from the joint commission the past couple years for MR safety to be very active,

involved. We have a multi disciplinary MR safety committee with involves technologists and physicists and physicians. And so, they're trying to make sure that, you know, that for implantable devices, they have a proper policy and procedure in how to handle them. Like I said, this is something new where back in the day, you never scanned patients with these type of devices. You couldn't. Now the last few years, they had conditional devices available. It's made it possible, but now it's -- it has limited your scheduling and the numbers are pretty high.

For Florida, we have a lot of folks with pacemakers, right? So I know our facility, my facility is we have hundreds of patients who are scanned with pacemakers over the year at MR, so it is definitely a logistical problem for the vendors to provide reps. who can go on site. So this is something that they're pushing pretty hard.

CHANTEL CORBETT: Is there a certain date or some kind of line where these newer versions, you know, were available, something to say whether they're --

MARK SEDDON: It depends on the vendor and some of them are retroactive.

CHANTEL CORBETT: Okay.

MARK SEDDON: Some of them are not. It just really depends.

CHANTEL CORBETT: Right. I mean, like if you say, like, yeah, I have a Medtronic, you know, and mine was put in, you know, eighteen months ago versus six months ago, are we both eligible, are we not, you know, that kind of thing.

MARK SEDDON: Yeah. So again, the cardiologist places the order for the --

CHANTEL CORBETT: The patient's cardiologist, they do that?

MARK SEDDON: -- they're the ones close enough --

Have you guys dealt with this?

ALBERT TINEO: Yeah, they should know. The cardiologists usually know each patient's --

CHANTEL CORBETT: That's why I'm asking. It is the patient's cardiologist, not an in-hospital cardiologist.

MARK SEDDON: Yeah. That's why we have to have a written order for both the Medtronic --

CHANTEL CORBETT: Right.

MARK SEDDON: -- and the Boston Scientific, they actually do have an order form that details exactly what settings. They have a default setting,

which is the protection, their safe mode that they're using and then they have, you know, if there's a variance from that, the physician can set what they want through the app.

NICHOLAS PLAXTON: I had a couple questions on that. Like that first company.

MARK SEDDON: Yes.

NICHOLAS PLAXTON: Like, what happens if they, they forget to set it up and there's no way to check, right? I mean, it's like, someone turned it off in the safe mode, and it's supposed to detect right? Let's say they didn't turn it off. So then how do you know? It's a surprise thing when you go in there.

MARK SEDDON: Right. That was one of the concerns. So when the representative goes on site, who does the programming, they have to give -- they give a print out and a piece of paper, the document that the patient brings with them when they come in.

NICHOLAS PLAXTON: That shows it's been --

MARK SEDDON: That shows it's been done. The print out that it's been performed.

NICHOLAS PLAXTON: Okay.

MARK SEDDON: It would be the same as -- because we're trusting the representatives when they

come on site to do it. The same type of trust with the representative that actually --

NICHOLAS PLAXTON: Okay.

MARK SEDDON: They're the qualified expert to go ahead and perform the procedure.

CHANTEL CORBETT: Yeah, that was my misunderstanding. That's what I was asking for, what kind of visual documentation or something.

NICHOLAS PLAXTON: How do you know?

MARK SEDDON: There's no way to know whether or not the pacemaker has been put in that mode for us without some type of device.

NICHOLAS PLAXTON: Okay.

MARK SEDDON: So we request when they show up, they come with that form that shows it has been done. And then, within the 14 -- it's one of those things that's turned on, it's 14 days is how long that, it's in that mode.

NICHOLAS PLAXTON: I guess the other question I have, too, like the safe mode, is that like, does it turn off? Because I mean, it's obviously in there for a reason and one time, after three hours, is he floating three hours without having a pacer do anything?

MARK SEDDON: It's still, so it's still

operating. It's operating in a method which is --

NICHOLAS PLAXTON: In sync with like a --

MARK SEDDON -- operating in a method which is compatible, within the conditions that they provide to us.

NICHOLAS PLAXTON: Okay.

MARK SEDDON: So it's not going to damage the device. And so, they're not turning it off per se, but they're setting it in a certain mode and a certain rate, usually like 65.

NICHOLAS PLAXTON: Okay.

MARK SEDDON: That's kind of a default. So there is, there is a -- we had that question, like, when you say it's safe mode --

NICHOLAS PLAXTON: Yeah.

MARK SEDDON: -- or protection mode, how dangerous is that to the patient.

NICHOLAS PLAXTON: That's what I'm wondering, yeah.

MARK SEDDON: No, it's still safe to the patient. It just in a, in a configuration that is protecting the machine, itself. Those questions, raised questions, why don't you always have it that way, but I don't know.

NICHOLAS PLAXTON: Yeah.

MARK SEDDON: I mean --

ADAM WEAVER: Make sure it works.

MARK SEDDON: Okay. Patient gonadal shielding, we already covered that, so I don't know if we need to go through all that. That was just the --

JAMES FUTCH: Just go through it.

MARK SEDDON: Okay. I was just going through that.

Okay. This was the NCRP handout that I just threw out there.

ADAM WEAVER: Where's the Lead Apron?

MARK SEDDON: Yeah, Where's the Lead Apron? That's actually available from the NCRP website, looking for a resource, they can provide a hand out front and back. It just has a basic statement that, you know, why we're no longer providing gonadal shielding. It's not recommended. And I think, there's also a website from NCRP that actually has some --

ADAM WEAVER: Questions and answers?

MARK SEDDON: Q and A. If you go to the next page, next slide. This is the back of it. More of the background. Next slide.

It does have some example questions and answers that they provide. So for technologists, while

they still would be changing the gonadal shielding, gonadal policy. So again, the key messages are the dose for the gonadal exam is too low to cause harm. Number two is the shielding can cover up clinically relevant anatomy and message three is that the GS can negatively affect the function of AEC. So some supporting documentation for our statements.

And then next one I think is for patients. Again, parallel to what we just mentioned. It's not as effective. Again, there's no benefit, but potential harm to the exam or potential detriment to the exam.

ADAM WEAVER: Detriment to the image?

MARK SEDDON: To the image.

NICHOLAS PLAXTON: Degradation.

MARK SEDDON: Degradation of the image.

And then this is a catch all. This was just, a chance to ask more, to make sure we have some discussion, which you really had good discussions today, just to point out, I think.

So some of the new things that we're looking at, we've created a Theranostics Task Force, a Theranostics Task Force within our facilities to look at all the features coming down. As far as, like -- Theranostics is where you, you have imaging

and therapy kind of combined, so this is some examples. I'll use an example.

Number 1 is diagnostic and therapy. It's where you do, like, imaging and therapy are similar pathways. So, you know, right now, there's a lot of work being done on PSMA, PET PSMA for imaging and then Lutetium PSMA for prostate cancer. For microspheres you're supposed to do Y90s. Obviously you do a mapping first to see where it goes and you do the therapy afterwards. Again, you follow the same pathway.

I think my next slide talks a little bit about, yeah, this is kind of the, like this is talking about Lutathera. You know, that spot Lutathera. So you got Ga-68 PET for imaging, and then you have the same targeting molecule. And Lutate, Lutathera for the treatment. And so you can see where it goes first, determine your dosimetry, determine how much to give and then afterwards, you can go ahead and do the actual treatment. So that's, that's kind of the concept behind Theranostics.

I'm not sure, for nuclear medicine out here, you're more aware of --

NICHOLAS PLAXTON: Yeah. We definitely do this. That's kind of like the, as we get more

targeted with our imaging, we can also create that for treatments. So -- and neuroendocrine imaging is a big one that's come up lately, where you --

MARK SEDDON: Yeah.

NICHOLAS PLAXTON: You know, before you couldn't really image because CT and MR are not really that good for it. But now we have the tracers that can go to the neuroendocrine tumors and then you train the radioisotope image on it, and give them an injection and go and treat what you imaged. So it's definitely the wave of the future for nuclear medicine.

MARK SEDDON: Yeah, that's sort of the way things are going.

I think the next slide is kind of showing that. There's a bunch of growth over the next few years. You know, Lutathera was approved in 2018 but the expectation was that some of the PSMA stuff will be approved this year.

Adam, you did some research on some of that stuff, right?

ADAM WEAVER: We're doing some of it. They're trying to finish it.

MARK SEDDON: Yeah. Yeah. So we've got some clinical trials going on with some of these things,

but, you know, there's a bunch of them coming down the pike. And the expectation is that --

ADAM WEAVER: Protein and --

MARK SEDDON: Yeah, yeah. So what's going to happen, if you look at the next slide.

NICHOLAS PLAXTON: Yeah. The F18 PMSA is supposed to be approved this week or something.

MARK SEDDON: Yeah.

NICHOLAS PLAXTON: That will really have a game change on that.

MARK SEDDON: So like here in 2017, this is from, I can't remember. The source is up there. So 87 percent is nuclear medicine focused. And then in 2030, they estimated 60 percent is going to be the market therapeutics. So that's really your big growth area.

So for, for like in Kevin's world, growth in potential medical events and everything else you looked at, you know, that's where you're going to see a lot more expansion because historically, besides, I mean, Zevalin has kind of gone away mostly, but you've got Policy One and some vagals (ph). There's not a lot of other therapy being used. I guess right now, the big utilization is Y90 microspheres.

CHANTEL CORBETT: And Lutathera.

MARK SEDDON: And Lutathera. If you think about it, the number one source of medical events is Y90 microspheres.

CHANTEL CORBETT: It's in a different category altogether, because it's a device.

MARK SEDDON: Yeah, it's a much more complicated procedure.

CHANTEL CORBETT: Yeah.

MARK SEDDON: A lot of these are becoming more complicated, too. Like Lutathera is becoming a complicated administration. The fusion with the --

CHANTEL CORBETT: It is, because it's still an injectable versus a device, so it's still under the --

MARK SEDDON: You have the amino acid and fusion.

ADAM WEAVER: You have to prep the patient.

MARK SEDDON: Pardon?

ADAM WEAVER: You have to prep the patient.

MARK SEDDON: Right. You have to prep the patient. There's a lot more going with it.

One of the things we rolled out this past year was GammaTile, which is basically old technology, old MR technology but in a new packaging for GBM,

certain type of brain tumors. Cs-131 seeds that are whole seeds they used back in the day. But now they're in these tiles that are biodegradable, I guess, you know. You can use them to go ahead and place them within the tumor bed and do a, a really better job of placement. Maintaining placement of those whoever places the seeds. Seeds migrate, they go wherever, so these actually stay where you want them to stay over time and your dosimetry is much tighter versus an external beam.

So does anyone else have experience with this?

CHANTEL CORBETT: Yeah. We were just looking at these, actually.

MARK SEDDON: Yeah. We started doing them.

JAMES FUTCH: Each of these little bumps is a separate seed?

MARK SEDDON: No. So there's four seeds within --

CHANTEL CORBETT: They're embedded in that mat.

ADAM WEAVER: They impregnate the material with the Cs-131.

JAMES FUTCH: Okay.

MARK SEDDON: The diagram on the top right corner shows the positions of the four seeds.

They're positioned in a location.

JAMES FUTCH: Oh, okay. Okay.

MARK SEDDON: So they're closer to one side versus the other so they're two different depths so you can kind of adjust your dose rate.

CHANTEL CORBETT: Surgery.

MARK SEDDON: Yeah. One side is bumpy rough, like you see on the picture. On the right, the backside is actually smooth. So the neurosurgeon can go ahead and determine which side is the appropriate one to place the closest to the tissue surface. It's implanted by the neurosurgeon with the oncologist present currently for the oversight as the authorization.

I'm not sure, Kev, I know you were talking about, I know there was talking about changing that, allowing more of a remote supervision. At some point, I'm not sure that was something that the vendor, I can't remember who the vendor was.

CHANTEL CORBETT: The nice thing about those are, the seeds by themselves, obviously, it's a lot easier to see if you drop one or misplace it.

MARK SEDDON: Yeah. You won't misplace seeds.

ADAM WEAVER: On the tile.

CHANTEL CORBETT: Nobody move.

MARK SEDDON: So one caveat is that it is four in a tile. So obviously, as we know from tiling a bathroom or, you know, not everything will fit so they can cut them. They have to be careful to cut them so they don't cut the seed. They're easy to cut.

ADAM WEAVER: Like marks on the back of it, the smooth side?

MARK SEDDON: Um, I don't remember if there's marks. I think there is. Yeah, there is marks on the back.

All right. Again, this is just information stuff. Just to -- I know we're over time. So there was a new reg., 8.39 revision, in the last year. I'm not sure everyone caught that. Some moderate changes to the patient relation criteria with some additional instructions. Gave a lot better information for those who are doing early release, as far as what to instruct your patients about and also a section on death of a patient following a pharmaceutical, which we dealt with.

ADAM WEAVER: Funeral homes.

MARK SEDDON: Yes. Funeral homes. A patient died immediately after being dosed with, like, 200 mSv. So it was fun. I think because they went

through renal failure at the same time. So, basically, the entire dose was there. So it was like, it was a lot of work with the morgue and with the funeral home and with the proper burial. And it hit the paper.

Next? That's just some more summaries from that. And, oh, and one other, just a caveat, was just for those sites who are doing I-125 seeds, Kevin, we're not a big fan for I-125 seeds at our facility because these things are -- if you're a busy site, they're a challenge to keep ahold of. So we've transitioned to use Savi Scout for, you know, in the process to eliminate the use of radioactive materials. But that is something definitely that -- there's other, there's the first one that come out. It uses the same practice, same work flow, but eliminates using, use of radioactive materials, which will make your licensees happy. Will make Kevin happy.

Keep that in mind if any of your sites are doing seeds for breast localization, which I'm not sure if anyone is. But I'm sure Chantel has some places.

CHANTEL CORBETT: Yeah. I have places that do both.

MARK SEDDON: Yeah.

CHANTEL CORBETT: It just depends on the user and what they really want. Some people are really happy with the I-125.

MARK SEDDON: All right. I know we're over time, so that's all I have.

So Brenda, do you want to give any updates?

BRENDA ANDREWS: Okay. Briefly. I was just going to go over the Council membership right quick. We have, of course, Nicholas Plaxton and Armand Cognetta who were recently reappointed for another three-year term. And now their terms will end on 5-12-24. So congratulations to them.

And then --

CHANTEL CORBETT: Woo.

BRENDA ANDREWS: Of course, we have John Danek and George Gilbright and Dr. Armstrong who were appointed in 10-23-19, which we announced that in our last meeting, but I just wanted to remind you all about that, too. Congratulations to them.

And the main thing coming up is we have eight members whose terms will end in August. So that's half the Board. So we're looking at vetting for that around the middle of June. I will send out an e-mail to current members to see if they want to

reapply for the position. And then we will start working from there once I know who wants to continue.

And the process is a little quicker now. So we're not having to go through the lengthy vetting like we did before. Reappointments are a lot easier. So if you want to get in, go ahead and you can let me know early if you want to, but we'll start doing that.

And we need to decide on where we're going to meet again. And in the back of your package is a calendar so we can talk about when you all want to have your next meeting.

MARK SEDDON: Is there a month we're looking at?

BRENDA ANDREWS: So we're looking at October 12th.

JAMES FUTCH: September, October.

BRENDA ANDREWS: September, October maybe.

JAMES FUTCH: So probably the week of --

BRENDA ANDREWS: Labor Day is the 6th of September.

JAMES FUTCH: The week of the 20th? September 20th? Any meetings to avoid? Any professional societies, this, that and the other thing?

CHANTEL CORBETT: FMGs are on the weekend, so it won't affect it.

BRENDA ANDREWS: September 20th sounds good to everybody?

REBECCA McFADDEN: The 20th?

CHANTEL CORBETT: Tuesday?

ALBERT TINEO: Tuesday is better for me.

REBECCA McFADDEN: Tuesday is better than Thursday.

BRENDA ANDREWS: The 21st.

ALBERT TINEO: The 21st.

MARK SEDDON: Is that okay?

CHANTEL CORBETT: Would it be here in Tampa again or Orlando?

BRENDA ANDREWS: Is that -- do you all want to continue meeting here?

KATHLEEN DROTAR: I'm fine.

BRENDA ANDREWS: It still works out for everybody?

MARK SEDDON: That's fine.

BRENDA ANDREWS: Okay. Good. So I will contact the hotel to make sure that that date is open. So right now, we'll put it pending until I hear from them to make sure we have the space. And that's it.

MARK SEDDON: Okay. I know we're over time. Is there any other business? Anyone have anything to bring up?

Cindy, do we have anything from you?

CINDY BECKER: No, not me.

MARK SEDDON: James? All right.

JAMES FUTCH: Thank you all for coming and participating and bringing your interest and your experiences and much appreciated.

MARK SEDDON: Okay. Thank you very much. With that, we'll adjourn the meeting then.

(Proceedings concluded at 3:13 p.m.)

CERTIFICATE OF REPORTER

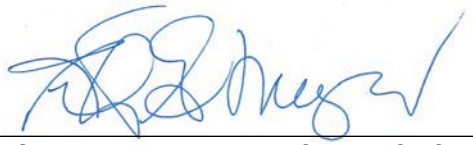
STATE OF FLORIDA:

COUNTY OF ORANGE:

I, RITA G. MEYER, RDR, CRR, CRC, do hereby certify that I was authorized to and did stenographically report the foregoing proceedings and that the foregoing transcript is a true and correct record of my stenographic notes.

I FURTHER CERTIFY that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties, attorneys or counsel connected with the action, nor am I financially interested in the outcome of the action.

DATED this 10th day of June, 2021.



RITA G. MEYER, RDR, CRR, CRC

92/19 93/7 93/11 94/15 94/20			**3500 [1]** 25/13 **36 [1]** 20/9	