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ADVISORY
COUNCIL ON
RADIATION PROTECTION

**CERTIFIED
TRANSCRIPT**

Bureau of Radiation Control
Hampton Inn & Suites
Tampa Airport Avion Park Westshore
5329 Avion Park Drive
Tampa, Florida 33607

DRAFT

Tuesday, May 25, 2021
10:04 a.m. - 3:13 p.m.

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



1 ADVISORY COUNCIL MEMBERS PRESENT:

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

12 FLORIDA DEPARTMENT OF HEALTH STAFF

13 Cynthia Becker, Bureau of Radiation Control
14 James Futch, Bureau of Radiation Control
15 Brenda Andrews, Bureau of Radiation Control
16 Gail Curry, Bureau of Radiation Control
17 Kevin Kunder, Bureau of Radiation Control
18 Clark Eldredge, Bureau of Radiation Control

DRAFT

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

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

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

12 JAMES FUTCH: Miss Brenda.

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

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

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

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

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

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

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

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

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

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

21 (Laughter)

22 MATTHEW WALSER: I have my papers.

23 JAMES FUTCH: Okay.

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

1 time. That's awesome.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 MARK SEDDON: All right. Thank you, Kathy.

1 And welcome, Joe, to your first meeting here.

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

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

9 ALBERT TINEO: Motion to approve.

10 JAMES FUTCH: Do we have a second?

11 MATTHEW WALSER: Second.

12 MARK SEDDON: All in favor?

13 ALL: Aye.

14 MARK SEDDON: Any nays?

15 (No Response)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 MARK SEDDON: Thank you, Cindy.

24 CINDY BECKER: You're welcome.

25 MARK SEDDON: Any questions for Cindy?

1 (No Response)

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

4 Gail. Medical quality assurance update.

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

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

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

19 (Laughter)

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

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

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

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

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

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

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

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

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

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

24 So I will give you a few statistics.

25 JAMES FUTCH: So can I say one thing before you

1 move on?

2 GAIL CURRY: Sure.

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

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

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

12 GAIL CURRY: Yes.

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

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

20 GAIL CURRY: Yes.

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

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

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

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

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

13 JAMES FUTCH: That's an important requirement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 So the number of licensed, as of last Friday,
4 the number of licensed general radiographers was
5 23,755. Radiologic technologist assistants were 35.
6 I do not have any numbers for our basic x-ray
7 machine operators. I can tell you that basic x-ray
8 machine operators podiatry, we have 52. We have
9 2,967 radiation therapy technologists; we have 9 PET
10 and we have 3,965 nuclear medicine techs. That's
11 what we have right now that are clear, active and
12 can go to work if they're not already working.

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

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

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

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

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

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

15 Right now, for July, which the renewal is open
16 90 days before the expiration date, so right now,
17 for general radiographers, we're looking at 126
18 people who have already renewed and that's at 9.76
19 percent, which is up 14 percent so far. So I see
20 that being an increase the closer we get to that
21 July deadline.

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

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

1 many, many, many emergency orders --

2 GAIL CURRY: Yes.

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

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

25 GAIL CURRY: We do. We get those questions.

1 JAMES FUTCH: Yeah.

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

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

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

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

6 ALBERT TINEO: Yep.

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

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

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

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

25 JAMES FUTCH: And then replace it when the next

1 one came in.

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

10 Yes, sir?

11 ALBERT ARMSTRONG: I have a question.

12 GAIL CURRY: Sure.

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

17 GAIL CURRY: No. Those are separate.

18 ALBERT ARMSTRONG: Okay. Because we have 400
19 attendees.

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

24 JAMES FUTCH: For the basics.

25 GAIL CURRY: Yes, the basic x-ray machine

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

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

7 ALBERT ARMSTRONG: Right. Right.

8 GAIL CURRY: Good question. Thank you.

9 JAMES FUTCH: So from a historical perspective,
10 all of it originally was part of the statute that
11 this section housed in 468 part four. And the
12 numbers used to be -- and you were talking about
13 basics. So the full basic was somewhere 3500 to
14 4500 years and years ago. And the basic machine
15 operator podiatric was about, about ten percent of
16 that. It was like 300 to, you know, somewhere in
17 that neighborhood. And then when the statute was
18 changed to allow the Board of Podiatric Medicine to
19 issue its certified podiatric x-ray assistant, then
20 the numbers started shifting.

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

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

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

13 ALBERT ARMSTRONG: Thank you.

14 JAMES FUTCH: Sure.

15 MARK SEDDON: Anymore questions for Gail?

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

1 thanks.

2 GAIL CURRY: Thank you. Thank you.

3 MARK SEDDON: All right. Anymore questions for
4 Gail?

5 (No Response)

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

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

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

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

1 years and a quarter; that type of thing.

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

4 JAMES FUTCH: That was --

5 MARK SEDDON: I thought that would be --

6 JAMES FUTCH: That was a big part of it.

7 CLARK ELDRIDGE: That was --

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

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

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

1 come to Florida.

2 CINDY BECKER: Wasn't that fun, Kevin?

3 MARK SEDDON: Expanding your skill set.

4 KEVIN KUNDER: Yes.

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

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

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

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

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

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

7 CINDY BECKER: Yeah. So --

8 MARK SEDDON: Very good. Well, thank you.

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

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

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

25 That leaves open her position, which is

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

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

7 (Laughter)

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

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

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

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

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

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

25 The main things that are probably going to come

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

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

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

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

1 done.

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

4 MARK SEDDON: Quick question.

5 KEVIN KUNDER: Yes.

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

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

11 MARK SEDDON: An option.

12 KEVIN KUNDER: Yeah, as an option.

13 CHANTEL CORBETT: They would actually be on the
14 licenses.

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

17 KEVIN KUNDER: Yes. An option.

18 MARK SEDDON: Makes sense.

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

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

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

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

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

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

20 MARK SEDDON: For the offender.

21 KEVIN KUNDER: I know which vendor it was.

22 MARK SEDDON: Okay.

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

1 there's been some other ones elsewhere.

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

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

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

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

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

19 KEVIN KUNDER: Yes. It's under investigation.

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

21 KEVIN KUNDER: But, yeah.

22 ALBERT TINEO: Something failed.

23 KEVIN KUNDER: Yes.

24 MARK SEDDON: Something failed.

25 ALBERT TINEO: Something failed.

1 JAMES FUTCH: At least one something.
2 Sometimes two.

3 KEVIN KUNDER: Yeah.

4 CHANTEL CORBETT: Just a quick question.

5 KEVIN KUNDER: Yes.

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

9 KEVIN KUNDER: Yes, I believe so.

10 CHANTEL CORBETT: Okay.

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

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

14 MARK SEDDON: Very good. Thank you.

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

18 KEVIN KUNDER: Yeah.

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

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

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

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

7 CHANTEL CORBETT: Yeah.

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

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

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

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

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

6 KEVIN KUNDER: I saw that.

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

9 KEVIN KUNDER: No. It's the same.

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

19 REBECCA McFADDEN: Thingy.

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

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

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

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

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

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

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

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

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

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

1 of technology certification that were not present in
2 1978 when our statute began. So if we have a
3 national registry that comes up with mammo and CT
4 and PET and all the other things, as long as they're
5 ionizing, we can add those to Florida certification
6 by endorsement.

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

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

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

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

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

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

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

21 MARK SEDDON: Right.

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

25 MARK SEDDON: Okay.

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

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

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

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

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

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

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

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

11 MARK SEDDON: Right.

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

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

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

22 MARK SEDDON: Owned.

23 CHANTEL CORBETT: Owned by --

24 MARK SEDDON: Let's say.

25 CHANTEL CORBETT: One entity and then there's

1 another entity --

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

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

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

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

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

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

24 MARK SEDDON: Right.

25 CHANTEL CORBETT: Then they even have ones that

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

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

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

11 MARK SEDDON: Right.

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

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

1 Digital Reaction, like those type companies.

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

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

6 CHANTEL CORBETT: Right.

7 MARK SEDDON: -- support.

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

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

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

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

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

1 MARK SEDDON: Exactly. Physician-owned
2 practices.

3 ALBERT TINEO: Yeah.

4 MARK SEDDON: Hospital-owned physician
5 practices.

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

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

21 MARK SEDDON: Is on the individual.

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

1 the normal.

2 MARK SEDDON: Okay. That's good.

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

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

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

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

24 MARK SEDDON: Right.

25 ALBERT ARMSTRONG: -- on behalf of the

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

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

6 ALBERT ARMSTRONG: Right.

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

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

16 ALBERT ARMSTRONG: Right.

17 JAMES FUTCH: You said the hospital owns it?

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

20 JOSEPH DANEK: What hospital is it?

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

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

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

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

11 CHANTEL CORBETT: For what?

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

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

16 MARK SEDDON: Doesn't clarify.

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

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

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

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

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

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

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

20 CHANTEL CORBETT: Yeah, it gets a little funky.

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

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

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

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

2 MARK SEDDON: This is a council for discussion.

3 JAMES FUTCH: We love worms.

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

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

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

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

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

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

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

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

21 CLARK ELDRIDGE: All right.

22 JAMES FUTCH: Three.

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

1 current status.

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

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

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

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

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

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

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

22 MARK SEDDON: Is that multiple infractions?

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

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

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

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

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

11 JAMES FUTCH: Somebody hit override maybe?

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

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

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

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

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

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

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

9 JAMES FUTCH: It wasn't a treatment beam.

10 MARK SEDDON: In service.

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

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

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

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

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

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

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

25 MARK SEDDON: So it's an equipment software

1 malfunction.

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

3 MARK SEDDON: Not a user error.

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

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

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

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

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

20 MARK SEDDON: Oh, one time.

21 CLARK ELDRIDGE: One time.

22 MARK SEDDON: One patient, one time.

23 CLARK ELDRIDGE: One patient, one time.

24 JOSEPH DANEK: Clark, a question for you.

25 Typical medical event like the one you're talking

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

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

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

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

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

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

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

1 wrong.

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

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

9 ALBERT TINEO: Right.

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

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

15 CLARK ELDRIDGE: Correct.

16 ALBERT TINEO: -- avoid it from happening
17 again?

18 CLARK ELDRIDGE: Yes.

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

25 JOSEPH DANEK: Yeah.

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

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

11 CLARK ELDRIDGE: This event?

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

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

17 MARK SEDDON: The existing criteria.

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

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

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

3 MARK SEDDON: No. Okay.

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

7 MARK SEDDON: The outside field dose is
8 significantly higher.

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

11 MARK SEDDON: Right.

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

14 MARK SEDDON: Yeah.

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

19 MARK SEDDON: Right.

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

25 MARK SEDDON: Yeah, because normally we see

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

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

13 MARK SEDDON: Right.

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

16 MARK SEDDON: Yeah.

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

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

1 discussed last week?

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

11 MARK SEDDON: Right.

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

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

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

23 MARK SEDDON: Okay.

24 CINDY BECKER: What's been submitted.

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

1 get those for our meetings.

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

4 MARK SEDDON: Right.

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

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

9 CINDY BECKER: Yeah.

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

13 CINDY BECKER: Right.

14 CLARK ELDRIDGE: Okay.

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

19 MARK SEDDON: Right.

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

22 MARK SEDDON: Yep. She's great.

23 CINDY BECKER: And Kate Pagine (ph).

24 MARK SEDDON: Kate Lawson (ph).

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

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

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

5 CINDY BECKER: Yeah.

6 MARK SEDDON: Thank you.

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

16 MARK SEDDON: How many times?

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

1 because it was medically necessary. It was
2 medically necessary.

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

8 CLARK ELDRIDGE: Right.

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

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

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

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

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

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

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

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

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

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

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

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

13 ALBERT TINEO: Very rare, though.

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

20 MARK SEDDON: Yeah. They silence it.

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

1 MARK SEDDON: Yeah.

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

4 MARK SEDDON: The NCRP has a recommendation
5 that once you get to 3 Gy, that every Gy is a
6 notification to the operator that they have got
7 4Gy, 5Gy, 6Gy, and so on, so they can make the
8 determination when they need to wrap it up if the
9 intervention is not being successful. As I say, the
10 physician has to know how long they've been working
11 with that patient at that location to determine if
12 they've exceeded skin dose considerations.

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

18 MARK SEDDON: No.

19 CLARK ELDRIDGE: No.

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

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

1 receiving notifications of the --

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

5 NICHOLAS PLAXTON: Exactly.

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

8 ADAM WEAVER: Same frequency.

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

17 CHANTEL CORBETT: Change the color of the
18 screen.

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

21 CLARK ELDRIDGE: Go from green to red.

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

24 CHANTEL CORBETT: Right. Yellow, orange, red.

25 NICHOLAS PLAXTON: Yeah.

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

6 NICHOLAS PLAXTON: Sure.

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

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

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

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

10 MARK SEDDON: Right.

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

13 MARK SEDDON: Yeah.

14 CLARK ELDRIDGE: You know.

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

18 CLARK ELDRIDGE: Okay. Any other?

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

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

4 MARK SEDDON: Yeah.

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

6 JAMES FUTCH: I think that makes sense.

7 There's three pages of it you probably want to
8 absorb a little bit.

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

11 JAMES FUTCH: I'll be your back up.

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

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

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

1 they've never gone to get the FDA approvals.

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

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

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

20 So James?

21 JAMES FUTCH: Sorry.

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

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

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

14 So where these folks finding these? They
15 are going online. They're finding, they're actually
16 showing up on several of your large online
17 marketplace and auction sites and they look sort of
18 like normal stuff. They make it sound get your
19 really cheap handheld x-ray. That's the big deal.
20 These things cost anywhere from 3 to 1500 bucks.
21 When your FDA compliant unit start three times that
22 and go up to, you know, so they might be \$2,000 to
23 \$6,000.

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

1 CLARK ELDRIDGE: Excuse me?

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

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

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

20 James? Next.

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

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

15 So, next.

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

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

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

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

13 James?

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

19 And then, James, one more.

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

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

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

12 This is their source to skin distance cone.
13 It's 100 cm and our code is 30, right? The FDA is
14 30.

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

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

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

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

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

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

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

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

24 NICHOLAS PLAXTON: That holds it together.

25 ADAM WEAVER: To hold that filter in place.

1 NICHOLAS PLAXTON: Amazing.

2 CLARK ELDRIDGE: It's actually screwed in.

3 There's a nice little screw set.

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

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

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

12 ADAM WEAVER: Yeah.

13 CLARK ELDRIDGE: All right.

14 JAMES FUTCH: Do we have time for questions?

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

16 JAMES FUTCH: Questions? Questions, anyone?

17 NICHOLAS PLAXTON: Where are we going for
18 lunch?

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

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

24 CLARK ELDRIDGE: Yeah.

25 MARK SEDDON: Okay.

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

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

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

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

13 BRENDA ANDREWS: We're scheduled to return at
14 1:30. It just depends on how fast they can serve
15 us.

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

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

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

4 CHANTEL CORBETT: Are they locking the room or
5 no?

6 BRENDA ANDREWS: I'm sorry?

7 CHANTEL CORBETT: Are they locking this room?

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

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

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

14 MARK SEDDON: Yeah. Usually.

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

17 CHANTEL CORBETT: You're volunteering to starve
18 yourself?

19 JAMES FUTCH: Yeah.

20 CHANTEL CORBETT: Let me ask.

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

22 JAMES FUTCH: Shall we adjourn?

23 MARK SEDDON: So we can adjourn for lunch.

24 We'll come back at 1:30.

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

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

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

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

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

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

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

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

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

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

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

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

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

20 MARK SEDDON: Revisit ten, right?

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

24 MARK SEDDON: Secondhand.

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

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

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

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

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

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

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

5 CLARK ELDRIDGE: Okay.

6 MARK SEDDON: Any comments on the first?

7 ALBERT TINEO: No.

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

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

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

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

11 JOSEPH DANEK: I got a couple questions on it.

12 CLARK ELDRIDGE: Please, fire away.

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

19 CLARK ELDRIDGE: Right.

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

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

1 --

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

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

11 CLARK ELDRIDGE: Right.

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

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

24 CHANTEL CORBETT: The unweighted.

25 CLARK ELDRIDGE: The unweighted. The fact that

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

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

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

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

13 CHANTEL CORBETT: The most clear would be
14 unweighted.

15 MARK SEDDON: Unweighted.

16 JOSEPH DANEK: You can put in parentheses or
17 something.

18 MARK SEDDON: The unweighted dosimetry
19 measurement and --

20 ADAM WEAVER: I think original confuses people.

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

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

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

3 CLARK ELDRIDGE: Yes.

4 CHANTEL CORBETT: Okay. Just clarifying.

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

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

11 CLARK ELDRIDGE: Just resubmit, do it again.

12 CHANTEL CORBETT: Okay.

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

17 CHANTEL CORBETT: Yeah.

18 MARK SEDDON: So, resubmit everything new.

19 CHANTEL CORBETT: Okay.

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

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

5 CHANTEL CORBETT: Everyone using fluoro.

6 CLARK ELDRIDGE: Fluoro.

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

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

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

13 ALBERT TINEO: Yeah.

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

17 MARK SEDDON: Okay. And then --

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

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

25 CLARK ELDRIDGE: Yeah. Inspectors are actually

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

5 MARK SEDDON: Make sure it's present.

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

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

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

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

21 MARK SEDDON: Right. I guess the --

22 CINDY BECKER: It used to be.

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

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

5 MARK SEDDON: Right.

6 CHANTEL CORBETT: They're not applying it.

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

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

15 MARK SEDDON: Yeah.

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

19 ADAM WEAVER: Right.

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

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

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

1 ADAM WEAVER: Yeah.

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

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

7 CINDY BECKER: That's correct.

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

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

12 CLARK ELDRIDGE: No, they don't.

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

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

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

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

22 CLARK ELDRIDGE: That's always been the case.

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

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

3 MARK SEDDON: Yeah.

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

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

11 MARK SEDDON: Right.

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

16 MARK SEDDON: Is there a grandfather period?

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

19 ALBERT TINEO: Yes.

20 CHANTEL CORBETT: You've got a lot of hospital
21 facilities, you know, that have got, I don't know,
22 50 people who have gone through whatever that role
23 is and there's no way --

24 CLARK ELDRIDGE: Right.

25 CHANTEL CORBETT: You've got the documentation

1 probably all the way back.

2 ALBERT TINEO: No way.

3 CLARK ELDRIDGE: No.

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

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

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

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

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

22 MARK SEDDON: That happens all the time.

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

25 ADAM WEAVER: That's right.

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

3 CHANTEL CORBETT: Exactly.

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

9 CHANTEL CORBETT: Oh, yeah, yeah. Absolutely.

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

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

15 CLARK ELDRIDGE: Yeah, exactly.

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

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

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

1 a --

2 ADAM WEAVER: Some kind of --

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

5 CLARK ELDRIDGE: It's the idea, yeah.

6 MARK SEDDON: Yeah.

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

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

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

17 MARK SEDDON: Yes.

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

21 MARK SEDDON: Right.

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

24 MARK SEDDON: That makes sense.

25 ADAM WEAVER: Yeah, start all the same time

1 with enough warning to registrants.

2 CHANTEL CORBETT: Yeah.

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

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

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

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

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

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

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

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

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

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

20 CHANTEL CORBETT: Right.

21 ADAM WEAVER: One badge per facility.

22 CLARK ELDRIDGE: Right.

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

1 CHANTEL CORBETT: Right.

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

7 ADAM WEAVER: Right.

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

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

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

1 and then end up going to take --

2 MARK SEDDON: Right.

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

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

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

14 MARK SEDDON: It's a small fraction.

15 CLARK ELDRIDGE: Yeah.

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

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

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

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

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

10 CLARK ELDRIDGE: That's true.

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

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

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

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

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

7 MARK SEDDON: Right.

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

10 MARK SEDDON: Yeah.

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

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

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

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

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

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

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

12 CLARK ELDRIDGE: Um --

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

17 CHANTEL CORBETT: Badged at.

18 MARK SEDDON: Badged at, I assume.

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

21 MARK SEDDON: And that's just one time.

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

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

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

5 CHANTEL CORBETT: Yeah.

6 ADAM WEAVER: If you modified it --

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

8 ADAM WEAVER: If you use your own method --

9 ALBERT TINEO: They're all the same thing.

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

15 ALBERT TINEO: Right.

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

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

20 ADAM WEAVER: I guess the only other question
21 is the effective dose in the first part.

22 Calculation of effective dose. We're really not
23 changing the effective dose. I mean, you're just
24 changing the overall dose. I mean, because
25 you're -- I mean, because you're not, you're just

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

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

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

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

14 ADAM WEAVER: Right.

15 MARK SEDDON: Yeah.

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

19 CLARK ELDRIDGE: Right. And so --

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

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

1 probably why it probably exists.

2 ADAM WEAVER: Yeah.

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

6 CINDY BECKER: Oh.

7 ADAM WEAVER: I mean --

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

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

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

14 ADAM WEAVER: Right.

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

19 MARK SEDDON: Right.

20 CLARK ELDRIDGE: -- and using alternatives for
21 that.

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

25 CHANTEL CORBETT: Yeah, but they're opposite.

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

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

4 ADAM WEAVER: I believe, right?

5 MARK SEDDON: There's four options?

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

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

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

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

14 ADAM WEAVER: Yeah. Right.

15 CHANTEL CORBETT: -- weighting factor, right.

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

20 MARK SEDDON: Yeah, yeah.

21 ADAM WEAVER: And some of those people --

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

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

1 CHANTEL CORBETT: Right.

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

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

6 ADAM WEAVER: Yeah.

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

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

13 MARK SEDDON: Right.

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

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

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

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

24 CHANTEL CORBETT: Renewals?

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

1 say, update and submit your RPP?

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

4 CLARK ELDRIDGE: No.

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

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

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

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

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

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

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

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

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

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

7 MARK SEDDON: Okay. All right.

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

10 MARK SEDDON: Use of the weighting factors?

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

13 MARK SEDDON: I mean --

14 ADAM WEAVER: Documentation of the weighting
15 factors, whatever.

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

25 CHANTEL CORBETT: Without a request, formal.

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

6 CHANTEL CORBETT: Right.

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

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

15 CHANTEL CORBETT: Yeah. If there's --

16 ADAM WEAVER: Some kind of guidance out there.

17 CHANTEL CORBETT: -- documentation guidance.

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

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

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

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

7 CHANTEL CORBETT: Yeah.

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

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

12 CHANTEL CORBETT: Yeah.

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

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

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

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

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

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

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

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

4 MARK SEDDON: Right. That's true.

5 ADAM WEAVER: Maybe NAV Lab, too.

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

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

10 MARK SEDDON: There is.

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

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

14 ADAM WEAVER: Yeah, it's not new.

15 CLARK ELDRIDGE: No.

16 MARK SEDDON: We're trying to refresh it.

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

21 MARK SEDDON: No.

22 ADAM WEAVER: Versus, what are they using now?

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

1 other.

2 MARK SEDDON: Pregnant apron?

3 CHANTEL CORBETT: Probably \$200 more or
4 something.

5 REBECCA McFADDEN: Add \$200 to the cost.

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

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

11 MARK SEDDON: Okay. I got you.

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

14 ADAM WEAVER: More ergonomically designed.

15 CHANTEL CORBETT: Yeah.

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

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

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

22 ADAM WEAVER: Right.

23 CHANTEL CORBETT: We digress.

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

1 Sorry.

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

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

10 ADAM WEAVER: Yeah.

11 MARK SEDDON: And then Information Notice
12 Number 108.

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

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

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

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

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

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

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

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

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

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

17 MARK SEDDON: Right.

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

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

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

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

3 MARK SEDDON: Yeah.

4 CLARK ELDRIDGE: It's not like --

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

6 (Laughter)

7 CINDY BECKER: No.

8 CHANTEL CORBETT: -- and you're done.

9 MARK SEDDON: Yeah.

10 Okay. Any --

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

13 MARK SEDDON: Any other questions for Clark?

14 CHANTEL CORBETT: Maybe to increase his mailbox
15 size.

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

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

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

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

8 CLARK ELDRIDGE: No.

9 MARK SEDDON: Correct. For gonadal shielding.

10 ADAM WEAVER: Yeah.

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

17 MARK SEDDON: Right.

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

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

24 CLARK ELDRIDGE: The product, yeah.

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

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

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

13 ADAM WEAVER: Right.

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

25 ALBERT ARMSTRONG: Okay. That's exactly, this

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

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

12 ADAM WEAVER: Patients complain.

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

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

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

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

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

24 MARK SEDDON: Kathy may.

25 ALBERT ARMSTRONG: Okay. Yeah, good.

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

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

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

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

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

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

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

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

13 MARK SEDDON: Right.

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

24 MARK SEDDON: Right. I will say --

25 CHANTEL CORBETT: Education.

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

10 CHANTEL CORBETT: Right.

11 MARK SEDDON: Because it's a regulatory --

12 CHANTEL CORBETT: Body.

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

15 ADAM WEAVER: It's a national body.

16 CHANTEL CORBETT: They can Google it.

17 MARK SEDDON: I'm sure they can.

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

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

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

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

3 KATHLEEN DROTAR: Yeah.

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

8 CHANTEL CORBETT: Right.

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

18 CHANTEL CORBETT: Communication.

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

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

1 we're changing the practice in the field.

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

6 ALBERT ARMSTRONG: I'm an old technologist.

7 ALBERT TINEO: Yep. It happens.

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

10 ALBERT TINEO: Oh, yeah.

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

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

18 CHANTEL CORBETT: Right. It's still new.

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

21 MARK SEDDON: Dental has not.

22 ADAM WEAVER: And chiropractic.

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

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

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

5 MARK SEDDON: Yeah.

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

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

9 (Laughter)

10 ADAM WEAVER: What else have you got for us?

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

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

15 JAMES FUTCH: Yeah, moving along.

16 MARK SEDDON: So James.

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

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

23 KEVIN KUNDER: You received, huh?

24 CHANTEL CORBETT: Traitor.

25 JAMES FUTCH: To my credit, to my credit.

1 ADAM WEAVER: It's the home office.

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

4 CHANTEL CORBETT: This particular one.

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

11 ADAM WEAVER: Wow.

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

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

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

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

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

25 And one thing we discovered is, although we

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

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

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

1 same thing. We did it before they did.

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

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

13 In our world, before we renew a license for the
14 12 hours of CE, we require the provider to send us
15 proof of that class completion and to a small
16 percentage of folks who renew close enough in time
17 to renewal so there isn't time for that to happen,
18 the providers have 30 days to supply that to us.
19 The technologists, themselves, must supply the class
20 certificate proof to the department.

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

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

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

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

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

1 us a call or, you know.

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

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

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

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

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

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

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

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

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

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

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

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

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

6 CHANTEL CORBETT: ARRT or A Plus credit?

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

9 JAMES FUTCH: That's okay.

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

12 JAMES FUTCH: Right.

13 KATHLEEN DROTAR: It's going through RCEEMS.

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

18 KATHLEEN DROTAR: Yeah. I hear you.

19 CHANTEL CORBETT: We'll just say approve.

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

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

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

9 JAMES FUTCH: Yeah.

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

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

17 CHANTEL CORBETT: Put them all on there.

18 KATHLEEN DROTAR: Not for 2022.

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

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

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

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

19 JAMES FUTCH: Exactly.

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

22 JAMES FUTCH: That was the difference at
23 least --

24 KATHLEEN DROTAR: In addition to --

25 JAMES FUTCH: -- between what we do currently

1 and what they're talking about.

2 CHANTEL CORBETT: Right.

3 JAMES FUTCH: What their new objective is.

4 They were focused on hands-on activities.

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

12 JAMES FUTCH: Yeah.

13 KATHLEEN DROTAR: James?

14 JAMES FUTCH: Yes, ma'am?

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

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

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

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

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

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

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

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

19 JAMES FUTCH: No. No.

20 CHANTEL CORBETT: Opposite.

21 REBECCA McFADDEN: Or opposite.

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

1 don't mean just rad tech.

2 CHANTEL CORBETT: The tech is not physically in
3 Florida.

4 JAMES FUTCH: They can't be.

5 REBECCA McFADDEN: But are they ARRT
6 registered?

7 JAMES FUTCH: It doesn't matter.

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

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

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

1 3D specs stuff for, they're just more advanced in
2 the training.

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

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

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

11 MARK SEDDON: Yeah, MR, but CT --

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

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

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

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

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

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

10 MARK SEDDON: I think what we --

11 JAMES FUTCH: Some kind of communication.

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

17 CHANTEL CORBETT: Part of the study.

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

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

23 MARK SEDDON: Okay. Yeah.

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

25 MARK SEDDON: If you want. Yeah, I put

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

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

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

8 (No Response)

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

11 JAMES FUTCH: We had some discussions --

12 MARK SEDDON: Go ahead.

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

15 MARK SEDDON: Yeah.

16 KATHLEEN DROTAR: Mm-hmm.

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

24 So if you want to go to the next slide.

25 So in the last few years, we have pacemakers

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

4 ADAM WEAVER: Programmed.

5 MARK SEDDON: So the programming it as a
6 scheduling issue. So usually, we generally have a
7 manufacturers rep. come on site to do the
8 programming. So we've been working with the
9 different vendors. They, especially Covid, when
10 perhaps we were limited to access to facilities and
11 for traveling around, we were working with different
12 vendors to go ahead and pilot out some of the
13 different products they have.

14 So Biotronik was the first one we did. They
15 have an auto detect system that will actually two
16 weeks before the patient is scheduled to have the
17 MRI study, they can put the device into an auto
18 protect mode and it will go ahead -- and you can
19 switch slides.

20 I think the next one talks about -- yeah,
21 Biotronik. So it will go ahead and detect when the
22 sensor in the pacer is within a 10 mT magnetic
23 field. Once it hits that, it will automatically
24 jump into safe mode. And so --

25 JAMES FUTCH: Sorry.

1 CHANTEL CORBETT: Is there an outward way to
2 verify?

3 MARK SEDDON: No. There's no outward way of
4 verifying it. Basically, what happens is the
5 activation is still done by the representative, but
6 it's done at the direction of the physician within
7 the physician's office. So it's done, you know, at
8 any points with the 14 weeks -- 14 days prior. And
9 then once the scan is done, after the MRI scan is
10 done, then it will go back into normal mode.

11 So it's sort of an auto detect when it's within
12 the magnetic field and then be a safe field once
13 it's completed, it will no longer be in that type of
14 situation.

15 So we started at one facility last summer and
16 it's been working fine and now all the Biotronik
17 pacemakers are to be initiated at the physician's
18 office and then auto detect when it comes on site to
19 be scanned.

20 So the next one we've been working with is
21 Medtronic. So theirs is a different type of system.
22 It's called a CareLink Express. I think this is the
23 one James was called about.

24 JAMES FUTCH: Yeah.

25 MARK SEDDON: Basically, the equipment to

1 program the device is on site. So it's actually
2 within the MR suite or at the MR suite. And so, it
3 allows for a remote support to walk the technologist
4 or nurse through programming and making the program
5 change to place it into a safe mode.

6 So we have a handheld wand that you hold up
7 against the pacer, the little device; a tablet which
8 controls it.

9 Typically, they'll go ahead and Facetime with
10 the, the representative remotely and then they can
11 go ahead and program the device, scan the patient.
12 When they're done, they go back and reprogram the
13 device. All under the supervision of the
14 representative virtually.

15 So this is -- have you ever had a logistical
16 challenge? You can go to the next slide.

17 I have a summary. Yeah, so this is kind of
18 work flow. So you have to have an order from the
19 physician. And so that they go ahead and place
20 the -- that they want the device placed into a
21 certain, certain setting to a certain mode. The,
22 the nurse or the technologist will go ahead and
23 program the device under the supervision of the
24 remote rep. And the remote rep. will review the
25 written order that they provide to us to make sure

1 that the -- they know how the setting should be.
2 And they're basically watching the entire process as
3 we're doing -- watching the screen, and they're
4 watching, you know, the technologist or the nurse
5 perform the change.

6 There's a print out once the device has made
7 the changes so you have a record of what has been
8 done to the pacer. They do the scan. And when it's
9 done, you have to go back in and reinitiate and
10 revert back to the original settings.

11 So we still have been doing this under the
12 pilot. Go to the next slide. And, sorry, this is
13 the order form.

14 So this is an example of -- the physician is
15 the one who actually creates the order for the
16 change of settings. Normally it's default settings,
17 but if they have specific settings they want to do
18 for the rate, how to set the pacemaker, they can go
19 ahead and determine that specifically. So the, the
20 rep. and the past rep. would be on site to do this,
21 but now the rep. is sort of guiding the nurse or
22 technologist to go ahead and do so.

23 Next slide.

24 CHANTEL CORBETT: And that order is coming from
25 the ordering.

1 MARK SEDDON: From the ordering physician.

2 CHANTEL CORBETT: Their cardiologist?

3 MARK SEDDON: Our cardiologist. Our physician
4 who is the one, who's ordering the pace, right? So
5 the cardiologist is the one who manages the
6 pacemaker and determines how they want the pacemaker
7 to be functioning.

8 CHANTEL CORBETT: Right.

9 MARK SEDDON: Or set the app. This is the next
10 one.

11 So our experience with Medtronic has been we
12 have had the rep. Because we're still piloting it.
13 We've had the rep. on site for every time we're
14 doing this. So even though we're doing it remotely,
15 we still have the rep. there to make sure it's being
16 done, physically present, because as we had talked
17 through, there is potential for connectivity issues
18 right, because you're in an MRI suite when you
19 shield it, and so having the ability to actually
20 dial out and talk to somebody via Facetime or some
21 type of remote device is challenging.

22 CHANTEL CORBETT: So they're not changing the
23 settings until they're already in the MR suite?

24 MARK SEDDON: When they show up at the MR suite
25 for the scan, that's when they get the settings

1 changed.

2 JAMES FUTCH: It's very different from Biotech.

3 MARK SEDDON: Right. The Biotech -- Biotronik,
4 they set theirs into an auto detect mode.

5 CHANTEL CORBETT: Right.

6 MARK SEDDON: They program it so that they turn
7 on the auto detect mode. When the person enters the
8 MR magnet, itself, it will detect the magnetic
9 field, enter protection mode and it will allow the
10 patient to be scanned without damaging the
11 pacemaker.

12 CHANTEL CORBETT: Right. I just wasn't sure if
13 there was a reason not do this, like, in an exam
14 room outside of the MR suite and not --

15 MARK SEDDON: Yeah. So for Medtronic, it has
16 to be done 30 minutes prior. So it's about 30
17 minutes prior, because they have to do interrogation
18 of the patient. There's some logistical steps to go
19 through and so that's why we -- we're probably in
20 two places. One with the nurse doing the program
21 change and one with the technologist doing the
22 program change. Again, in both cases, the
23 representative who would normally do it is doing it
24 with them, but remotely.

25 CHANTEL CORBETT: Right.

1 MARK SEDDON: But the problem is, you know,
2 does that connection fail. So what do you do in
3 that type of situation.

4 So the reason why, for all, all of us, the big
5 reason besides Covid is, scheduling can be a
6 challenge because right now, whenever you have
7 pacemaker patients for MRI, they have to be
8 scheduled like 9 to 5, Monday through Friday only.
9 They have to be scheduled in advance because you
10 have to make sure there's a representative available
11 to come on site to be there to actually be present.
12 And as we all know in the hospital world, you know
13 the MRI schedule is never on time, so you're always
14 delayed, delayed, and so, just a lot of logistical
15 problems. So having remote access, you can actually
16 scan those patients at different hours, and then
17 have ability to have remote support to make those
18 changes.

19 The third study we're going to start up is with
20 Boston Scientific. Theirs is called Latitude. It's
21 very similar to the Medtronic work flow with remote
22 access. You have the equipment left on site. Their
23 remote is actually through the actual program,
24 itself. You can actually go ahead and talk to the,
25 to the individual there through the device, itself.

1 And the individuals, they're actually seeing on
2 their end, what the programmer, the device is doing
3 to the, to the pacemaker.

4 So the one nice thing about them is that when
5 it goes to MR protect mode for their, it has the
6 auto protection time out. So rather than at the end
7 having to go back and turn off that change or make
8 the change back, it will automatically, after three
9 hours, after you set that up, it will automatically
10 turn off. So you don't have to worry about going
11 back in and having a rep. available again after the
12 study to, to go ahead and turn it off.

13 So, so those are three things that out there.
14 They've been available. I think Covid really kind
15 of put the fire under the vendors to go ahead and
16 push this pretty hard. St. Jude or Abbott, the
17 other vendor out there with pacemakers, they also
18 have a version, we'll probably do a pilot with them
19 later on, so this is something out there. The
20 Biotronik version is the easiest because it's less
21 labor intensive. It saves a lot of time in
22 scheduling, but the other vendor products that are
23 out there, are something is coming down the pipe.

24 So anyone have any questions on that?

25 ADAM WEAVER: Does the patient know what kind

1 of pacemaker is --

2 MARK SEDDON: Yeah. The, yeah, the patients
3 are very aware of it because they constantly have
4 to -- they constantly have to be consulting with the
5 representative because they're in the doctor's
6 office. So it's, again, there's a lot of
7 representative contact with the pacemaker within the
8 physician's office. It's just when they actually
9 come to be scanned for the MRI scan, then there's a
10 coordination of the rep. to come on site to go ahead
11 and do that.

12 JAMES FUTCH: That's what I was saying we're
13 always being available for being a resource on this
14 because we, we were contacted by a completely
15 different hospital system who didn't really have a
16 problem. It was more of an internal communication
17 problem, I think. And we ended up redirecting them
18 I think to their internal medical physics support
19 and marketing development team. I don't know if
20 they ever contacted you, but we offered you to talk
21 to -- the medical physicists --

22 MARK SEDDON: Yeah, I mean usually, like for
23 us, our MR safety committee, there's been a big push
24 in the past -- from the joint commission the past
25 couple years for MR safety to be very active,

1 involved. We have a multi disciplinary MR safety
2 committee with involves technologists and physicists
3 and physicians. And so, they're trying to make sure
4 that, you know, that for implantable devices, they
5 have a proper policy and procedure in how to handle
6 them. Like I said, this is something new where back
7 in the day, you never scanned patients with these
8 type of devices. You couldn't. Now the last few
9 years, they had conditional devices available. It's
10 made it possible, but now it's -- it has limited
11 your scheduling and the numbers are pretty high.

12 For Florida, we have a lot of folks with
13 pacemakers, right? So I know our facility, my
14 facility is we have hundreds of patients who are
15 scanned with pacemakers over the year at MR, so it
16 is definitely a logistical problem for the vendors
17 to provide reps. who can go on site. So this is
18 something that they're pushing pretty hard.

19 CHANTEL CORBETT: Is there a certain date or
20 some kind of line where these newer versions, you
21 know, were available, something to say whether
22 they're --

23 MARK SEDDON: It depends on the vendor and some
24 of them are retroactive.

25 CHANTEL CORBETT: Okay.

1 MARK SEDDON: Some of them are not. It just
2 really depends.

3 CHANTEL CORBETT: Right. I mean, like if you
4 say, like, yeah, I have a Medtronic, you know, and
5 mine was put in, you know, eighteen months ago
6 versus six months ago, are we both eligible, are we
7 not, you know, that kind of thing.

8 MARK SEDDON: Yeah. So again, the cardiologist
9 places the order for the --

10 CHANTEL CORBETT: The patient's cardiologist,
11 they do that?

12 MARK SEDDON: -- they're the ones close
13 enough --

14 Have you guys dealt with this?

15 ALBERT TINEO: Yeah, they should know. The
16 cardiologists usually know each patient's --

17 CHANTEL CORBETT: That's why I'm asking. It is
18 the patient's cardiologist, not an in-hospital
19 cardiologist.

20 MARK SEDDON: Yeah. That's why we have to have
21 a written order for both the Medtronic --

22 CHANTEL CORBETT: Right.

23 MARK SEDDON: -- and the Boston Scientific,
24 they actually do have an order form that details
25 exactly what settings. They have a default setting,

1 which is the protection, their safe mode that
2 they're using and then they have, you know, if
3 there's a variance from that, the physician can set
4 what they want through the app.

5 NICHOLAS PLAXTON: I had a couple questions on
6 that. Like that first company.

7 MARK SEDDON: Yes.

8 NICHOLAS PLAXTON: Like, what happens if they,
9 they forget to set it up and there's no way to
10 check, right? I mean, it's like, someone turned it
11 off in the safe mode, and it's supposed to detect
12 right? Let's say they didn't turn it off. So then
13 how do you know? It's a surprise thing when you go
14 in there.

15 MARK SEDDON: Right. That was one of the
16 concerns. So when the representative goes on site,
17 who does the programming, they have to give -- they
18 give a print out and a piece of paper, the document
19 that the patient brings with them when they come in.

20 NICHOLAS PLAXTON: That shows it's been --

21 MARK SEDDON: That shows it's been done. The
22 print out that it's been performed.

23 NICHOLAS PLAXTON: Okay.

24 MARK SEDDON: It would be the same as --
25 because we're trusting the representatives when they

1 come on site to do it. The same type of trust with
2 the representative that actually --

3 NICHOLAS PLAXTON: Okay.

4 MARK SEDDON: They're the qualified expert to
5 go ahead and perform the procedure.

6 CHANTEL CORBETT: Yeah, that was my
7 misunderstanding. That's what I was asking for,
8 what kind of visual documentation or something.

9 NICHOLAS PLAXTON: How do you know?

10 MARK SEDDON: There's no way to know whether or
11 not the pacemaker has been put in that mode for us
12 without some type of device.

13 NICHOLAS PLAXTON: Okay.

14 MARK SEDDON: So we request when they show up,
15 they come with that form that shows it has been
16 done. And then, within the 14 -- it's one of those
17 things that's turned on, it's 14 days is how long
18 that, it's in that mode.

19 NICHOLAS PLAXTON: I guess the other question I
20 have, too, like the safe mode, is that like, does it
21 turn off? Because I mean, it's obviously in there
22 for a reason and one time, after three hours, is he
23 floating three hours without having a pacer do
24 anything?

25 MARK SEDDON: It's still, so it's still

1 operating. It's operating in a method which is --

2 NICHOLAS PLAXTON: In sync with like a --

3 MARK SEDDON -- operating in a method which is
4 compatible, within the conditions that they provide
5 to us.

6 NICHOLAS PLAXTON: Okay.

7 MARK SEDDON: So it's not going to damage the
8 device. And so, they're not turning it off per se,
9 but they're setting it in a certain mode and a
10 certain rate, usually like 65.

11 NICHOLAS PLAXTON: Okay.

12 MARK SEDDON: That's kind of a default. So
13 there is, there is a -- we had that question, like,
14 when you say it's safe mode --

15 NICHOLAS PLAXTON: Yeah.

16 MARK SEDDON: -- or protection mode, how
17 dangerous is that to the patient.

18 NICHOLAS PLAXTON: That's what I'm wondering,
19 yeah.

20 MARK SEDDON: No, it's still safe to the
21 patient. It just in a, in a configuration that is
22 protecting the machine, itself. Those questions,
23 raised questions, why don't you always have it that
24 way, but I don't know.

25 NICHOLAS PLAXTON: Yeah.

1 MARK SEDDON: I mean --

2 ADAM WEAVER: Make sure it works.

3 MARK SEDDON: Okay. Patient gonadal shielding,
4 we already covered that, so I don't know if we need
5 to go through all that. That was just the --

6 JAMES FUTCH: Just go through it.

7 MARK SEDDON: Okay. I was just going through
8 that.

9 Okay. This was the NCRP handout that I just
10 threw out there.

11 ADAM WEAVER: Where's the Lead Apron?

12 MARK SEDDON: Yeah, Where's the Lead Apron?
13 That's actually available from the NCRP website,
14 looking for a resource, they can provide a hand out
15 front and back. It just has a basic statement that,
16 you know, why we're no longer providing gonadal
17 shielding. It's not recommended. And I think,
18 there's also a website from NCRP that actually has
19 some --

20 ADAM WEAVER: Questions and answers?

21 MARK SEDDON: Q and A. If you go to the next
22 page, next slide. This is the back of it. More of
23 the background. Next slide.

24 It does have some example questions and answers
25 that they provide. So for technologists, while

1 they still would be changing the gonadal shielding,
2 gonadal policy. So again, the key messages are the
3 dose for the gonadal exam is too low to cause harm.
4 Number two is the shielding can cover up clinically
5 relevant anatomy and message three is that the GS
6 can negatively affect the function of AEC. So some
7 supporting documentation for our statements.

8 And then next one I think is for patients.
9 Again, parallel to what we just mentioned. It's not
10 as effective. Again, there's no benefit, but
11 potential harm to the exam or potential detriment to
12 the exam.

13 ADAM WEAVER: Detriment to the image?

14 MARK SEDDON: To the image.

15 NICHOLAS PLAXTON: Degradation.

16 MARK SEDDON: Degradation of the image.

17 And then this is a catch all. This was just, a
18 chance to ask more, to make sure we have some
19 discussion, which you really had good discussions
20 today, just to point out, I think.

21 So some of the new things that we're looking
22 at, we've created a Theranostics Task Force, a
23 Theranostics Task Force within our facilities to
24 look at all the features coming down. As far as,
25 like -- Theranostics is where you, you have imaging

1 and therapy kind of combined, so this is some
2 examples. I'll use an example.

3 Number 1 is diagnostic and therapy. It's where
4 you do, like, imaging and therapy are similar
5 pathways. So, you know, right now, there's a lot of
6 work being done on PSMA, PET PSMA for imaging and
7 then Lutetium PSMA for prostate cancer. For
8 microspheres you're supposed to do Y90s. Obviously
9 you do a mapping first to see where it goes and you
10 do the therapy afterwards. Again, you follow the
11 same pathway.

12 I think my next slide talks a little bit about,
13 yeah, this is kind of the, like this is talking
14 about Lutathera. You know, that spot Lutathera. So
15 you got Ga-68 PET for imaging, and then you have the
16 same targeting molecule. And Lutate, Lutathera for
17 the treatment. And so you can see where it goes
18 first, determine your dosimetry, determine how much
19 to give and then afterwards, you can go ahead and do
20 the actual treatment. So that's, that's kind of the
21 concept behind Theranostics.

22 I'm not sure, for nuclear medicine out here,
23 you're more aware of --

24 NICHOLAS PLAXTON: Yeah. We definitely do
25 this. That's kind of like the, as we get more

1 targeted with our imaging, we can also create that
2 for treatments. So -- and neuroendocrine imaging is
3 a big one that's come up lately, where you --

4 MARK SEDDON: Yeah.

5 NICHOLAS PLAXTON: You know, before you
6 couldn't really image because CT and MR are not
7 really that good for it. But now we have the
8 tracers that can go to the neuroendocrine tumors and
9 then you train the radioisotope image on it, and
10 give them an injection and go and treat what you
11 imaged. So it's definitely the wave of the future
12 for nuclear medicine.

13 MARK SEDDON: Yeah, that's sort of the way
14 things are going.

15 I think the next slide is kind of showing that.
16 There's a bunch of growth over the next few years.
17 You know, Lutathera was approved in 2018 but the
18 expectation was that some of the PSMA stuff will be
19 approved this year.

20 Adam, you did some research on some of that
21 stuff, right?

22 ADAM WEAVER: We're doing some of it. They're
23 trying to finish it.

24 MARK SEDDON: Yeah. Yeah. So we've got some
25 clinical trials going on with some of these things,

1 but, you know, there's a bunch of them coming down
2 the pike. And the expectation is that --

3 ADAM WEAVER: Protein and --

4 MARK SEDDON: Yeah, yeah. So what's going to
5 happen, if you look at the next slide.

6 NICHOLAS PLAXTON: Yeah. The F18 PMSA is
7 supposed to be approved this week or something.

8 MARK SEDDON: Yeah.

9 NICHOLAS PLAXTON: That will really have a game
10 change on that.

11 MARK SEDDON: So like here in 2017, this is
12 from, I can't remember. The source is up there. So
13 87 percent is nuclear medicine focused. And then in
14 2030, they estimated 60 percent is going to be the
15 market therapeutics. So that's really your big
16 growth area.

17 So for, for like in Kevin's world, growth in
18 potential medical events and everything else you
19 looked at, you know, that's where you're going to
20 see a lot more expansion because historically,
21 besides, I mean, Zevalin has kind of gone away
22 mostly, but you've got Policy One and some vagals
23 (ph). There's not a lot of other therapy being
24 used. I guess right now, the big utilization is Y90
25 microspheres.

1 CHANTEL CORBETT: And Lutathera.

2 MARK SEDDON: And Lutathera. If you think
3 about it, the number one source of medical events is
4 Y90 microspheres.

5 CHANTEL CORBETT: It's in a different category
6 altogether, because it's a device.

7 MARK SEDDON: Yeah, it's a much more
8 complicated procedure.

9 CHANTEL CORBETT: Yeah.

10 MARK SEDDON: A lot of these are becoming more
11 complicated, too. Like Lutathera is becoming a
12 complicated administration. The fusion with the --

13 CHANTEL CORBETT: It is, because it's still an
14 injectable versus a device, so it's still under the
15 --

16 MARK SEDDON: You have the amino acid and
17 fusion.

18 ADAM WEAVER: You have to prep the patient.

19 MARK SEDDON: Pardon?

20 ADAM WEAVER: You have to prep the patient.

21 MARK SEDDON: Right. You have to prep the
22 patient. There's a lot more going with it.

23 One of the things we rolled out this past year
24 was GammaTile, which is basically old technology,
25 old MR technology but in a new packaging for GBM,

1 certain type of brain tumors. Cs-131 seeds that are
2 whole seeds they used back in the day. But now
3 they're in these tiles that are biodegradable, I
4 guess, you know. You can use them to go ahead and
5 place them within the tumor bed and do a, a really
6 better job of placement. Maintaining placement of
7 those whoever places the seeds. Seeds migrate, they
8 go wherever, so these actually stay where you want
9 them to stay over time and your dosimetry is much
10 tighter versus an external beam.

11 So does anyone else have experience with this?

12 CHANTEL CORBETT: Yeah. We were just looking
13 at these, actually.

14 MARK SEDDON: Yeah. We started doing them.

15 JAMES FUTCH: Each of these little bumps is a
16 separate seed?

17 MARK SEDDON: No. So there's four seeds
18 within --

19 CHANTEL CORBETT: They're embedded in that
20 mat.

21 ADAM WEAVER: They impregnate the material with
22 the Cs-131.

23 JAMES FUTCH: Okay.

24 MARK SEDDON: The diagram on the top right
25 corner shows the positions of the four seeds.

1 They're positioned in a location.

2 JAMES FUTCH: Oh, okay. Okay.

3 MARK SEDDON: So they're closer to one side
4 versus the other so they're two different depths so
5 you can kind of adjust your dose rate.

6 CHANTEL CORBETT: Surgery.

7 MARK SEDDON: Yeah. One side is bumpy rough,
8 like you see on the picture. On the right, the
9 backside is actually smooth. So the neurosurgeon
10 can go ahead and determine which side is the
11 appropriate one to place the closest to the tissue
12 surface. It's implanted by the neurosurgeon with
13 the oncologist present currently for the oversight
14 as the authorization.

15 I'm not sure, Kev, I know you were talking
16 about, I know there was talking about changing that,
17 allowing more of a remote supervision. At some
18 point, I'm not sure that was something that the
19 vendor, I can't remember who the vendor was.

20 CHANTEL CORBETT: The nice thing about those
21 are, the seeds by themselves, obviously, it's a lot
22 easier to see if you drop one or misplace it.

23 MARK SEDDON: Yeah. You won't misplace seeds.

24 ADAM WEAVER: On the tile.

25 CHANTEL CORBETT: Nobody move.

1 MARK SEDDON: So one caveat is that it is four
2 in a tile. So obviously, as we know from tiling a
3 bathroom or, you know, not everything will fit so
4 they can cut them. They have to be careful to cut
5 them so they don't cut the seed. They're easy to
6 cut.

7 ADAM WEAVER: Like marks on the back of it, the
8 smooth side?

9 MARK SEDDON: Um, I don't remember if there's
10 marks. I think there is. Yeah, there is marks on
11 the back.

12 All right. Again, this is just information
13 stuff. Just to -- I know we're over time. So there
14 was a new reg., 8.39 revision, in the last year.
15 I'm not sure everyone caught that. Some moderate
16 changes to the patient relation criteria with some
17 additional instructions. Gave a lot better
18 information for those who are doing early release,
19 as far as what to instruct your patients about and
20 also a section on death of a patient following a
21 pharmaceutical, which we dealt with.

22 ADAM WEAVER: Funeral homes.

23 MARK SEDDON: Yes. Funeral homes. A patient
24 died immediately after being dosed with, like, 200
25 mSv. So it was fun. I think because they went

1 through renal failure at the same time. So,
2 basically, the entire dose was there. So it was
3 like, it was a lot of work with the morgue and with
4 the funeral home and with the proper burial. And it
5 hit the paper.

6 Next? That's just some more summaries from
7 that. And, oh, and one other, just a caveat, was
8 just for those sites who are doing I-125 seeds,
9 Kevin, we're not a big fan for I-125 seeds at our
10 facility because these things are -- if you're a
11 busy site, they're a challenge to keep ahold of. So
12 we've transitioned to use Savi Scout for, you know,
13 in the process to eliminate the use of radioactive
14 materials. But that is something definitely that --
15 there's other, there's the first one that come out.
16 It uses the same practice, same work flow, but
17 eliminates using, use of radioactive materials,
18 which will make your licensees happy. Will make
19 Kevin happy.

20 Keep that in mind if any of your sites are
21 doing seeds for breast localization, which I'm not
22 sure if anyone is. But I'm sure Chantel has some
23 places.

24 CHANTEL CORBETT: Yeah. I have places that do
25 both.

1 MARK SEDDON: Yeah.

2 CHANTEL CORBETT: It just depends on the user
3 and what they really want. Some people are really
4 happy with the I-125.

5 MARK SEDDON: All right. I know we're over
6 time, so that's all I have.

7 So Brenda, do you want to give any updates?

8 BRENDA ANDREWS: Okay. Briefly. I was just
9 going to go over the Council membership right quick.
10 We have, of course, Nicholas Plaxton and Armand
11 Cognetta who were recently reappointed for another
12 three-year term. And now their terms will end on
13 5-12-24. So congratulations to them.

14 And then --

15 CHANTEL CORBETT: Woo.

16 BRENDA ANDREWS: Of course, we have John Danek
17 and George Gilbright and Dr. Armstrong who were
18 appointed in 10-23-19, which we announced that in
19 our last meeting, but I just wanted to remind you
20 all about that, too. Congratulations to them.

21 And the main thing coming up is we have eight
22 members whose terms will end in August. So that's
23 half the Board. So we're looking at vetting for
24 that around the middle of June. I will send out an
25 e-mail to current members to see if they want to

1 reapply for the position. And then we will start
2 working from there once I know who wants to
3 continue.

4 And the process is a little quicker now. So
5 we're not having to go through the lengthy vetting
6 like we did before. Reappointments are a lot
7 easier. So if you want to get in, go ahead and you
8 can let me know early if you want to, but we'll
9 start doing that.

10 And we need to decide on where we're going to
11 meet again. And in the back of your package is a
12 calendar so we can talk about when you all want to
13 have your next meeting.

14 MARK SEDDON: Is there a month we're looking
15 at?

16 BRENDA ANDREWS: So we're looking at October
17 12th.

18 JAMES FUTCH: September, October.

19 BRENDA ANDREWS: September, October maybe.

20 JAMES FUTCH: So probably the week of --

21 BRENDA ANDREWS: Labor Day is the 6th of
22 September.

23 JAMES FUTCH: The week of the 20th? September
24 20th? Any meetings to avoid? Any professional
25 societies, this, that and the other thing?

1 CHANTEL CORBETT: FMGs are on the weekend, so
2 it won't affect it.

3 BRENDA ANDREWS: September 20th sounds good to
4 everybody?

5 REBECCA McFADDEN: The 20th?

6 CHANTEL CORBETT: Tuesday?

7 ALBERT TINEO: Tuesday is better for me.

8 REBECCA McFADDEN: Tuesday is better than
9 Thursday.

10 BRENDA ANDREWS: The 21st.

11 ALBERT TINEO: The 21st.

12 MARK SEDDON: Is that okay?

13 CHANTEL CORBETT: Would it be here in Tampa
14 again or Orlando?

15 BRENDA ANDREWS: Is that -- do you all want to
16 continue meeting here?

17 KATHLEEN DROTAR: I'm fine.

18 BRENDA ANDREWS: It still works out for
19 everybody?

20 MARK SEDDON: That's fine.

21 BRENDA ANDREWS: Okay. Good. So I will
22 contact the hotel to make sure that that date is
23 open. So right now, we'll put it pending until I
24 hear from them to make sure we have the space. And
25 that's it.

1 MARK SEDDON: Okay. I know we're over time.
2 Is there any other business? Anyone have anything
3 to bring up?

4 Cindy, do we have anything from you?

5 CINDY BECKER: No, not me.

6 MARK SEDDON: James? All right.

7 JAMES FUTCH: Thank you all for coming and
8 participating and bringing your interest and your
9 experiences and much appreciated.

10 MARK SEDDON: Okay. Thank you very much. With
11 that, we'll adjourn the meeting then.

12 (Proceedings concluded at 3:13 p.m.)

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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

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