ADVISORY
COUNCIL ON
RADIATION PROTECTION

CERTIFIED TRANSCRIPT

Bureau of Radiation Control

Hampton Inn & Suites

Tampa Airport Avion Park Westshore

Tampa, Florida 33607

Thursday, May 18, 2023

10 a.m. - 2:55 p.m.

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

ADVISORY COUNCIL MEMBERS PRESENT:

Randy Schenkman, M.D., Retired (Chairman)
Nicholas Plaxton, M.D.
Adam Weaver, MS, CHP
Chantel Corbett, AS, CNMT, RT (N), RSO
Rebecca Coffey McFadden, RT(R)
William "Bill" Atherton, DC, DACBR, CCSP
Joseph Danek, CHP
Jennifer L. Peterson, M.D.
Kathleen Drotar, Ph.D., M.Ed., RT. (R)(N)(T)
Albert Tineo, MS, CNMT

FLORIDA DEPARTMENT OF HEALTH STAFF
BUREAU OF RADIATION CONTROL:

James Futch, Environmental Administrator
Clark Eldredge, Interim Bureau Chief
Dontavia Wilson, Regulatory Supervisor/Consultant
Charlie Hamilton, Environmental Specialist III
Brenda Andrews, Business Consultant

GUEST SPEAKERS (Appearing Remotely):

Yoav Kimchy and Israel Hershko - Check-Cap, Ltd. Isfiya, Israel
Darrel Fisher - Versant Medical Physics & Radiation Safety. Richland, Washington

AGENDA

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RANDY SCHENKMAN: Well, welcome everybody.

ADAM WEAVER: Welcome.

RANDY SCHENKMAN: It's good to see everybody without masks.

So we'd like to get the meeting started. Why don't we start with introductions.

ADAM WEAVER: Start with me?

RANDY SCHENKMAN: Yeah. Move around this way.

ADAM WEAVER: Adam Weaver, University of South Florida. Radiation safety -- laser safety officer.

JENNIFER PETERSON: I'm Jennifer Peterson. I'm a radiation oncologist at Mayo Clinic.

NICHOLAS PLAXTON: Morning. I'm Dr. Nicholas Plaxton, one of the physicians, nuclear medicine physicians at Bay Pines VA.

ALBERTO TINEO: Alberto Tineo from Halifax Health. I'm the hospital's representative.

DONTAVIA WILSON: Good morning, everyone. My name is Dontavia Wilson. I am the program administrator for the certification unit for Radiation Control.

CLARK ELDREDGE: I'm Clark Eldredge, Interim Chief of Bureau of Radiation Control and filling in until they finally find a permanent replacement for Cindy.

RANDY SCHENKMAN: Hi, I'm Randy Schenkman. I'm a retired radiologist; chairperson here. And I worked at Baptist Hospital in Miami when I was working.

JAMES FUTCH: James Futch, Bureau of Radiation Control, Rad Tech certification program and many other things.

BRENDA ANDREWS: Many. I'm Brenda Andrews with the Bureau of Radiation Control. I'm the operations and management consultant.

CHARLES HAMILTON: Charlie Hamilton, Bureau of Radiation Control, licensed evaluator and reviewer.

WILLIAM ATHERTON: Good morning. Bill Atherton, chiropractic radiologist in private practice in Miami, Florida.

REBECCA McFADDEN: Good morning. This is Becky McFadden. I'm the radiologic technologist and I am from Orlando Health.

CHANTEL CORBETT: Chantel Corbett from Fusion Physics. I'm the nuclear medicine technologist representative.

JOSEPH DANEK: I'm Joe Danek, retired. Previously worked for Florida Power and Light NextEra Energy.

And Darrel Fisher, good to see you. You look

the same as you did 50 years ago when we were in school together.

(Laughter)

RANDY SCHENKMAN: Okay. We need to approve the minutes from the meeting of September 22nd, 2022.

ALBERT TINEO: Move to approve.

RANDY SCHENKMAN: Huh?

ALBERT TINEO: I move to approve it.

RANDY SCHENKMAN: Oh, okay.

ADAM WEAVER: Second.

RANDY SCHENKMAN: All right. All in favor?

MEMBERS: Aye.

RANDY SCHENKMAN: Any opposed?

(No Response)

RANDY SCHENKMAN: No. Okay. We pass.

JAMES FUTCH: All right. So --

RANDY SCHENKMAN: Next will be the Bureau update by Clark.

CLARK ELDREDGE: Okay. All right. Some items of note that the Bureau has been involved in for the last -- since the last meeting.

Forgetting the Christmas season, starting in January, we had eight staff trained and six participate in providing PRND, preventative radiologic nuclear detection support for the January

3rd Governor's inauguration. Mr. Futch was instrumental in that since he had to deal with multiple meetings beforehand with the security detail -- planning and providing them guidance on what needed to be done for the radiation protection, because the folks there kind of lost their institutional knowledge on it.

Later in January, we had what usually would be a routine scrapyard alarm, nuclear -- where, it was Palm Beach County, I believe, or in Palm Beach County where the alarm went off. Our folks, you know, responded or provided phone support initially. And then the county or the local emergency coordinator got involved and it was blown out of proportion with concerns about there is a, you know, a military gauge radium paint who is -- they helped to truck aside, sent the people to the hospital who were around it in case it was -- so, yes, it got blown out of proportion, which ended up with John Williamson, you know, the environmental administrator, having to give a training on these issues to the surveillance and investigation, EPPI groups to educate folks that once again, on those responses.

JAMES FUTCH: It was like an aircraft gauge?

CLARK ELDREDGE: Aircraft gauge, yeah. We've been having lots of fun with stolen moisture density gauges this past couple months. In February, you know, two density gauges showed up on EBay. They'd been stolen from a rail yard in Orlando in August of 2022. And we passed that off to FBI and NRC.

Then just earlier this month, we had seven gauges stolen in two events. Five from an area in Tampa -- I can't remember the other two -- where they broke into a site where they were prepping for road construction with all the other, and just pillaged the site and ended up taking the five gauges with them, with all the other stuff they stole. Very professional job on that one. Apparently, it's the second time that some sort of group might have hit a construction site recently and road construction site and just pillaged it in the middle of the night.

We've been -- our agency, IMPEP, Integrated -- don't ask me, I can't tell you the acronym. But it's the NRC federal review of our materials licensing, Integrated Materials Performance Evaluation Program. Auditors from NRC and from other agreement states come to your state and review your procedures and make sure all your licensing is

up to snuff. They've been doing the accompaniments with our field inspectors and they've been getting -- we've been great so far. No -- nothing has been noted of any concern about the accompaniments, back to solving good reviews there.

The actual on site will be the week of June 12 in Tallahassee, where they'll come and actually review all the procedures of the licensing group there.

In March, the Bureau housed a training for hazardous response teams from the FBI, National Guard, civilian support teams, Reedy Creek Improvement District and other city and municipal hazardous response teams in Orlando for a couple days and so that was, you know, part of that grew out of our communications over, with the stolen gauges. So the Tampa and Miami offices and Orlando, FBI folks came to our office, out to our Orlando lab for training on radiation detection and clean up of -- or response during an event that involves radioactive materials.

JAMES FUTCH: We ended up loaning them some button sources and some equipment, too.

CLARK ELDREDGE: I didn't know that.

JAMES FUTCH: Yeah. It was kind of surprising

to find out the FBI doesn't have any check sources for any of their radiological gear. They have three welding rods. So we, we loaned them some things.

CLARK ELDREDGE: So James, again, and Charlie, they were -- they went from Tallahassee down to assist John Williamson and Reno Faudy (ph), Mark Sykes, the crew down there with the training.

In April, another fun one. We got a call transferred from California, called the NRC, and then NRC transferred to us, about malicious diversion of three Category 2 radiography sources. This California firm had sold radiography sources to an oil company in Venezuela. To get there, you know, you have to set up a, a shipping company, a broker and a transport agent. And they were -- it went from California to Miami, and then had to go to Bogota before Caracas since you can't necessarily go directly between the U.S. and Caracas at this time.

The shipping of the transport, the transporter in Miami supposedly had a beef with the broker being owed money, and so they decided to hold on to the three Iridium sources and put them in their bathroom at their office.

JAMES FUTCH: Like, originally, 100 curies or 150 curies. It's an industrial radiography source.

Three of them.

CLARK ELDREDGE: Three of them. And they -- was it October, November that they put them aside? So this was, you know, the week of May 10 -- I mean April 10. So they actually decayed down a good bit, which is a good thing, but they'd been sitting there. I think they were 16 curies each at that point. Something like that.

So after getting the phone call on a Monday, we coordinated with our FHP cohorts in the -- we do the PRND activities with, and made it -- first made a call to the transport agent and that's when we -- oh, these guys owed me money. I thought this was worth something. I was going to hold it until they paid me. Oh, and then said, no, the sources weren't in his office anymore.

So our staff, with FHP, went two days later went and drove around their offices; didn't see anything from the outside. Went in to -- went in to interview at the office and they were still there and offered them the option of, you know, do you want to surrender these now or not? You know, you're unlicensed. You have no authority to hold on to these type things and so they surrendered them at that time.

By Friday that week, the California company had arranged for their -- it was on the way back to California. Their agent in Tampa came over to the Orlando lab where we had stored them and shipped them from Miami up to Orlando. And then they came to pick them up and shipped them back to California.

Jorge Laguna, who's our inspections coordinator, has been traveling internationally for the IAEA. So previous, last year, he went down to Brazil for IAEA for a regional meeting of radiation protection officials for South America, Central America, to talk about guidance on dealing with radioactive materials, dealing with Radon, dealing with, you know, management licensing. And so, they invited him to participate in an African Regional Training and Summit sponsored by IAEA. So he was in Zimbabwe there for a few days presenting on behalf of the IAEA.

Now, this is also coordinated through the Conference Radiation Control Program Directors, which is the national organization of state radiation agencies. So -- since he's a member of that, he got tapped to represent, tour with the IAEA since they have an inter-agency coordination agreement, support radiation protection throughout

the world.

And then come to May, the national meeting in Houston, Mr. Laguna presented on his trip and I actually talked with Don Miller, had a facility session with Don Miller on FDA of the proper radiation machine labeling and concerns as I presented before about how we're getting the Chinese machines with no -- they haven't been FDA approved. And the fact we actually will find other machines from -- being imported without proper FDA labeling, even though they've actually been approved. They have their five 10Ks.

So -- and that covers what we've been up to recently.

RANDY SCHENKMAN: Anybody have any comments, questions?

JAMES FUTCH: Clark, was there any follow up from NRC to clarify if something like the California source thing happens again, what's the -- what kind of -- it felt like we were out on uncharted territory.

CLARK ELDREDGE: That's a weakness in the NRC regs in the shipping -- in fact, if I can get the group, let me get the right name.

JAMES FUTCH: I know when Kevin came down the

hall when he first got the call, things were on a fairly smooth glide slope because he had gotten the shipper down in Miami to at least tentatively agree to give up the sources, but that's when the shipper called the company in California to ask them how much this was worth. And, and that's when the shipper found out that they were no longer at the address that they were legally supposed to be at. They had moved them some place else. So things kicked into overdrive at that point.

CLARK ELDREDGE: Right. Well, the, the folks from California actually had gotten a call from Caracas saying where are our sources? It has been six months. And so then started to --

JAMES FUTCH: It took them that long to ask where the sources were?

CLARK ELDREDGE: And that's -- yeah, five months, something like that, which is really odd it decided to take them that long. And there is somewhat of a weakness in our current federal structure about when things are shipped, and getting feedback that they're shipped, a notification to other states that sources like this are coming through. That's not part of it and I'm trying to get the, the name of the group. The TS --

REBECCA McFADDEN: My question would be, who would handle all of the expenses that surround that issue? I mean, is that something that the, the transporter would cover or does the State just cover it without --

CLARK ELDREDGE: The licensee, until it's officially in the other person's hands, they're --

REBECCA McFADDEN: So it's the people in California who would be the shipper or the person who sent it, would be responsible for all that?

JAMES FUTCH: Yeah. One of the questions we had was, how could it take so long for the authorities, the radiation authorities at the national or state level where it's supposed to happen, to find out about it. That it didn't get shipped. I mean, it was, like Clark said, five, six months since.

ADAM WEAVER: Are these true Category 2 sources?

JAMES FUTCH: It was --

ADAM WEAVER: -- as defined as increased controls?

JAMES FUTCH: It was three, 150 curie Iridium 182. I don't know off the top of my head.

ADAM WEAVER: So, yeah. They're Cat 2's, if I

remember correctly.

CHANTEL CORBETT: But with any sources, I think really, like, your shipper and receiver are really the only ones that know what approximate time it should be, you know, there.

CLARK ELDREDGE: Right.

CHANTEL CORBETT: So anybody in the middle, like you said --

ADAM WEAVER: If they follow the increased controls, those should be tracked more, as part of, Part 37 in the State's equivalent.

CLARK ELDREDGE: Again, it's the fact that --

ADAM WEAVER: I know it's coming from California.

CLARK ELDREDGE: The licensee shipping to Florida.

ADAM WEAVER: But then it's shipped, right. In theory, they should have notified you guys that these things were coming, but --

RANDY SCHENKMAN: Is that what you're trying to get the Government to do?

CHANTEL CORBETT: Yeah, because you're saying there's not a requirement.

CLARK ELDREDGE: There's not a requirement for that, so there is no --

RANDY SCHENKMAN: Is that what you're trying to --

ADAM WEAVER: -- when you ship those.

CLARK ELDREDGE: There is some actual review or something and I'm trying to remember the TS, there's a national work group on transportation security for sources.

ADAM WEAVER: Within DOT.

CLARK ELDREDGE: TS, it's out of -- not Chattanooga. Oak Ridge. Oak Ridge Labs, they've got a contract to manage the -- I'm trying to get their -- because they just sent me an e-mail because I met them at the CRCPD meeting.

It's an alphabet soup acronym. I cannot remember. TSURIG, something like that.

ADAM WEAVER: Yeah, yeah. I think I've heard of them.

CLARK ELDREDGE: Okay. Transportation Security United -- Unified Stakeholders Group. TSUSG.

ADAM WEAVER: Okay.

CLARK ELDREDGE: Operated out of ORNL. Oak Ridge National Lab.

RANDY SCHENKMAN: And they're trying to get these tracked or --

CLARK ELDREDGE: That was one of their -- that

is one of their issues right now is the tracking of these sources.

ADAM WEAVER: It really goes to the manufacturer who shipped them first. He or -- that company should have, you know, made sure he complied with Part 37, which does require you to notify.

JOSEPH DANEK: Does not? It does not require?

ADAM WEAVER: It does require. Cat 2 sources.

JOSEPH DANEK: Yeah, I think.

CLARK ELDREDGE: There's also the current issue about applying the Part 37 down to some levels of Cat 3 sources also. I don't know the details.

ADAM WEAVER: They're trying -- they're working on a draft, I believe is where the NRC is.

RANDY SCHENKMAN: Okay. Any other comments about this?

JOSEPH DANEK: Just real quick. NRC was out of Atlanta, California, headquarters that was involved in this?

CLARK ELDREDGE: It was, they've got a national help group or something. So it was --

JOSEPH DANEK: Probably out of headquarters.

CLARK ELDREDGE: Headquarters.

JOSEPH DANEK: Yes. King of Prussia.

CLARK ELDREDGE: When the call was transferred,

it was basically blind transferred without any information and it was, Kevin said, all of a sudden, we're talking to a guy from California and what's this all about?

RANDY SCHENKMAN: Okay. Are we ready to move on?

Okay. Next we will have from our gentlemen on the screen, Introduction to a Tungsten-181 X-ray Imaging Capsule for Colorectal Cancer Screening.

ISRAEL HERSHKO: Can you see my screen?

RANDY SCHENKMAN: Yes.

ISRAEL HERSHKO: Okay. So do you want to introduce yourself?

YOAV KIMCHY: Yes. Good morning, everyone. My name is Yoav Kimchy. My background is physics, mathematics and environmental engineering with a Ph.D. in single processing physics.

I founded the company Check-Cap in 2005 and currently serving as the CTO of the company.

ISRAEL HERSHKO: And good morning. I am Israel and my background is electro optics and business management. And I'm with Check-Cap around seven years and, like, 25 years in the medical device industry.

DARREL FISHER: Thank you. My name is Darrel

Fisher. I'm a proud graduate of the University of Florida with a doctorate in medical physics with Versant. Now, Versant is the company that took over for Dave Muller, leading provider of health physics services in the U.S. And a gold sponsor of the Health Physics Society.

My background includes 35 years as a senior scientist at Pacific Northwest National Laboratory here in Richland, Washington. And I've served previously on the, the NRCs advisory committee on the medical use of isotopes, supporting Check-Cap in this presentation.

CLARK ELDREDGE: This is Clark. If you -- that went away. One of our screen was somehow copying. That was ours? Okay. Whatever. It cleared up.

ISRAEL HERSHKO: Yeah, I move it.

RANDY SCHENKMAN: Thank you.

JAMES FUTCH: Darrel, thank you for the introduction. We won't hold it against you, the University of Florida part.

JOSEPH DANEK: I've got you to deal with that.

JAMES FUTCH: Gentle ribbing.

YOAV KIMCHY: In the presentation, we'd like to talk about the clinical need, how the system is designed, the imaging principles, the capsule

components, including the 181 x-ray source, the method of use, and Darrel is going to talk about the regulatory elements and questions.

Next slide, please.

Okay. So colorectal cancer can largely be prevented by finding pre-cancerous polyp detection. A lot of people are reluctant to do optical colonoscopy because it requires all cleansing and sedation and prep, which is the, probably the worst part of it.

What we're developing is a low-dose system. It's basically a capsule that you swallow. You go on your daily routine and it does not require a polyp preparation.

The capsule, we've received FDA designation as a life saving device. And we've received CE mark approval at the European part of FDA from the European market.

Next slide.

So colorectal cancer is very slow-growing process. It starts at benign polyps, which gradually and slowly grow in the colon over a decade, a decade and a half, and no symptoms are felt by the patient. And then it starts, some of the polyps become cancerous.

Stopping the process is like, basically finding the polyps before they become cancer. And with colonoscopy taking them out so the patient doesn't even proceed through the cancerous stage.

If you look at the average risk population, about 75 percent, no polyps. About 25 percent have polyps which grow slowly and might become cancerous and about 0.5 percent of average risk of the population have cancer at one stage or the other.

Next slide.

And obviously, if you find it early or even in the polyp stage, there's more than 90 percent chance that the patient will be completely cured. So it's a very well worth looking and stopping.

In terms of how the system works, we have three elements in the C-Scan System. One is the capsule, which is a single-use ingestible capsule. Travels naturally in the body. It has a low dose, ultra low dose x-ray scanning technology.

The tracker is a device that is put on the back of the patient. It has autonomous control. It communicates with the capsule. It has two functions. One is to track the position of the capsule with a less than one centimeter accuracy. And also to command the capsule in the scan. It's

scanning only when it's moving. And also to collect all the data from the capsule so it can be retrieved and afterwards downloaded.

The third part of the system is a C-Scan View. It's a cloud-based analysis suite used by the physician to use the data and look for possible suspects. Most of the patients will have nothing, because that's the prevalence of polyps is less than, let's say 25 percent or less. Those patients that do have something, the patient will be advised to go through colonoscopy to remove the polyp.

The next slide.

So the intended use is for people, and now it's 45 years and older, to get screened. And it's to find patients that have suspect findings that might be a source of polyps. Can take it out by advising the patient to go to a colonoscopy.

Next slide.

As I said, the procedure is simple. You take the capsule. You take some psyllium fiber capsule with each meal and some iodine-based contrast agent with each meal, one tablespoon. And then you swallow the capsule and it moves naturally in your body. You continue to do your normal routine. The tracking system monitors the position of the

capsule; tells it when to scan and collects all the data. And once the capsule is excreted, all the date is recorded to be downloaded later.

Next slide.

Some things that you're advised not to do when you have the test. One is travel. The other is go near high energy or electromagnetic interference because our tracking system is based on electromagnetic signals and this might interfere with it.

Medical procedures, such as CT and MRI can be disruptive to the system. And swimming or scuba diving is not advised, as well as high intensity sports, since the recorder might fall off. Anything else is -- you can do anything. You can work. You can sleep; shower, anything that is normal in your routine until the capsule is gone.

Right now, the directive is to collect the capsule at the end of the procedure. For that, we've added a system of, or a set of collection system that allows the patient to look inside the stool once the stool comes out, and collect the capsule and send it back. Actually send it to the decaying center.

Next.

The way the system works, we have an x-ray source inside the capsule. Basically a collimator that is turning with a slow motor. Three beams. And these beams are x-rays and two physical phenomenas are used the imaging. One is x-ray florescent from the contrast agent mixed in the stool and the other is contents gathering that comes from both the contents of the stool, of the colon, and the tissue beyond. These are in two different energies and the capsule is able to collect these two different energies and actually use those to find the distance between the capsule and the colon wall.

So it basically maps the inside of the colon, disregarding the content, the stool, because x-rays that travel through that. And we're able to find the distance to the colon wall. So any protrusion, such as a polyp, will appear in the reconstruction.

Next.

The capsule itself, you can see here. The inside, it has the x-ray imaging system. The radiation source goes inside that hole. Detectors, electronic communication, radio frequency communication. The capsule is very sturdy. That means that tungsten of two millimeters in thickness

blocks all the radiation. It's open with a spring shutter, so any time that it's not working for any reason, either it's not scanning or no battery or whatever, the spring-loaded shutter keeps the shutter closed and no exposure to the patient.

Next slide.

The source, itself, is Tungsten-181, which has a half-life time of 121 days. Maximum activity is 50 mCi. Usually we -- patients will have 30, 35 mCi. The most emission energy is around 60, 70 keV. Effective dose to the patient for the whole duration of the study, of the test, is about 0.06 mCi. We tested it for Iso 2919 and it's obviously tested for white test, both the canister, itself, and the capsule, itself, before it is shipped out of our facility.

And the next slide.

In terms of exposure to the patient, you're probably aware of exposure of other medical imaging, so we're looking at a very low exposure to the patient relative to chest x-ray or other, other imaging modalities.

Next.

This is data from the study that we did post FDA approval in the European regulatory process. So

you see patients with all size of polyps. And that's six millimeters and up, we had 66 percent sensitivity. Polyps larger than ten millimeters, we had 76 percent sensitivity for those polyps. And we had large polyps, 40 millimeters and above, which are the ones that might have about 40 percent chance of becoming cancerous, the system found all of them. We had about, I think, four of these very large ones.

You can see also the correlation to -- comparison to fecal stool testing that was done in those patients and you see the results in terms of the percentage of detection for those patients for those polyps. Specificity was 82 percent.

Next slide.

Here you can see how data looks on the viewing system once the data is downloaded. And you can see on the left, top left side, that's the 2D scan and we can see the suspect finding.

Bottom left, you can see the 2D slides and on the right, you see the 3D reconstruction. Middle, on the bottom, you can see the position of the suspicious finding. It's about -- a cancerous colon. And the position, you do measurements that can basically decide if that's something that

requires further investigation and colonoscopy.

Next slide.

These are examples of polyps. A small one at the top, five millimeters. Bottom is the 20 millimeter. On the right side, you see the colonoscopy images. In the middle is the 3D reconstruction on the capsule and on the left, how the physician or the -- an analyst looks at the data before it's decided if it's a suspect finding.

Next slide.

And I pass it to Darrel.

DARREL FISHER: Thank you. And thank you to those of you from the Council who made this presentation possible.

There have been a number of questions of regulatory concern on the Check-Cap capsule. And first of all, I'd like to just briefly go over how it's designated by the FDA.

As mentioned, it has breakthrough device designation as an investigational device. With an IDE, Investigational Device Exemption, approved by the Food and Drug Administration for pivotal clinical trial use. This is important to gather sufficient data on safety and efficacy prior to final FDA approval.

The C-Scan System is authorized under the Code of Federal Regulations for medical use as a sealed source device, manufactured, labeled, packaged and distributed under 10 CFR 30 and 10 CFR 32.74. Specifically for pivotal clinical trials, research as an advanced approach for identifying subjects with elevated risk of colon polyps and to collect clinical trial efficacy data.

Next.

Is an Institutional Review Board at the participating institution required? And the answer is yes. Prior to use, an IRB review is required to approve and monitor the use of the Check-Cap C-Scan System for research purposes.

Another question, are sealed source inventory requirements applicable? And the answer is yes. The capsules are managed as individual, discrete sources; therefore, the requirements in the Code of Federal -- Code of Federal Regulations for semiannual physical inventory and recordkeeping are applicable. However, since these capsules are used immediately on receipt and are not stored by the licensee, it would -- it would not be expected that the inventory would take place on a semiannual basis.

Next.

What is the diagnostic exam process? The capsules are received by the participating hospital and soon thereafter, administered to the patient by the licensee's authorized user. The patient then returns home, leaving the center. The capsule, as mentioned, travels through the GI tract over a period of 24 to 72 hours with a mean transit time of about 52 hours and is excreted naturally.

According to instructions, the patient collects the capsule using the special capsule collection kit provided for return to the manufacturer.

The most important requirements for the licensee are the following: Maintaining complete records of radioactive material receipt and administration to the patients. The licensee also maintains record of authorized user training and record of instructions given to patients on radiation safety.

Next.

Is leak testing required? The answer is no. The capsule design and manufacturing have been subjected to rigorous sealed source leak testing for conformance with the requirements of ISO 2919:2012, and ISO 9978:2020. The manufacturer performs

additional capsule wipe testing prior to shipment to insure that, to insure each capsule maintains sealed source integrity. With each shipment to a clinical site, the manufacturer provides a certificate stating that the sealed source has been leak tested and shown to be within the regulatory limit for, for leaching.

These capsules are designed that they would not leak any radioactive material unless crushed and ground. So the -- they're very -- they have very strong seal source integrity and the Tungsten-181 is embedded within Tungsten metal and would not dissolve.

Is a written directive required? The answer is no. Under 10 CFR 35.40, the capsule is a low-dose diagnostic tool and a written directive is not required for patient use.

Who is the authorized user? The authorized user oversees or administers capsule ingestion and may be named on the radioactive materials license. This varies by state. Some states would require, require it; others would not.

Under 10 CFR 35.590, training for use of sealed sources, the authorized user is a physician certified by a specialty board who has completed a

minimum of eight hours of classroom and laboratory training in basic radion nuclide handling techniques specifically applicable to the use of the device.

Next.

Does the authorized user receive training by the manufacturer? Yes. The authorized user must become familiar with the training materials provided by Check-Cap. There is on-site training. It includes training in all processes, procedures, instructions for medical use, including radiation safety, as provided by the manufacturer in the, in the manufacturer's documentation.

Is medical events reporting required for an unusual incident? The capsule is ingested and later expelled. Since the Tungsten-181 source is shielded, most of the time in the window closed or off position, and since the anticipated radiation dose to the patient is very, very small, less than, as mentioned, on average, about .06 mSv, the probability of a reportable medical event meeting the criteria is essentially completely unlikely, unless administered to the wrong patient. So medical event reporting would be highly unusual.

Do the patient release criteria in 10 CFR 35.75 apply? Yes, the criteria applies, but it is not

physically possible for a radiation dose to a member of the public to exceed the criteria given in 10 CFR 35.75.

Backing this up is extensive scientific review performed for Check-Cap, showing that all -- for all relevant exposure scenarios, including those with the most conservative assumptions, the radiation dose to any member of the public would not exceed .1 rem or one mSv in a year.

Must the licensee report the loss or theft of the capsule? The answer is yes. Under 10 CFR 20.2201, reports of theft or loss, requires each licensee to report within thirty days after an occurrence, any loss, stolen or missing licensed material. However, keep in mind that this section applies to the licensee and to loss of radioactive material controlled by the licensee or within the premises of the facility. However, losses that may occur by intervention of a medical patient after release from the hospital or clinic, such as failure to retrieve an excreted capsule, would constitute actions beyond the control of the licensee and not regulated under 20.2201, whether or not the loss by the patient is intentional or unintentional.

The commissioners of the NRC have recently

reiterated the fact that patient interventions are not regulated.

Next.

Is capsule disposal into the sanitary sewer system permitted? The answer is no. The Check-Cap instructions for use do not permit disposal of these capsules by release into the patient's sanitary sewer system. A used capsule should always be returned to the manufacturer or to its licensed facility designated for disposal instead of disposal into the sewage.

What happens if the patient dies before the capsule is excreted? If the patient should die before the capsule passes completely, it should be removed by a medical procedure and returned to the manufacturer or to a licensed facility according to the instructions for use provided by Check-Cap.

There are probably many other questions that could apply and so we would invite you to ask additional questions if necessary.

RANDY SCHENKMAN: I have a question. What happens if somebody can't swallow that capsule? It's very large.

Did you hear me?

ISRAEL HERSHKO: Yoav?

YOAV KIMCHY: Yes. I will answer. Until now, we had about a thousand such patients with the capsule and I think maybe seven or eight capsules, the patients could not swallow. It's part of our exclusion criteria, if the patient cannot swallow capsules, large capsules, and we usually find them before they come into the process.

We found mixing it with a little bit of apple paste or -- to make sure, usually makes it easier for patient to swallow. And that's our experience so far. So we had about, I think not more than eight patients that could not swallow the capsule, but maybe I'm wrong.

ISRAEL HERSHKO: I just put you on mute, so can you unmute? Okay.

RANDY SCHENKMAN: Are you looking to make the capsules smaller?

ISRAEL HERSHKO: I believe that in the future, the next generation will make it smaller, but it will take a few years.

NICHOLAS PLAXTON: I had a question. I don't know if you guys can hear me.

I was wondering, you know, since they swallow the pill, are you doing any diagnostic on the small bowel, even though it's, you know, less common to

have cancer in the small bowel, but since it's passing through, do you have any kind of analysis for the small bowel as well as the large bowel?

YOAV KIMCHY: Right now we don't. Right now we concentrate on the colon because that's, that's where most of the patients have problems.

WILLIAM ATHERTON: Hi. Could you explain the benefit of the test versus the -- so if it's a positive test, then the -- it's a recommended colonoscopy, correct? And what -- so the benefit comes if the test is negative, correct? And then what's the recommendation, another test for five years or is there a recommendation for the test?

YOAV KIMCHY: Yes. That would be a recommendation. Obviously, it will need to align with what the FDA provided. Yes, but that's usually a good direction.

JOSEPH DANEK: My understanding, there is some clinical trials going on right now at Mayo Clinic in Florida. Is that true? Somebody mentioned that to me. Is that true? So right now, there is some clinical trials?

CHARLES HAMILTON: Currently we have one licensee. It's a broad scope medical. Only broad scope medicals can -- are allowed to do the

procedures. Clinical trials that last through December of this year and they are licensed for 500 mCi total of Tungsten-181, no capsule to exceed 50 mCi, and that's Mayo Clinic Jacksonville.

JOSEPH DANEK: I'm just looking at your notes and all that. You said the patient can return it to the manufacturer licensed facility. I would imagine that would be the licensed facility that would -- you wouldn't want to send them directly to the manufacturer. It would go through the licensee.

ISRAEL HERSHKO: Let me take this. The patient is, is getting an envelope with the address and the phone number that our party in the U.S. and then the capsule is sent to solution in Ohio for decay.

JOSEPH DANEK: What is the contact radiation level on the, on the device? I know it's got 121 day half life but just -- before decay or whatever. I know it's very low. What is it roughly? Contact radiation on the device, the capsule.

ISRAEL HERSHKO: Yoav, can you --

YOAV KIMCHY: I don't remember it by heart. I don't remember the number, but it's, it's less than a mGy area, but I don't remember.

JOSEPH DANEK: I'm sorry, what did you say?

ADAM WEAVER: Less than a mGy.

YOAV KIMCHY: I don't remember by heart, but I have a -- I'll look it up. I can give you the results in a few minutes.

JOSEPH DANEK: Okay. That's fine.

ADAM WEAVER: It's pretty low energy.

ISRAEL HERSHKO: The capsule --

JOSEPH DANEK: I understand. Just curious.

ISRAEL HERSHKO: The capsule is sent by the patient in expected package to the site in Ohio for decay. So it's off all the time and meets the requirement of expected package, and no radiation exposed to anyone in the, in the -- no way human exposure.

NICHOLAS PLAXTON: I'm just curious. How many of these have you lost down the sewer?

ISRAEL HERSHKO: In the, in the states, we lost until now, two. One in Mayo, Rochester and one in New York.

CLARK ELDREDGE: And that's out of how many?

ISRAEL HERSHKO: It was -- we had starting about 45 patients and now we have, like, in the people town, we have about 20, 22. So together, it's like 66, 65.

After we lost the capsule in, in Rochester, we decided to, to change the collection kit to be more

robust and they now -- the people don't try -- the patient is getting the new collection kit that is more friendly and robust that the capsule cannot be lost in the sewer.

NICHOLAS PLAXTON: How much do the capsules cost, approximately?

ISRAEL HERSHKO: I think that we cannot tell you this.

(Laughter)

ADAM WEAVER: Good try.

JAMES FUTCH: Especially the people down in Hialeah. The shippers down there. They might be new customers.

CLARK ELDREDGE: What kind of -- how did you all do your dose study? What was your -- what were you doing to figure out what your estimated dose to the patient is?

YOAV KIMCHY: We used TOD in the lab and we have hired a radiation specialist, Dr. Grossman, that did the analysis with us. So we have both theoretical and actual measurements.

CLARK ELDREDGE: I think it was mentioned that the shutter opens when the object is being moved. It's sensing movement in the system. Does -- yeah. Do you have some way to restrict it just to the

large colon or is it imaging all the way through until, you know, what's the control mechanism?

YOAV KIMCHY: Sure. We know exactly the position of the capsule all the time. We have a few mechanisms that understand when the capsule gets into the colon. And out of an average of 52 hours, the capsule scans about 40, 45 minutes at the most.

ISRAEL HERSHKO: We can sense, we can sense the, the capsule and get into the cecum and from that moment, the capsule or the tract can send commands to the capsule for scanning.

WILLIAM ATHERTON: Is there any concern for -- I know the dose is very low, but it sounds like that's, like, a whole-body dose. Is there any concern for the actual, the dose being so close to the radiosensitive lining of the colon? Is that a concern or is it too low to be a concern?

YOAV KIMCHY: We did do a total analysis of the actual exposure to the patient's tissue. The colon tissue. We're looking at the mGys and I think it's 2.3 mGys, an average. We have complete records with the FDA on that.

CLARK ELDREDGE: So what's the dose rate or exposure rate when it is open?

YOAV KIMCHY: I have all the tables. I'll give

you in a moment. I'll get back to you just a second.

JOSEPH DANEK: So who reviews the, I guess like the scan results? You've got the track on the person's back and I'm just trying to understand the logistics.

ADAM WEAVER: Who can interpret the results?

JOSEPH DANEK: What's that?

ADAM WEAVER: Who can interpret the results?

JOSEPH DANEK: Yeah, I mean the capsule and the tracking mits. Again, the procedure's been done. The capsule goes back, I guess with the tracking. What's the logistics on how the results, scan results, who reads them, who interprets them?

YOAV KIMCHY: Sure. So we have two processes. The first one is the -- we have analysts right now that are looking at each patient's data and coming up with possible optics.

And then physician writes up -- looks at this data and decides if the patient is positive or negative. Some physician. And he decides that the gastroenterologist who is trained with quite a few cases in order to understand that that's the suspected needs to send for colonoscopy.

That's the process that we're currently

running. The idea is when we have enough data, the technical analysis will be done with AI, with artificial intelligence, and then a physician will sign off after looking at or reviewing the data from that.

ISRAEL HERSHKO: The first, the first -- the first part of the, the process is that the patient is sending the track separately from the capsule to our -- we have a, in New York, a site that gets it to the --

YOAV KIMCHY: The cloud.

ISRAEL HERSHKO: Sending the data to the cloud. And then the analysis team is taking the data from the cloud and starting work on the data.

NICHOLAS PLAXTON: How fast is the turn around time? How long does it take to get the results?

YOAV KIMCHY: A few days, literally.

CHANTEL CORBETT: And then those results are sent back to the facility for the authorized user to do the final review and report?

YOAV KIMCHY: Right now in our clinical data, in our clinical trial, we've trained four, five gastroenterologists and they will do all the data analysis.

CHANTEL CORBETT: Right. So those people would

either have to be added to a license in Florida or the person that's the authorized user in Florida would have to overread the report.

ISRAEL HERSHKO: Currently, the licensee is not doing the analysis.

ADAM WEAVER: Have you had any adverse effects, like, not passing the, the device?

YOAV KIMCHY: I think the longest patient that we had was something like 300 hours. That's a very big outlier. And it was taken out of a colonoscopy. I don't remember, there were a few patients, maybe -- I don't remember the exact, but nothing that, you know, obviously no deaths or anything like that.

ISRAEL HERSHKO: We didn't have any serious adverse events. We have only a minor adverse event like headache or stomachache, stomach pain. And those are the, the worst event that we have.

WILLIAM ATHERTON: And the one that you said that they had to remove, you said they removed it by colonoscopy. What was the reason?

YOAV KIMCHY: That's correct.

WILLIAM ATHERTON: What was the reason?

YOAV KIMCHY: Just the colon immobility. It was -- stayed in the, in the cecum -- that's the beginning of the colon -- and didn't move out from

there.

ADAM WEAVER: Got stuck.

NICHOLAS PLAXTON: I have a question about, like, when you guys have, or if you have a patient that died, to retrieve the device, is that a nuclear regulation or is that -- it seems a little aggressive. You think you would just leave it in there.

YOAV KIMCHY: Darrel can answer that.

DARREL FISHER: Yeah. The requirements would be up to the individual state regulating the procedure. There isn't a radiation hazard, but the, the idea of leaving a radioactive source in a corpse to some people is not a good idea when it can be easily removed. So -- and also, it's important to return the capsule to the manufacturer and not leave it behind. We don't wish it to become an orphaned source in a corpse. The probability of a patient dying during this procedure is remote. However, it could easily be retrieved.

NICHOLAS PLAXTON: Do you guys reuse the capsules?

DARREL FISHER: No. These are single-use capsules.

WILLIAM ATHERTON: And do you produce the

source from your own company or -- where do you produce the source?

ISRAEL HERSHKO: Yes. We have a second site in Israel that we pay to produce the sources and everything is controlled by the standard regulation.

CLARK ELDREDGE: How long is the -- I mean, since we're talking about, of course, radioactive source, what is the sort of maximum time between manufacture and use for these things? How long can they sit on the shelf before your source is decayed too low?

YOAV KIMCHY: It's two to three weeks at the most.

ISRAEL HERSHKO: The current status that we are not putting the capsule at least on storage. It goes directly to the licensee and within one or two days, it has been swallowed.

JAMES FUTCH: Anybody else?

RANDY SCHENKMAN: Well, we really thank you for this presentation. This was just a very good presentation and we appreciate it. And we also appreciate your answering all of our questions, so thank you.

JAMES FUTCH: Israel, do you have any questions for us?

ISRAEL HERSHKO: Maybe I have a request. We're working with a few sites in Florida and would like, would be happy that you guys will work with them in order to get the licenses as soon as possible. We'd like to, to get as much as -- more sites for the study in order to get the final, to get the device to the U.S. market.

JAMES FUTCH: You were talking about more sites. Dr. Plaxton seemed interested in the small bowel. I don't know if that means the VA has got an interest or what.

ISRAEL HERSHKO: Be patient.

NICHOLAS PLAXTON: How many people do you need here for your study to get, for FDA approval? What's the ballpark number?

ISRAEL HERSHKO: Currently, we have 752. And on those days we are in the contact with the FDA to enlarge the study for about 1500.

JAMES FUTCH: We have several facilities represented at the table and other people who deal with more facilities represented at the table. So if your facilities wanted to become interested -- to be a part of using this device as part of the study, what additional questions, what issues may you have?

CHANTEL CORBETT: Yeah. It's still going to

come back to, they have to have an IRB, so it's a limited pool as to who can do it at this point.

ADAM WEAVER: Has to be a medical broad scope, too.

CHANTEL CORBETT: It has to be broad scope license, so that strictly limits, you know, who can do it. And the authorized user, I'm assuming, has to be the final read. So are they just doing an overread of the interpretation that the manufacturer sends, you know, to be compliant.

ADAM WEAVER: Yeah. Interpretation is a big question in this state.

CHANTEL CORBETT: Yeah, I mean a lot of states don't require the authorized user, you know, to be listed on a license to read a study, but in Florida it is, so --

JAMES FUTCH: So Darrel, you guys, that might be a -- something to talk further about with the sites, I guess. Kevin is not here, so I'm not sure what his opinion is, but Chantel is pretty knowledgeable about that, advising facilities.

DARREL FISHER: So those sites who are interested in participating should contact Check-Cap. Facilities with specific questions on the radiation aspects, health physics, radiation

protection, may contact me at any time and will facilitate response to questions and provide technical support to whatever degree is requested?

JAMES FUTCH: Darrel, so this, this is a public meeting in Florida, so the minutes of this will eventually appear on our website, along with the agenda, and the, and the presentation, itself.

Do you have -- do you want to send us the contact information that you would like, like to be posted there or --

DARREL FISHER: Yes. I will send that directly to you.

JAMES FUTCH: Okay.

RANDY SCHENKMAN: Okay. Well, if no one else has any comments on either side, again, we thank you and the presentation is over.

JAMES FUTCH: Thank you guys. We much appreciate it.

YOAV KIMCHY: Thank you.

(Applause)

JAMES FUTCH: We're going to sign off, I think, and move on to other stuff.

ISRAEL HERSHKO: Bye, bye.

JAMES FUTCH: Take care.

RANDY SCHENKMAN: Well, that was very

interesting.

JAMES FUTCH: I have to breathe a huge sigh of relief. Thank you, God. Thank you, Rob. I think that worked pretty well.

WILLIAM ATHERTON: Where were they?

JAMES FUTCH: Darrel is in Washington State and Yoav and Israel are actually in Israel. Tel Aviv, I think. And then we had Joe pulled the rabbit out of the hat from 50 years ago going to school with Darrel. What are the chances of that?

WILLIAM ATHERTON: Fifty years ago?

RANDY SCHENKMAN: That's really funny.

JAMES FUTCH: Really small world. That's incredible.

RANDY SCHENKMAN: Okay. Well, first of all, I would like to welcome Dontavia, is that it?

DONTAVIA WILSON: Dontavia.

JAMES FUTCH: If I might jump in for a second. We have menus for lunch, which is a half hour or so away. And what do you want to do, Brenda?

BRENDA ANDREWS: Yes. If you would write your name on the menu and circle what you would like to order and pass those back in to me, I'm going to take them over so they will have our lunches prepared when we get there.

(Stood at Ease)

JAMES FUTCH: I have one question before we move on while Brenda is -- to Dontavia. By the way, thank you for MQA. The first MQA person from the new crew.

What did you not want to say before the Check-Cap crew? What were you thinking, because we're putting it in the notes now.

CHANTEL CORBETT: I mean, the biggest question going in, what they answered, is it going to be the licensee's responsibility to track these down if they don't come back to the manufacturer. So assuming that the Florida regs are going to approve the same as the NRC, that would be a no, but Florida regs and NRC don't always agree, so --

WILLIAM ATHERTON: It didn't seem that much more simple than a colonoscopy to me.

CHANTEL CORBETT: It's the lack of sedation, it's the --

NICHOLAS PLAXTON: Much prep. It's a huge difference.

KATHLEEN DROTAR: The prep.

WILLIAM ATHERTON: You still have to swallow and put those things on your back.

NICHOLAS PLAXTON: Screening. I agree the

screening of the poop is --

REBECCA McFADDEN: The preop showed you have to drink the capsule with the iodinated contrast drink, so you're still drinking like a --

KATHLEEN DROTAR: No, it was one tablespoon of iodinated for the first three or four days.

CHANTEL CORBETT: Yeah.

ADAM WEAVER: Just iodinated fluid once a day.

REBECCA McFADDEN: It wasn't like a gastrograph, something nasty to drink.

CLARK ELDREDGE: They said it was a teaspoon, tablespoon.

CHANTEL CORBETT: Tablespoon.

RANDY SCHENKMAN: And it was something before --

CLARK ELDREDGE: It was several days before you start taking --

NICHOLAS PLAXTON: Sedation, and then there's complications from a colonoscopy. You can get a perforation, so there's a lot of risk involved.

To me, I'm like, if they're not reusing the capsules why not just let them go away because they have the data on the backpack thing and, like, just flush them all away and not retrieve them.

REBECCA McFADDEN: But it may be the thing in

the capsules.

ADAM WEAVER: I bet you they reuse the detectors. I bet you they reuse some of them --

NICHOLAS PLAXTON: Some of the insides. That's what I'm thinking.

ADAM WEAVER: Some of the insides. It's an expensive detector.

REBECCA McFADDEN: I think he answered you like, oh, no, they're not reusable. They want it back.

NICHOLAS PLAXTON: Yeah, I think so. I bet you they do, especially the thing with the person dying that was kind of like --

CHANTEL CORBETT: That doesn't surprise me, though.

KATHLEEN DROTAR: No.

ADAM WEAVER: Any kind of medical device is cut out before --

KATHLEEN DROTAR: Yeah.

NICHOLAS PLAXTON: I would just leave it in there.

CHANTEL CORBETT: Right, yeah, that's pretty typical.

NICHOLAS PLAXTON: Not really.

ADAM WEAVER: Only if you're cremated.

CLARK ELDREDGE: The issue there, if the person is being buried, it's like that's one thing. If they're being cremated and they're grinding it up --

ADAM WEAVER: Like hips.

CHANTEL CORBETT: Yeah. I mean you don't know and that's the other thing, I mean --

NICHOLAS PLAXTON: Hip replacements. They take out the --

KATHLEEN DROTAR: Outside the VA they do.

JAMES FUTCH: You guys, one at a time. One at a time.

KATHLEEN DROTAR: They know when you take things out.

NICHOLAS PLAXTON: No way. I guess a lot of people aren't buried anymore.

ADAM WEAVER: They do because it messes up their machine. Their equipment.

CHANTEL CORBETT: Talking about taking out knee replacements now.

NICHOLAS PLAXTON: It messes up their --

ADAM WEAVER: Not necessarily, I guess. Also probably religion may come into play, too. Certain religions.

NICHOLAS PLAXTON: Yeah.

JAMES FUTCH: He didn't want to say how

expensive the device was.

NICHOLAS PLAXTON: I'm sure they're expensive.

ADAM WEAVER: We didn't have a need to know that.

CHANTEL CORBETT: That's because, well, usually in trial, though, it's different than what they end up being, too.

NICHOLAS PLAXTON: Sure.

CLARK ELDREDGE: And that's basically proprietary business.

CHANTEL CORBETT: Right.

JAMES FUTCH: I mean, you know, if it cost $10,000 per capsule or something.

WILLIAM ATHERTON: They may not want people to know the design of a capsule, either. That's why they want to retrieve every single capsule. They don't want people to dissect it.

NICHOLAS PLAXTON: I don't know who's going after that thing, digging through the sewers.

REBECCA McFADDEN: Someone is cracking it open. They want to see what's inside. It happens.

NICHOLAS PLAXTON: Yeah.

RANDY SCHENKMAN: And what were they saying about the interpretation? It has to be interpreted by --

CHANTEL CORBETT: Well, they have people who are interpreting the data there.

NICHOLAS PLAXTON: Yeah, analysts, which are non-medical.

ADAM WEAVER: A few people in the states.

CHANTEL CORBETT: Which is fine.

NICHOLAS PLAXTON: Probably.

RANDY SCHENKMAN: And then they send the interpretation --

CHANTEL CORBETT: Back to the facility.

NICHOLAS PLAXTON: Actually, only the ones that are positive are being then screened, overread by a doctor is what it sounds like. But it's only doctors that have -- are in the study. Not the authorized user.

CHANTEL CORBETT: Well, you would have to have a read, though. It's the same as giving a therapy capsule and a patient walking out nowadays. I mean, you know, you still have to read that as an administration.

NICHOLAS PLAXTON: I agree, that that probably, if it becomes, like, a thing.

CHANTEL CORBETT: A thing.

NICHOLAS PLAXTON: Yeah, I agree, that's probably how it would have to be.

ADAM WEAVER: It sounds like they have a computer AI looking at it first.

JAMES FUTCH: Clark can see that.

NICHOLAS PLAXTON: They will eventually.

REBECCA McFADDEN: That's what they said. And then someone looks at that and then it goes to the doctor.

ADAM WEAVER: It converts that raw data into a nice picture.

CHANTEL CORBETT: Right.

NICHOLAS PLAXTON: Yeah.

KATHLEEN DROTAR: And they were saying, too, that it's gastroenterologists that are doing that, so, under licensing.

CHANTEL CORBETT: No, no, no, that's what I'm saying. It's the same kind of thing. You can have a cardiologist read a study and you can have a gastroenterologist read a study, but as long as they're overread by an AU.

KATHLEEN DROTAR: Yeah. I wish that they were giving the patient the capsule by a gastroenterologist is what I heard.

ADAM WEAVER: Yeah, but there's not many GIs listed as authorized users. It's not a common part of their practice.

KATHLEEN DROTAR: Yeah. Well, that would be --

CHANTEL CORBETT: Not usually.

ADAM WEAVER: It's not a common part of their practice.

NICHOLAS PLAXTON: I mean, they could. There's nothing that prevents them, but --

CHANTEL CORBETT: Right.

ADAM WEAVER: Maybe if they were associated with a hospital.

KATHLEEN DROTAR: Yeah, that's what I was thinking.

JAMES FUTCH: So Dr. Fisher has provided his contact information for facilities or the general public.

CHARLES HAMILTON: By the way, what Chantel said, though, at least one authorized user on the license has to make an interpretation for every diagnostic study.

KATHLEEN DROTAR: Right.

CHANTEL CORBETT: Right.

CHARLES HAMILTON: But so can everybody else in the world.

ADAM WEAVER: Yeah. And they can do it after, after the fact. After the -- they have looked at it first.

CHANTEL CORBETT: Right.

ADAM WEAVER: Then it comes down to the authorized user in Florida. He or she can look at it and say --

CHANTEL CORBETT: Right.

ADAM WEAVER: -- I agree, I don't agree. Whatever.

CHANTEL CORBETT: Right. See above. Here's my signature.

ADAM WEAVER: Yeah. What can I charge.

CHANTEL CORBETT: Right.

CLARK ELDREDGE: I have a question. What part of the analysis is the practice of medicine, which means it has to be an MD, you know, OD that's -- or DO, I mean, that's doing the interpretation or signing off on it.

CHANTEL CORBETT: I don't know any AUs that are not already.

CLARK ELDREDGE: Right. But I'm saying even the pre-stuff.

CHANTEL CORBETT: That I know of. Maybe there are.

ADAM WEAVER: Right.

CLARK ELDREDGE: I know the PA is the final signature that covers it.

NICHOLAS PLAXTON: Yeah. I mean, there should be someone, there should be, some doctor should be overreading this.

CHANTEL CORBETT: Yeah.

NICHOLAS PLAXTON: Which it sounds like they're doing now, but I think there's four doctors.

CHANTEL CORBETT: Right. And I mean, in other states, the authorized users are not on licenses. I mean, they don't have to be to read studies. I mean, it is different depending on the states, so --

NICHOLAS PLAXTON: Mm-hmm.

ADAM WEAVER: It comes down to cost. Is it a lot less.

WILLIAM ATHERTON: Some people don't want to go --

CHANTEL CORBETT: And is it going to be covered.

WILLIAM ATHERTON: Some people don't want to go.

ADAM WEAVER: That is true.

CHANTEL CORBETT: That's going to be really what it really comes down to, because a lot of people aren't going to be cash pay to avoid it.

NICHOLAS PLAXTON: It would be interesting to know, like, how many people don't screen for

colonoscopies. I'm sure it's pretty high.

CHANTEL CORBETT: I mean, what is the box thing that, you know, they're sending out nowadays. I mean, that's pretty popular it seems like.

JOSEPH DANEK: Yeah, that's true.

NICHOLAS PLAXTON: What is the box? What box?

CHANTEL CORBETT: The colon --

ADAM WEAVER: Analyzing your sample.

CHANTEL CORBETT: You send in your sample.

NICHOLAS PLAXTON: Like the blood?

ADAM WEAVER: Your sample.

RANDY SCHENKMAN: You send in the stool.

NICHOLAS PLAXTON: The whole stool?

JOSEPH DANEK: You send it in and they check the blood.

KATHLEEN DROTAR: Yeah. A little sample.

CHANTEL CORBETT: Yeah, I don't remember the name of it. It's on T.V.

KATHLEEN DROTAR: I can't, either. I just see the little blue and white box.

JOSEPH DANEK: It's on T.V.

CLARK ELDREDGE: Cologuard.

RANDY SCHENKMAN: Cologuard, that's right.

KATHLEEN DROTAR: Yeah, Cologuard.

CHANTEL CORBETT: Cologuard, right. They send

you a kit, you collect your stool, you send it back, they do the analysis, and they say, oh, you're high probability, low probability.

NICHOLAS PLAXTON: I mean, yeah, it's a fancy version of the guaiac card, where you just swipe it.

CHANTEL CORBETT: Yeah.

NICHOLAS PLAXTON: I mean, the problem with that is usually, if you're getting blood in your stool, you're already further along. You already have cancer.

RANDY SCHENKMAN: Right. This is looking for --

CHANTEL CORBETT: I mean --

RANDY SCHENKMAN: -- earlier than that.

CHANTEL CORBETT: But I mean, like, primary physicians are using that now, though, for the initial screening. Like, at 50. Even if they're not having issues.

NICHOLAS PLAXTON: Well, that's what I'm saying. But that means that a lot of people must be refusing to get colonoscopies is what I'm saying. Because colonoscopy is definitely the best.

CHANTEL CORBETT: It's the gold standard. But it's expensive and it's a procedure.

NICHOLAS PLAXTON: Yeah, and it takes time.

There's risk of the.

ADAM WEAVER: It's also -- yeah, money plays into it.

CHANTEL CORBETT: Yeah.

ADAM WEAVER: That other test is very reasonable.

JOSEPH DANEK: Some people don't want to get knocked out. Are afraid to get knocked out.

CHANTEL CORBETT: Yeah.

RANDY SCHENKMAN: And this finds it earlier.

NICHOLAS PLAXTON: Yeah. This is definitely way earlier.

RANDY SCHENKMAN: This is finding the polyps rather than the cancer.

KATHLEEN DROTAR: Insurance pays for one every ten years.

CHANTEL CORBETT: Right.

NICHOLAS PLAXTON: Yeah, it definitely has a benefit, that's for sure.

KATHLEEN DROTAR: Well, colonoscopies, the insurance reimbursement is one every ten years, so if this is in between they're checking for polyps.

NICHOLAS PLAXTON: Yeah.

KATHLEEN DROTAR: Because that's not going to show on Cologuard, I don't think.

NICHOLAS PLAXTON: Nope.

KATHLEEN DROTAR: Pros and cons. Sounds like medicine.

CHANTEL CORBETT: Right. Yep. Always fun the discussions we have.

NICHOLAS PLAXTON: Yeah.

RANDY SCHENKMAN: Okay. Now we're going to move on. First we're going to welcome Dontavia Wilson. She is going to go over the Medical Quality Assurance update and we just want to thank you and welcome you.

DONTAVIA WILSON: Thank you. Thank you for having me. It is definitely a pleasure to actually be here and to see each of you.

To kind of get started with the few things that I would like to provide you all, within our office, we have, we have about three processors that process all of our radiology technologists' applications, okay? We have experienced, well, and I feel like, honestly, MQA has experienced a lot of vacancies within each office. I kind of feel like that's a worldwide thing. But we have actually filled every position.

Everyone is -- or the newest ones that we have, they are being trained. So our -- the increase

within our workload has definitely, you know, it's picked up. Our applications have been processed and we're on an average -- applications are being processed within an average of no more than two days initially.

The number of applications that we've received and processed since the last annual Council meeting is a total of 2,578 applications. For -- more so the fiscal year is what the data provided me with. With the number of licensed or licenses that were issued for that time span, for radiology technologists, were 1,797 applications -- or, yes, applications. For radiologist assistants, they were only five. However, with the applications received, we have a lot of open applications because the applicants are deficient.

One of the most common deficiencies that we have when trying to approve or make someone eligible to sit for the exam for ARRT, is the -- a photo I.D.

But for the most common deficiency when trying to issue a temporary license, would be the photo I.D. The difference is, if an applicant applies, like Zam, to the department first, then to ARRT, the department will receive the exam results automatically, right? However, if the applicant

registers with ARRT first, then applies with the department, the applicant actually has to submit those exam results to us. So that kind of, I feel like, it puts a little delay within processing.

And then also, with the endorsement applications, if an applicant applies by endorsement, that means they have already submitted their registration to, or they've already registered for the ARRT and they've already tested, a lot of times it -- they submit an application by endorsement, either they haven't tested and it just kind of, you know, put that delay out there.

So I would say if, you know, you come across students or anyone that is trying to apply for a radiology technologist application, that they would need to submit, I would prefer, or the office would prefer if they would -- if they're trying to sit for the exam, to submit the application to the department first and then register with ARRT. To kind of -- because once we go in to process the list that we receive, then we can actually sync the information, versus to having to sit and actually wait on the applicant to, you know, send in all of their documentation, okay?

KATHLEEN DROTAR: Actually, there's a problem

with that. If the, if the graduate or student submits to Florida first before applying for the ARRT, then their certification is only for Florida. It doesn't pertain to the national exam.

DONTAVIA WILSON: I didn't quite hear that.

JAMES FUTCH: Would you share the mike?

KATHLEEN DROTAR: Oh, I'm sorry. When a graduate or student -- I'm a program director.

RANDY SCHENKMAN: It's not on.

KATHLEEN DROTAR: Not on. Oh, there we go.

ADAM WEAVER: He had to turn it on.

JAMES FUTCH: That's okay. Now we're going to compete with the lawn crew outside.

KATHLEEN DROTAR: So I had a student that did that at one time and she applied to the State -- actually, the application got to the State before the one got to ARRT.

DONTAVIA WILSON: Okay.

KATHLEEN DROTAR: And she was only licensed in the State of Florida. So if the students don't apply to ARRT first, then, then they're not going to have a national certification, which is the whole object of ARRT.

CHANTEL CORBETT: ARRT is going to issue the certification regardless.

KATHLEEN DROTAR: No. She had to retake the exam because she's only in Florida.

JAMES FUTCH: Same exact test. ARRT will not recognize passage for Florida as acceptable for endorsement in the ARRT. They'll make them take the test again. This is, so -- let me back up.

CHANTEL CORBETT: Are they selecting a different option on the ARRT testing site?

JAMES FUTCH: No.

KATHLEEN DROTAR: No.

JAMES FUTCH: That's an ARRT thing. They don't accept -- so let me back up for just a second. So Dontavia works in the Division of Medical Quality Assurance, which is a sister division to the one we're here in, Bureau of Radiation Control, so we're both Department of Health employees. And Dontavia is on the half that is dealing with the applications on the incoming side for, you know, whatever endorsement or for exam for Rad Techs, radiologist assistants, as well as EMTs, paramedics, mental health. I've forgotten --

DONTAVIA WILSON: I have eight different professions.

CHANTEL CORBETT: Nuclear profession.

JAMES FUTCH: There's a lot of different

things. So the issue, we've been wrestling with this for a number of years, all of us from all three sides, about the optimal way to do this.

Here are the constraining factors. When they apply to the State of Florida, when Kathy's applicants apply to the State of Florida, they will also be applying to ARRT. And they will -- wow, suddenly my mike became much more powerful. Thank you, Rob. I'll lean closer.

So if they do that, ARRT will not let them take the test for both purposes, so --

CHANTEL CORBETT: Did that change?

KATHLEEN DROTAR: No.

JAMES FUTCH: Could be. ARRT has undergone a lot of changes over the years.

CHANTEL CORBETT: It's been twenty years since I took mine.

JAMES FUTCH: So let's say the application gets processed through Florida first. And then it goes to ARRT and the ARRT application gets there, you know, secondarily. There's a spot where ARRT will ask them a choice. If you would like this to count for the ARRT, check here, and it will count for the ARRT. If you would like this to count for the State of Florida, check here, and it will count for the

State of Florida. There's no let it count for both.

CHANTEL CORBETT: So they need to have it checked. They need to count it for the ARRT.

JAMES FUTCH: Because that's what they care about the most.

CHANTEL CORBETT: Well, yeah, because that way it would be national regardless of how it --

JAMES FUTCH: If you do it the other way, you're going to take the test twice.

CHANTEL CORBETT: Right, which is retarded.

JAMES FUTCH: We will accept their results and their registration certification for endorsement in Florida. ARRT will not accept any state, not just Florida, that uses their test, who passes -- whose applicant passes by the same passing score, administered in the same testing center, by the same personnel, under the same procedures that they use, because it's their process.

CHANTEL CORBETT: Right. But what I'm saying is, if they select the one that says use for ARRT, the State of Florida accepts that. So there's no reason to select the one that says use for Florida.

JAMES FUTCH: We do accept it -- we do accept it, but we don't actually always get the result back from ARRT.

DONTAVIA WILSON: That's where the applicant would actually have to send us, which --

CHANTEL CORBETT: Well, I mean, it sounds like that's going to be the way it's going to have to be.

JAMES FUTCH: We get something back. Eventually, the applicant will sell us either the scores or send us the actual license from ARRT. But that's another little hurdle, little bump in the process. They filled out an application for this purpose.

CHANTEL CORBETT: Right.

JAMES FUTCH: Signed the whole thing that says, I want to do this, you know, by exam, so forth and so on. Now they've got a license. They want to come in by endorsement.

CHANTEL CORBETT: So basically, they just need to skip the exam part and do it by endorsement and just --

KATHLEEN DROTAR: No, that doesn't happen, either.

JAMES FUTCH: So, so as to what is the best, you'll probably get three different answers for what is the best. If your goal is to start work immediately upon your date of graduation, I think that's the driving force behind the students

applying to, to us at all because then they get a temporary license. And those facilities that will let them work on a temporary license, they can go to work on a temporary license. If it wasn't for that tiny little factor, I think it would probably be best for all concerned to just apply straight to ARRT, get that; apply to us by endorsement.

CHANTEL CORBETT: Right. These days, aren't the results immediate or no?

KATHLEEN DROTAR: Not working. So -- and I'm glad you're here.

JAMES FUTCH: You guys need to have a chat at lunch.

DONTAVIA WILSON: Yes. I'm going to give you my business card as well.

JAMES FUTCH: Extensive discussion at lunchtime.

KATHLEEN DROTAR: I would let you finish. You were going to present and then we can talk.

DONTAVIA WILSON: I didn't have much. That was more so the main thing of, you know, what I want to kind of talk about as far as what, the temporary license being issued or, and how the applicants apply from or for exam versus to endorsement.

KATHLEEN DROTAR: Yeah, because we've always

sent that verification letter to show the -- to show that they completed the educational component. And in December, my students applied for temporary license; waited two months for a license and it's been, you know, this is -- we've been sort of trying to work this out.

And then students -- so this time, we said, okay. Wait until you get your ARRT back and then apply. Also, a couple of the students that -- graduates at that time, that applied for that temporary, when they went to change and sent their ARRT results in to get it changed to permanent, because the temporary hadn't been issued, they were charged another $45 to apply for that after having paid $50 for their -- for the temporary license. Yeah. And we also had a student in West Palm who was told when they called DOH, that the temporary license was no longer being issued.

DONTAVIA WILSON: No, the temporary licenses are still being issued. It is actually a part of the eligibility approval letter for the exam. Like I said, the only issue that I've been made aware of is more so of having the I.D. match or the I.D. match what they have submitted for ARRT. It doesn't match. So then an issue occurs, and we're like, um,

can you actually send this or send a copy in to us so that, you know, we can actually, you know, get it over to ARRT.

KATHLEEN DROTAR: Yeah. So I think maybe I could help you with that.

DONTAVIA WILSON: Yes. Let's work together.

JAMES FUTCH: I think it's an excellent idea if you --

DONTAVIA WILSON: Let's work together.

RANDY SCHENKMAN: Coordinate here.

JAMES FUTCH: Specifically you two.

DONTAVIA WILSON: Yes.

JAMES FUTCH: With specifics, even if you don't have them today, for all those things you mentioned. What I have seen -- We have a single Department of Health, depending if you count the number of employees, 15,000 or so, something like that. And MQA is in the same building, floor above us, but there's a lot of moving parts. Kind of like this meeting. And you mentioned, one of the things they applied by exam and they paid $50 and it's $45 for endorsement. And for some reason, somebody told them they had to pay again.

Typically, what happens is, Dontavia's staff actually have to go in, find the money that was used

for the exam process, like $50, and then using that new application, or at least the new page that says yes, I want to apply by endorsement, transfer it --

DONTAVIA WILSON: Yep.

JAMES FUTCH: -- in the very complicated system they use to apply it to this new application. You can tell this doesn't sound like a process they want to go to too many times. Obviously, your person obviously got the wrong information from whatever staff person gave it to them. They shouldn't be allowed to do that.

KATHLEEN DROTAR: Two people I know. And also on the application, itself, it says that -- where is it? When you're applying by endorsement, that then you have to -- then you go and apply for the, for the -- to the ARRT and apply for the exam. And that's sort of -- yeah. There's, there's a few things, so I appreciate you being here.

DONTAVIA WILSON: Let's --

JAMES FUTCH: I'm glad we're all here.

KATHLEEN DROTAR: We can talk later.

CHANTEL CORBETT: I think the only weird thing I had, I had somebody call and try to get hired as a CT tech that had their provisional window for ARRT, because they give a three-year window that they have

to take their exam. And they were under the impression that they could work during that time.

JAMES FUTCH: Yeah.

CHANTEL CORBETT: Yeah. And they'd actually been tentatively hired and then that person called me and said, um, HR said this is going on but I don't think this is right. So we caught it in time, but it was --

JAMES FUTCH: We have a -- in addition to that, there's a great deal of confusion that we've seen over the years about ARRT and us because we use the ARRT's exam. We use their testing process. People will send things to us and they'll call us ARRT. I don't, I don't know what to do with some of that, but, yes.

DONTAVIA WILSON: I'm sorry.

JAMES FUTCH: I very much wish ARRT will consider our exams be eligible for endorsement for ARRT. That would help a lot, but they don't.

RANDY SCHENKMAN: That's it? Okay.

DONTAVIA WILSON: That's all I have.

RANDY SCHENKMAN: Charlie, do you have anything to add here on radioactive materials update?

CHARLES HAMILTON: Oh, yeah.

RANDY SCHENKMAN: Okay.

CHARLES HAMILTON: Do you have the slides?

JAMES FUTCH: You got ten minutes.

CHARLES HAMILTON: Okay. I can do it in five.

JAMES FUTCH: We'll have to finish with Charlie.

CHARLES HAMILTON: Good morning. I'm Charles Hamilton. I'm here representing the material section for licensing in the absence of our fearless leader Kevin Kunder.

A couple things on personnel. We have, currently we have three license evaluators and we'll show you on the numbers, we're doing about 200 licensing actions a year. We're advertising. Finally got a candidate for a vacant evaluator position, which has been vacant since August. So we've been having a hard time getting qualified applicants to apply and then get them to agree to work and not telework for the salary that we offer.

So the number of licenses, we currently have 1532. You'll see on there, 648 of those are 5Cs, which are outpatient medical facilities. Some, what, 172 hospitals. So 70 percent of our licenses are all Category 5 medical licenses. That also accounts for 70 percent of the workload, which I say we do about 200 licensing actions per month. It

comes out to about right around 2,000 per year.

The top industrial license category we have is, of course, portable gauges, which are the most likely to be stolen. And then, what is it, scroll up real quick. A little bit more. So, okay. So 3B, that's nuclear pharmacies. We've got 34 of those and 18 industrial radiographers. So that fluctuates a little bit. But, of course, the growing one, the most growing one is either mobile nuclear medicine or outpatient standalone medical facilities.

And as we discussed before, we do have, we do have -- you have to be a broad scope medical to do the Cap Tech for the clinical trials if it's not FDA approved yet. We currently have five broad scope medicals, of which one, Mayo Clinic, is now performing clinical trials until approximately June or December of 2023 or until the FDA approves it.

So you've got the information, contact information if you wanted to contact to pursue the clinical trials for the Cap Tech system.

And lastly, I wanted to talk about an upcoming NRC comment.

JAMES FUTCH: You're going to probably have lots to discuss.

CHARLES HAMILTON: -- comments for rule making. It's regarding extrasuvasions (ph). So historically, NRC has not required the reporting of a medical event for anything that has to do with extrasuvasions (ph). But there's been --

JAMES FUTCH: This is the STC one.

RANDY SCHENKMAN: Extravasations.

CHARLES HAMILTON: Right. So they're now considering it. And again, 8-24 is for public comment about what they may or may not do in relations to the rule change.

So currently, again, anything to do with extrasuvations does not, will not constitute a medical event. But there's a potential with -- if the rule, the rule changes go through, they're going to define what extrasuvations are. What's the definition -- highlight the definitions.

JAMES FUTCH: Do you want me to show it?

RANDY SCHENKMAN: In medicine, we call it extravasations.

CHARLES HAMILTON: Thank you.

RANDY SCHENKMAN: That's how, that's how it -- Extravasation.

CHARLES HAMILTON: Extravasation. Okay.

JAMES FUTCH: Let me jump in. There's a lot of

documents about this. The, the NRC has this meeting that Charlie is talking about that's taking place next week about the rule making. There is an STC that went out to all the states, which is what I was showing a second ago, that has a summary of the history that's happened with this. The -- this started a little while ago. There's a particular device from a particular company --

CHANTEL CORBETT: That benefits.

JAMES FUTCH: -- that Charlie is talking about. This is actually the slides from the public meeting that's going to take place on May 24th of next week. And they're looking for, you want to go back to what you were talking about?

CHARLES HAMILTON: Yeah. I'm going to just --

JAMES FUTCH: So the rule language is in here. Let me just scoot down to it. So this is what you'd see if you actually dialed into this thing next week. This lady, Irene Wu, is going to be on. She's going give you some history.

And here's the public rule making petition. And then, Mr. DiMarco is going to get on and talk about what the rule language is, which is going to show up here in red in just a second. Is the proposed ruling which -- so these are the newer

revised definitions.

CHANTEL CORBETT: So there's no quantification that I've seen on this, right? So it doesn't say if there's a certain percentage or certain, you know.

JAMES FUTCH: No. Not that.

CHANTEL CORBETT: There's no way. It just says leakage.

JAMES FUTCH: Nothing we have seen anywhere in these docs.

NICHOLAS PLAXTON: Crazy.

JAMES FUTCH: We get the impression that there's a, there's a company that had a device that's used to measure the amount of extravasation near the injection site and other places. And they've made some headway with that in, in a certain state. There's been a letter from some Congressional members to NRC suggesting they need to do something to revisit this issue, which is the driving force, I think, behind the rule making. And this is what staff, based upon their advisory committee on medical use of isotopes, has, has given them guidance and this is the product of that.

But Chantel, you're right. There -- I haven't seen anything in here that specifies, well, quantitatively, what is the suspected radiation

injury? What is the level --

CHANTEL CORBETT: Right. To my knowledge, nothing we inject in nuclear medicine is going to fall into that last category as a diagnostic.

ADAM WEAVER: Yeah, diagnostic.

CHANTEL CORBETT: I mean, therapy is a different story, but it's not specifically saying therapy. It's saying all injections.

JAMES FUTCH: Right.

NICHOLAS PLAXTON: Yeah.

JAMES FUTCH: I believe, if you follow through with this, there's a whole bunch of questions that they have.

CHANTEL CORBETT: Is conflict of interest one of them, because I mean --

ADAM WEAVER: Who submitted the request?

CHANTEL CORBETT: Right. The request was submitted by the device manufacturer to change this. It's just beneficial to them.

JAMES FUTCH: There is a part of this that appears to allow for, at least some aspects of, of the parties involved would like to allow for the use, of course, not just this company's device, but also the facility's existing equipment and their existing radiation staff to monitor and whenever

they hit that level, whatever that level will be, then declare that to be a medical event.

NICHOLAS PLAXTON: But that's not going to happen with imaging. You're never going to get to that level. You can blow the whole -- you can inject the entire thing into the muscle and not even hit the vein. You're not going to have a medical event.

JAMES FUTCH: Let me show you -- so everything you see on here is conceivable. Doggone it. Hold on.

NICHOLAS PLAXTON: You'll have a wasted exam.

ADAM WEAVER: You won't get your image.

NICHOLAS PLAXTON: You just won't get your image and you'll have to repeat it.

CHANTEL CORBETT: Right. That's what I was saying. If your definition is like, an extravasated dose, period, any bit of it, that's a whole different animal.

JAMES FUTCH: Anyway, we collected a large number of documents for this. What Kevin, I think, wants is just to make sure the Council's aware this meeting is taking place next week so that you can, you know, listen in to it. And I think he wanted us to show you the questions and the rule making

language right now, if we still have time. It's 12 o'clock. Do we take a break and come back to this? Yeah, probably.

NICHOLAS PLAXTON: Break it.

JAMES FUTCH: We might be here for a little time. Since it's lunch time.

RANDY SCHENKMAN: You have a lot of stuff in here, too. Extravasation events that cause permanent functional damage?

CLARK ELDREDGE: Right. These are -- the report to NRC from the ACMUI subcommittee is included in your packets. And they have their options listed of how to determine how to address what the described parameters are and the potential options involved and how it could be adopted.

CHANTEL CORBETT: Right.

CLARK ELDREDGE: Right.

CHANTEL CORBETT: So just say opposed and be done?

JAMES FUTCH: Before we go to lunch, let me just scroll down here and show you the questions because they go on for a while.

Just about the definitions. What term should they use when describing it. What criteria should they use to define suspected injury and the same

thing for the methods for medical attention.

And then there's some more proposed rule language using those definitions. For any administration which extravasation can occur, must involve procedures that provide high confidence that extravasation that requires medical attention for suspected radiation injury, ding, ding, ding, the two brand-new key words --

CHANTEL CORBETT: Right.

JAMES FUTCH: -- will be detected and reported. So wide open, at this point, for what those are. The written procedures in (a) must address how they determines that it meets the criteria for a medical event.

CHANTEL CORBETT: Once they establish the criteria, so --

JAMES FUTCH: Yeah. And then, of course, retain a copy of the procedures and there's something about retaining the records and the reports.

And here's more questions. What steps to take to minimize the chance -- you guys can read. What steps should the licensee take when it's discovered? What imaging technologies procedures should be used to help identify during or after the injection?

So this would be where, I guess, folks would step in and say, not some extra device that we have to buy from wherever the heck else it comes from. We have tools, if you do have tools, to do it or not.

CHANTEL CORBETT: Yeah.

JAMES FUTCH: Next set of questions.

RANDY SCHENKMAN: Well, in here, they have the conclusion and recommendations.

JAMES FUTCH: Let me throw that up there so you guys can see that.

Sorry. I have that in the wrong place here. What page are you on?

RANDY SCHENKMAN: It's the last page.

JAMES FUTCH: Here you go.

RANDY SCHENKMAN: And option four is just above it. The page before. There it is.

CHANTEL CORBETT: I mean, basically, there's like, you know, there's option four, it says, like, an aide is going to have to determine that it's caused by radiation. Like the injury. But then it says that dosimetry is not going to be required, so I'm not sure how you're going to say it's a radiation-induced injury with no dosimetry. That doesn't make any sense.

NICHOLAS PLAXTON: And again, these are diagnostic levels that are not going to -- there's no possibility --

CHANTEL CORBETT: I mean, technically, it could be anything, though. We have a ton of therapy injections now.

NICHOLAS PLAXTON: Yeah.

JAMES FUTCH: So before we started sending out stuff about this and talking about it with you, how high visibility did this issue have? Was anybody aware of this?

NICHOLAS PLAXTON: Oh, yeah. It's gone to -- well, it came out a few years ago, because specifically, because of this company came out with a device to measure, you know --

JAMES FUTCH: Right.

NICHOLAS PLAXTON: -- they used to strap it on your arm and measure this, you know, if there's been or hasn't been an extravasation. So, but the thing is, is that's not medically necessary and it's a waste of time. So it's like --

JAMES FUTCH: You're thinking for diagnostic.

NICHOLAS PLAXTON: Yeah, definitely diagnostic. And there's very few, like, the thyroid treatment is oral. We do Xofigo now, which is the alpha emitter,

so that doesn't matter.

CHANTEL CORBETT: You've got the Lutetium stuff now. There's actually a liquid iodine injection now, too.

NICHOLAS PLAXTON: Yeah, that's the only one that you can consider. Yeah.

JAMES FUTCH: So was the committee aware of the meeting next week?

NICHOLAS PLAXTON: I'm not sure of the committee, but this has been brought up at our -- the Society of Nuclear Medicine multiple times, so -- and there's, like, a resounding, you know, the only people that are pushing for this are the people that work for the company.

ADAM WEAVER: Is it into the balloon?

JAMES FUTCH: So if this --

CHANTEL CORBETT: I mean, to my knowledge, there's no known injuries from this.

NICHOLAS PLAXTON: Yeah, there isn't. There's not.

ADAM WEAVER: Yeah, for diagnostic. Even therapy would be an acute injury.

CHANTEL CORBETT: Even therapy -- yeah, I was going to say even therapy, I don't know of any.

NICHOLAS PLAXTON: Even if you use -- what we

use, I don't think would cause an injury.

JENNIFER PETERSON: I've seen it from therapy. I had patients that actually had that. Extravasation and soft tissue damage.

RANDY SCHENKMAN: And had what?

JENNIFER PETERSON: Had extravasation and soft tissue damage to their arm. But it happened weeks later. It wasn't --

KATHLEEN DROTAR: From what?

ADAM WEAVER: It wasn't, wasn't immediate.

NICHOLAS PLAXTON: From what? From what type of --

KATHLEEN DROTAR: From what?

JENNIFER PETERSON: Yttrium-90.

CHANTEL CORBETT: The level.

ADAM WEAVER: It wasn't immediate?

KATHLEEN DROTAR: From what?

ADAM WEAVER: Yttrium-90.

NICHOLAS PLAXTON: Yttrium-90, which goes along with Lutetium.

ADAM WEAVER: Pure beta in there.

NICHOLAS PLAXTON: Yeah, which those are different. Those are the only two cases that would even be legit for this, but they're pushing for everything.

CHANTEL CORBETT: Right.

NICHOLAS PLAXTON: All diagnostic imaging and then you read this little thing here.

CHANTEL CORBETT: But again, it's kind of like the medical event definition now. You have to have this, this, and, you know, 5 rem. That kind of thing.

NICHOLAS PLAXTON: Yeah.

CHANTEL CORBETT: So as long as it includes enough caveats that you're not ever going to meet all three of them, you know, three or four of them, then you're never going to have to report them.

NICHOLAS PLAXTON: But the idea is that --

CHANTEL CORBETT: Ideally it won't make it through anyway.

NICHOLAS PLAXTON: Their goal is that it doesn't matter what it is, you would have to buy the device and you have to measure every single dose every time.

CHANTEL CORBETT: Right. Yeah. And you have to come up with a protocol of how you're going to determine this.

NICHOLAS PLAXTON: Which is a waste of time.

CHANTEL CORBETT: And then who's going to determine what's okay on that list, you know.

RANDY SCHENKMAN: Well, if you look under these conclusions and recommendations, look at number four.

ADAM WEAVER: It's going to be dependent on the radio nuclei involved.

CHANTEL CORBETT: No, I know. That's what I was -- yeah.

RANDY SCHENKMAN: There's no clinical evidence that patients are being harmed, either from excess radiation dose or compromised diagnostic studies because of radiopharmaceutical extravasation. So what's the point of this?

CHANTEL CORBETT: Right. Yeah.

NICHOLAS PLAXTON: To sell their device. That's all it is. And if they require it, if it becomes a rule, then everyone has to use their, like everyone has to us it every time.

CHANTEL CORBETT: Right. They're going to want their device to be the way to evaluate it.

REBECCA McFADDEN: They can to use it probably for CT or is this --

NICHOLAS PLAXTON: It's just like a waste of time.

CHANTEL CORBETT: Oh, no. This is radio pharmaceuticals.

KATHLEEN DROTAR: This is radio pharmaceuticals.

RANDY SCHENKMAN: This is radio pharmaceuticals.

REBECCA McFADDEN: Oh, wow.

NICHOLAS PLAXTON: Yeah. I love this one line that stood out to me. I don't know where they're getting their data from. Where it says a review of four studies of 2,613 patients, they said that the nuclear pharmacist, you know, radio pharmaceutical extravasations was reported as 17 percent, which, you know, I'm not arguing that number. But then they go to say, but however, chemotherapy and IV contrast is .009 percent and .24 percent.

KATHLEEN DROTAR: What? There's no way. Somebody got their numbers reversed.

ALBERT TINEO: No way. No way.

CHANTEL CORBETT: There's no way.

NICHOLAS PLAXTON: No way.

ALBERT TINEO: Absolutely no way.

NICHOLAS PLAXTON: Because like the IV injection is the same no matter if you're using radio pharmaceutical.

KATHLEEN DROTAR: Right.

CHANTEL CORBETT: Right. Saline. Like

whatever.

RANDY SCHENKMAN: Where did you read that from?

NICHOLAS PLAXTON: Saline. Whatever it is. In their discussion on frequency of extravasations.

CHANTEL CORBETT: An earlier section.

NICHOLAS PLAXTON: That just -- it doesn't matter what you're injecting, it's always going to be the same. Like, you're going have the same amount of, like, leakage. You can't get a perfect IV stick without -- there's always going to be some leakage. The fact that those numbers, and I love the .09 percent of chemo. I mean, I want to know how they're doing that.

KATHLEEN DROTAR: How can you compare people on chemo with viable veins.

JOSEPH DANEK: That's pretty accurate.

CHANTEL CORBETT: Right. They're the worst veins of the group.

KATHLEEN DROTAR: Yeah.

NICHOLAS PLAXTON: Yeah.

RANDY SCHENKMAN: Well, they had somebody who didn't know how to put an IV in. That's all.

CHANTEL CORBETT: Yeah. No, what we're saying is the likelihood of that being so much smaller than nuclear --

NICHOLAS PLAXTON: I'm pretty sure the only reason is like, probably the chemotherapy and IV contrast, there's no way to measure how much has been extravasated. You know what I mean? There's been no --

CHANTEL CORBETT: Right. That's kind of why I was surprised they haven't determined a quantification rule on this. Like it just says, it is. Like, you have to figure it out.

NICHOLAS PLAXTON: Yeah. You can obviously measure it a lot of easier on a -- with a radiation detector than you can for chemotherapy.

CHANTEL CORBETT: Right.

NICHOLAS PLAXTON: There's just no way.

CHANTEL CORBETT: I mean, most likely to be imaging at that point because --

JAMES FUTCH: Yeah, so I think that's actually --

ADAM WEAVER: They're going to have some residual anyway. Natural leakage.

NICHOLAS PLAXTON: Right.

JAMES FUTCH: -- this report comes from the NRC Advisory Council on medical use of isotopes. So I think that the point of that paragraph is to point out that fact, that this is not consistent with the

reported extravasations from these other types of use of IV and because of that, this data should be questioned.

RANDY SCHENKMAN: Yeah.

NICHOLAS PLAXTON: I agree completely.

JAMES FUTCH: That's the point I think they're making. These are similar types of injections to that being performed for radio pharmaceuticals; therefore, the extravasation rate should be similar.

NICHOLAS PLAXTON: It makes no difference.

RANDY SCHENKMAN: But then go down lower and it says, for non-radio pharmaceuticals, the criteria for extravasation needs to be pain, swelling or redness, okay? But --

JAMES FUTCH: Right.

RANDY SCHENKMAN: -- it says, one reason these studies show higher extravasation rates for radio pharmaceuticals is that the criteria to be counted as extravasation in these studies, was visualized increased uptake tracer at the injection site.

CHANTEL CORBETT: Because you can see it. Right.

RANDY SCHENKMAN: It does not take much activity to be visualized on a gamma camera or PET scanner image. So they're not even comparable.

NICHOLAS PLAXTON: They're not at all.

CHANTEL CORBETT: Yeah. No.

KATHLEEN DROTAR: No. It's crazy.

NICHOLAS PLAXTON: The only time we actually -- the only time we've even gone into this realm is, like, when we do our DAT scans for brain imaging for Parkinson's Disease. And so what we do is, we're imaging just the head. But it's so sensitive, if you don't get all the tracer in, you have a bad extravasation, then you're not going to get all the radio tracer up there and you can get a false positive -- or yeah, false positive. And so, we -- on all those patients, we image the injection site, just to make sure there's not this big blowout of radio tracer in the arm. We're not quantifying it, but we can just --

CHANTEL CORBETT: But you know, inpatients have a cannula that says in them. So you're going to have an IV that most likely has a little bit of the tracer in it anyways that's going to be visualized. So it's like, you're not going to pull the IV after every inpatient and put a new one in so that you can prove that it's not, it's not realistic.

NICHOLAS PLAXTON: Yeah.

ALBERT TINEO: It's just insane.

JAMES FUTCH: So the -- go back to the public meeting. These questions go on and on. These documents are on the NRC site. If you go and -- you can go to the links that we gave, but you can just go to Google NRC extravasation, May 24, and you'll find the landing page where these slides are. So you can go pull them down; share them with the facility.

Again, our -- I think our interest from Radiation Control is if this NRC rule making proceeds over the next couple of years and is adopted, then we'll, as an agreement state, have to do something to be compatible with that over the rule making. It will probably take us three more years after that. And, you know, the time is now, I guess, to make your voices heard in the community about these kinds of issues that you're talking about to the, to the NRC and answer these questions.

This is what, you've got a 90-day comment period to get answers from as many folks in the community about these, these many points that they're, they're asking. I think it's 16 of them. Oh, 14. And then this is how they want comments to go in. The regular place. Commenters checklist, regulations.gov or you can just e-mail them.

Any questions?

NICHOLAS PLAXTON: They're probably getting a lot of hate mail.

CHANTEL CORBETT: As soon as they put this idea out, they started getting hate mail.

NICHOLAS PLAXTON: Yeah, I'm sure.

JAMES FUTCH: Yeah. Charlie, anything to add?

CHARLES HAMILTON: No. I was finished at 12, like I was told to.

RANDY SCHENKMAN: You were what?

CHARLES HAMILTON: I was finished at 12 like you told me.

NICHOLAS PLAXTON: He stopped at 12.

(Laughter).

RANDY SCHENKMAN: Okay. Well, I guess if we are done with this -- are we done with this? Okay. Lunchtime. Yeah, if anybody has comments after, after lunch, we can bring it back up then.

JAMES FUTCH: Brenda is saying we need to be back at 1:30.

RANDY SCHENKMAN: Okay. We have to be back at 1:30.

(Proceedings recessed at 12:11 p.m.)

(Proceedings resumed at 1:30 p.m.)

RANDY SCHENKMAN: All right. We're going to

get started. Before we move on, does anybody have any questions about this NRC, this whole thing we just went through? The extravasation medical events?

NICHOLAS PLAXTON: I strongly disagree.

ADAM WEAVER: Hopefully they're not successful.

NICHOLAS PLAXTON: Yes.

RANDY SCHENKMAN: Well, I guess we all should just send our comments in. I mean, that probably would be a good idea.

ADAM WEAVER: As a group.

NICHOLAS PLAXTON: I'm positive that the Society of Nuclear Medicine has probably sent multiple.

CLARK ELDREDGE: There is a position paper out there from them.

NICHOLAS PLAXTON: Yeah.

CLARK ELDREDGE: The link will be posted with our stuff. We just didn't think it was, third-party position papers weren't necessarily what we should be providing in our packets.

NICHOLAS PLAXTON: No. I'm sure they already made a strong statement against this because this is a -- yeah, I mean, it's not for the benefit of the patient.

CHANTEL CORBETT: Right, yeah.

RANDY SCHENKMAN: Well, I guess all of us should try to write to them and let them know.

Okay. Now we are going to get the report on the Conference of Radiation Control Program Directors, et cetera, et cetera, et cetera.

CLARK ELDREDGE: Actually, we're going to start with the radiation machine program update.

RANDY SCHENKMAN: Okay.

CLARK ELDREDGE: And then I'll go into the Age 58 task force.

RANDY SCHENKMAN: Okay.

CLARK ELDREDGE: Which you all will get, too.

JAMES FUTCH: Do you want to put the agenda up?

CLARK ELDREDGE: Yeah. So, notes. Where's my other notes?

Okay. So, section notes, radiation machine, one, start kudos for one of our folks, Lisa Gabfest (ph) who --

RANDY SCHENKMAN: Do you want to put anything up on the screen?

CLARK ELDREDGE: No. I will when I give the slide presentation. For now, nothing to show until we get the slide presentation.

RANDY SCHENKMAN: Okay.

CLARK ELDREDGE: Miss Gabfest received a meritorious service award for her work on the committee that reprised the state suggested regulations on the use of particle accelerators Part X from CRCPD. So that's been updated and released.

Last November, we issued a denial for a registrant who wanted -- a law firm who was requesting a registration to use an XRF to measure the presence of lead in peoples' shins.

RANDY SCHENKMAN: What --

NICHOLAS PLAXTON: What for?

CLARK ELDREDGE: Lawsuit. They actually had done this in Michigan. And Michigan, during, you know, following up on Flint, Michigan issue with the lead in the water and so they wanted to use it in a lawsuit here in Florida.

So -- wait. I'm not -- so basically, it was denied. They then filed a, all I will say is we denied them for the request since it didn't sit in our statutes. There's no authorization for non-medical use type thing for what they were saying. They filed a challenge to the denial. They've since voluntarily withdrawn the challenge.

Program staffing, as you all heard last time, it took a long time to replace Larry and then

Larry's replacement didn't last but a month. Then we had Dana, who came on board, but then Mary left and now we have three. So actually, the people who process the registrations are fully staffed right now. However, technical folks, Ginny left us in November. We advertised three times; seven applicants. Five withdrew. One was interviewed but currently is overseas in Bulgaria taking care of family.

Another applicant was -- he was a Ph.D. in chemistry. The other applicant, one of the other applicants who agreed to be interviewed was a Ph.D. in environmental science, also in Europe. They didn't have U.S. working papers so we couldn't proceed farther with them.

David, who's our -- he's an electrical engineer who works for us, is the one who does our research on new devices and whatnot, he's leaving in June. June 1 is his real retirement date. Since -- he actually had closed down his engineering business, his manufacturing business, and worked for the State, so we were kind of a retirement job in the sense he was no longer responsible for marketing, for hiring and firing and all that type of stuff. And it was a -- and now his wife said it's time to

fully retire.

So we will be down two staff, technical staff. It will be just Lisa and I.

We currently have -- we've crossed the 20,000 registration threshold this past bit with the 63,000 machines registered in the State.

So far for this renewal cycle, out of those, you know, over 20,000, about 18,000 have actually paid their registration fees so far this year to about 2.6 million. While -- so that leaves about 2,000 that haven't paid yet for about 230k. And of course, there will be some percentage of those that disappeared and never bothered to tell us.

I think I told you all last time, we were able to renegotiate the MQSA, medical quality assurance. So that's all going well so far. We, we are churning inspectors like in everything else. We had one gentleman retire. We were able to hire another person who has now completed their training and will be starting, able to do MQSA inspections in another month or two after they get their final authorization from FDA.

One consideration facility is, we've had some questions about physicists in training. So the requirements to do physics for MQSA is a different

level than the State of Florida licensure for a medical physicist. So an MQSA, a physicist in training can actually meet the full Federal requirements to do all, all the calibration, examination, stuff for a mammography machine, but they wouldn't be legally allowed to sign off on it under Florida Statutes because you have to be a full physicist rather than physicist in training. A full licensed medical physicist before you can sign something off. So they can do the work, but they would still have to have the supervising physicist would be the one to sign off on the final reports to be able to meet Florida Statutes.

We have -- we do issue the Florida MQSA medical physicist letter. This is a letter that states that we have reviewed their qualifications and determined that they meet the MQSA requirements for an MQSA facility. This is a service we offer so that facilities don't have to have a whole stack of the physicist paperwork on -- in their files. They can just take the letter and have that demonstrate this person who's doing their physics work is qualified. Otherwise, the facility, itself, has to track their initial qualification, as an MQSA, a physicist and all their CEs, and how many machines they've

actually evaluated, because there's two levels. You have to -- I do not remember. I cannot tell you the numbers off the top of my head, but you have to survey X number of machines every two years and you're good for two years from the first of those numbered machines. And you have to have, in certain, 16 hours of CE every three years and it's from that first hour that CE, to three years. And so, they don't have to do the math on that.

We've had one medical event since last meeting. One wrong site that was palliative treatment of three different sites. Base of skull, sacrium and lung -- sacrum and lung, sorry. The patient requested the sacrum be treated first, but when they set him up, they set up the new treatment delivery was for the skull base fields rather than the sacrum. Sacrum base fields rather than the -- rather than for the -- they used the skull fields for the sacrum treatment. Say that right.

Now, let's get this thing going. Okay. So this is a presentation that was given at the CRCPD annual meeting last week. Program control directors, their National Radiation Protection Conference, their annual protection conference.

So this, the NCRP has been, maybe roughly every

ten years or so now, issuing a report on the dose to the public in the United States. Over, you know, when the report in 1980 was released, it was primarily, a large chunk was background and, you know, 55 percent of your dose was indoor radon. And in '09, it was somewhat surprised to see that medical became a very large chunk of the exposures, specifically CTs.

And so, in the last update, for the medical exposures, in 2016, what they really did was they looked -- since nothing is really going to change with the environment particularly, cosmic is not going to change, ground base isn't going to change per se. The consumer products is such a small sliver; things like that. They went and updated the medical exposures.

And so, once again, NCRP is gearing up to update the medical exposures. So in concert with the CRCPD, the FDA, the NRC, DOE, alphabet soup, radiation agencies, all were preparing -- were doing preliminary work for the NCRPs next update to medical radiation exposure patients in the U.S. to update the ionizing radiation exposure for the population of the U.S.

So one of the recommendations from that report

was that they improve the data collection for future updates. So last November, there was an all interested parties meeting in DC where we -- I'm actually on the committee, by the way. I was there. Where we went over and talked about the previous report and started working on concepts for methodology collection; things like that.

Okay. So there's the motley crew involved. And if I could name people, I'm having a brain fart here. In the back, the tall guy in the back is Don Miller, FDA. Up in front is Adelle Selpn (ph). I cannot say peoples' names for the life of me. In the middle, Melissa Martin, health physicist. Lisa Brudigan (ph), Texas. Jeffrey Elie (ph) is in front of me on the right. A bunch of other people I don't know their names. I can't remember them. About a third these folks were actually authors on the previous NCRP report and are members of the NCRP.

So outcomes from the last meeting, that first meeting was actually setting up some milestones, looking at how we can collect the data, store it, looking for focus groups. To work on -- groups to focus on specific tasks.

So going forward, of course, the sites collecting -- they actually have surveyed states to

see what they can support in this project. And that's why I talk to you about it because we'll be acting in this and going to facilities and collecting data.

Identify the professional societies that can assist and provide us data. Nuclear medicine, ACR; you name it. Appropriate -- the appropriate alphabet soup of usual suspects. And, of course, once we determine what the proper data collection will be format, setting up training for that.

We met again in March. Came out of that. The survey that was just released for the State's new system, yeah, we put together an introductory letter that we'll be sending out to the project partners or groups that we collect data from.

So, so far, the states that have replied to the survey, in green. Grays haven't offered their comments in how they'll be able to support it or not.

And dates, this was -- certain questions about what actual dose evaluations or exposure, I should say. Most states, there was a little language problem I saw in the survey. Was that we used dose when we really meant exposure measurements. Although some people were actually looking at dose

evaluations.

And where almost everybody evaluated dental CTs, hardly anybody evaluated cone-beam CT and nobody is actually doing -- taking when they're doing their medical, materials inspections aren't looking at dose data for nuclear medicine or exposure data, all right, and, of course, when they're actually doing active measurements during the inspections.

Again, radiography, those are folks who have seen what we do on our inspections. We get in there and we actually take our meters and put them in the beam and look at the quality of the -- what's coming out of the beam, kVp, mR rates; things like that. Whether or not the machines are actually consistently operating. Doing, you know, taking multiple shots and is the dose consistent. Is there any drift going on between shots.

And again, cone-beam NCT and CT, themselves, not many states have the capacity to look at that at this time.

All right. And then what other things they're looking for. Suggest that we could, you know, can you look to the physicists reports. Whatever facility records, such as what's the actual number

of measurement or procedures done in a given time. Any other data that could be used.

And so, that's where you'll probably be hearing from us. More as we, since the State of Florida has the authority to ask you a lot of questions that we don't, but we'll still have the authority to go in and say how many times you're operating your hardware. We may be maybe being more thorough in our investigations, but it will probably be some sort of random sample, I assume, once it gets to that point. The lucky winners who get to have us go more throughly into their practices to collect the data for the national exposure.

CHANTEL CORBETT: So are there going to be a set number of questions? Like, are there going to be set questions? In other words, like so if you're going to ask them how many times have you done an exam on this unit, like, because every unit has got a different way to look those things up or the capacity to hold that record.

CLARK ELDREDGE: Right.

CHANTEL CORBETT: So I wasn't sure, are you going to let licensees know that those questions are coming so they can make sure they know how to get that data, if they can get that data? Or is that

just going to be a live, like on the fly, surprise?

CLARK ELDREDGE: No. If you think of the previous NEC surveys, I don't know if you're familiar with the NEC surveys. That's where we look, go through and randomly select, whether it's chiropractic or dental or some particular slice of medical radiation exposure, and work with the national organizations; develop a survey. We contact the people beforehand; let them know we're coming in. This is what we're looking at for this national survey to see what the extent of --

CHANTEL CORBETT: Okay.

CLARK ELDREDGE: -- the procedures are, what doses are being given; things like that. So I would expect for those folks who get selected --

CHANTEL CORBETT: Be something similar to that?

CLARK ELDREDGE: Be something familiar to that. Past years, okay. We will -- back up. In this, I suspect we'll end up using the ICRP standard, if you want to call it that. Exposure to dose coefficients for various procedures. They've got their library of those coefficients converting from exposure measurements to different procedures to actual dose to the patient.

They will also -- previously, they looked at,

to get actual counts of procedures and stuff. There's some insurance reporting databases. There are some other national surveys, industry surveys out there that sell their -- sell data that was used in the previous surveys for the NCRP report.

We work with AAPM as well as ACR, as I said, getting their cooperation and guidance on these things. So this is still very much in the developmental stage because the NCRP, itself, won't be looking to probably start anything in earnest until probably '26. So we've got about a year and a half on the CRCPH committee to get our stuff going. And then probably a year, year and a half to build up the information to give to NCRP for their analysis and review and publishing.

So this is probably 18 months to 24 months away before we go forward with that.

NICHOLAS PLAXTON: I've got a quick thing. So I know when we do CTs, or even like the PET CTs, there's the -- we put a number in our reports of, like, how much radiation the patient got. But is this a matter of, you know, I guess how you extract that data, right? Because being in our electronic report doesn't help you, right? If there was some kind of electronic system that it would transfer to,

and then you can automatically get the data.

REBECCA McFADDEN: You can buy a system that does that.

CHANTEL CORBETT: I was going to say some of the hospitals have it.

REBECCA McFADDEN: Clario, they do a combined. So basically, they're really --

NICHOLAS PLAXTON: Keeps track of people, right?

REBECCA McFADDEN: They track all of their radiation activity. They're pretty expensive, but they're pretty awesome tools.

CHANTEL CORBETT: Yeah, the bigger hospital facilities have those pretty much.

REBECCA McFADDEN: Yeah. Patient trackers.

NICHOLAS PLAXTON: Do you use any of that or no?

CLARK ELDREDGE: Well, that's something we'll be trying, yes, all of the above.

NICHOLAS PLAXTON: Okay.

CHANTEL CORBETT: Because those kind of facilities would be the perfect ones to start with, honestly, because they can give you data --

CLARK ELDREDGE: Right.

REBECCA McFADDEN: They've already given --

NICHOLAS PLAXTON: It's already there. It's much easier.

REBECCA McFADDEN: Mainly when you're pulling the dose, you're looking at DAP or CT, so that's when you're plugging in those numbers, but --

CLARK ELDREDGE: But the flip side, we'll need to do that because, of course, someone represents age and market share, and that part of the thing is, who -- what folks are using what equipment? Which hospitals versus, in this case, if we're talking -- this is primarily diagnostic. You know, diagnostic centers. So, you know, the age of the equipment, what -- so that, that will actually reflect some on what the dose is given, et cetera. And so --

CHANTEL CORBETT: That greatly varies, too. Some of the hospitals have older equipment than outpatient centers.

REBECCA McFADDEN: Yeah. Hospitals are the ones that have the oldest, usually.

CHANTEL CORBETT: The problem is the older x-ray equipment, none of those connect to anything, regardless of what software you have.

REBECCA McFADDEN: Yeah.

CLARK ELDREDGE: So there will be some statistical analysis for trying to, you know, do we

look at scattered across the country versus, you know, how many types of different folks are doing at different levels and different work. Subsampling of those things to try to get a statistically valid sample.

NICHOLAS PLAXTON: I know this is a little bit off because I know you're dealing with the machinery side of it, but like, it's kind of interesting because with our PET CT reports, like I said, we generate -- that number is generated by the scanner from the CT portion and then put in our report. But we're not -- the actual dose is not being transferred into the report. The report doesn't have the radiation.

CHANTEL CORBETT: See, like the software I'm talking about, pulls it straight from the CT into that and you can run a CT report just on the CTs and you can run a report on IR, you can run a report on the cath labs.

NICHOLAS PLAXTON: That's what I'm saying. With nuclear medicine, when we inject patients, all that radiation is not being tracked.

CHANTEL CORBETT: Correct.

NICHOLAS PLAXTON: So even in the PET CT, you're just getting half the dose, really, because

the other half is the FDG radioactivity. So it's actually something that we should probably address, though. Like, we're putting in, like, half the results of the -- which is kind of misleading.

CLARK ELDREDGE: Which may end up being something like, what's the total activity you used.

NICHOLAS PLAXTON: And we know exactly because we measure how much -- we measure the syringe first --

CHANTEL CORBETT: The residual.

NICHOLAS PLAXTON: -- and then the residual afterwards, so we know the rest went in the patient and we put that in our report. So the --

CLARK ELDREDGE: Right.

NICHOLAS PLAXTON: -- we know the mCi that are given to the patient. But we can easily convert that. But we should be converting it and writing it in with the CT.

CHANTEL CORBETT: Biologicals are different on every one of them. That whole worm hole.

NICHOLAS PLAXTON: Yeah. So I mean, we would have the numbers, but like right now, you would have to calculate it out. It should be automated, actually, to put it in there. I mean, I notice, obviously, that's why it's being tracked in nuclear

medicine, because we're injecting the radioactivity instead of a device giving it to them.

CHANTEL CORBETT: It's not machine produced.

NICHOLAS PLAXTON: For the patient, they should actually have it all tracked in one of these systems.

RANDY SCHENKMAN: Any other questions? Are you all done?

Okay. Now we've got James up.

JAMES FUTCH: All right. Let's start with this. So technology section update. Let's start with the completion of a two-plus-year journey, which involved the Council, I think at least twice, on the rule making for my part of the regulations, which is 64E-3; most of the Rad controls in 64E-5. And this was Section .009 of the Florida Administrative Code, was the standards for CE courses.

So this was where we made a few changes to literally two pages of the rules so that we would be in compliance with the national standards consensus that AART has set up with the other state licensing agencies and what they call RCEEMS. The societies that approve CEs for the radiologic professions, so ACR, ASRT and all the rest.

There's this national consensus standards and if we want to still be part of that, we still want to have our CE be accepted by the other groups for Florida Rad Techs, and if we want national CE to be accepted in Florida for use in renewing Rad Tech licenses. So basically, you don't have to have separate CE for all the organizations, this had to be adopted.

So we started this in the spring of 2021, I think, and that's just how long it takes to get through the regulatory process with two pages' worth of not very many changes. So let me show you what we have as a result of that.

And what we have is this little piece of paper here. And so this is the -- as big as I can make it. I think actually, maybe I can make it bigger. It might go off the screen. It might do that. Okay.

So this is the section of the standards, talks about a lot of things. Anything you see in yellow highlight was changed.

So the first thing you notice is that, yes, after probably ten or twelve years, we finally figured out how to spell the word emission correctly (laughter). And by the way, it does not have two

M's in it. And nobody caught that, ever, all along the food chain.

So this is the section of the rule where it talks about which kinds of topic areas will be accepted for what we call technical credit as opposed to personal development.

WILLIAM ATHERTON: So who finally caught it?

NICHOLAS PLAXTON: Spellcheck.

WILLIAM ATHERTON: Spellcheck.

JAMES FUTCH: No. Kelly Nesmith, who was a CE coordinator for years and years ago -- probably caused it to start with -- was reviewing this, I don't know how many times, and finally said, I don't think that's right. Turns out she was correct. Twice.

CHANTEL CORBETT: Your brain corrects a lot of things.

JAMES FUTCH: Yeah, there you go. So a little further on, we had a section where all the yellow stuff is added, unless you see it struck through. So we added a section on -- and you all have seen this at least twice in previous meetings and given your support of it, so I kind of want to say we finally did it.

And so this was to give credit for the hands-on

component for CE credit, which in some situations, we weren't doing before with some types of CE.

This was never in here. Oh, look at that. There's another misspelling. Oh, my god.

REBECCA McFADDEN: Attempts.

JAMES FUTCH: Ay, yi, yi. Okay. I don't care. Whoever comes after me and fills my position after I retire can fix the word attempts. Let's just say maybe this is not -- I pulled this off of the rules, say. I don't think this was in -- I will say I don't think this was in our draft which was submitted. I think the Florida Department of State made that mistake.

Anyway, the important part here is, we never had a limitation, we never thought it was necessary. AART and the other RCEEMS has a limitation on the number of times you can attempt a CE course and attempt to pass it with 75 percent, after which you aren't going to get credit for. We kind of relied upon, I think, the marketplace and the intelligence for people to figure out you can't take a CE course, like, you know, thirty times until you finally pass it. But now there's a reason why you really can't.

This was in here before. This sentence was removed. By the removal of this sentence, you now

can actually count the time it takes to take the post test questions as part of the learning activity.

Now, one caveat to this, which the lawyers pointed out, which I really loved, they said, um, do you mean the actual time for the individual technologists to take their particular post test or do you mean there's just a certain amount of time we're going to get you in approving this activity for, say, three credit hours? And we said, this is why they're lawyers. No, we actually mean just a certain amount of proof time. If Becky takes it and it takes her ten hours, we don't give her ten hours of credit post test.

REBECCA McFADDEN: I'm a slow reader.

JAMES FUTCH: This one right here is huge. In the infinite -- I don't know how you say this. In the infinite specialization segmentation of what is the smallest amount of CE that anyone will actually take, and it's a fifteen-minute segment. We used to approve whole books for, like, however many hours it took to review the whole book. And we don't do that anymore. So now books are going to now be approved on a chapter basis. You can take chapter three out of the book and not chapters one and two, or however

many else there are, and that's all you have to do.

Each one of those will have its own CE course number assigned to it. So if it has fifteen chapters, it's going to have fifteen CE numbers. You can see where this kind of turns into a little bit of slightly more work on our part.

CHANTEL CORBETT: On your end.

JAMES FUTCH: Yeah. But this is the way we must do it now in order to conform to the national standards consensus.

CHANTEL CORBETT: So to make sure I understand that right. Like, so you buy a forty CE book, you know, with forty chapters.

JAMES FUTCH: Right.

CHANTEL CORBETT: And you only need five CEs this cycle, so you can just take chapters one through five; save the rest for later?

JAMES FUTCH: That's right. You still have to take the whole CE activity, but it will be forty separate CE course numbers for that book. Yes.

CHANTEL CORBETT: Oh.

ADAM WEAVER: Each chapter.

CHANTEL CORBETT: You still have to complete the whole thing, so it doesn't really matter.

JAMES FUTCH: Each one of those is an activity.

So if you only want to do chapter five, you only have to do chapter five.

WILLIAM ATHERTON: But each chapter has to be approved.

CHANTEL CORBETT: I thought you just said you had to complete the whole thing.

JAMES FUTCH: For us. When we say you have to complete the whole thing, we mean the whole CE activity for which the course number has been assigned.

CHANTEL CORBETT: Okay. So each chapter -- that's what I was saying. If you only wanted five CE's out of the forty of that cycle, that will be five and be done.

JAMES FUTCH: This is correct.

ALBERT TINEO: You can use the rest of it for the following.

CHANTEL CORBETT: Right. Okay. Exactly. That's what I'm saying.

ALBERT TINEO: That's awesome.

CHANTEL CORBETT: Yeah, it actually works out well.

KATHLEEN DROTAR: Yeah, there's some CE providers that, here's the book and --

CHANTEL CORBETT: Actually, like forty a year,

but that's because it's a book.

JAMES FUTCH: Yeah, this one, we implemented it, it's a three-year cycle. Other groups are implementing it, so there's this -- staff tells me there's a little bit of -- it was approved up here and they don't want to submit it down here because we'll make them do it chapter by chapter. This group up here is still doing the whole book. So they're going to get approved up there. Then we still have to take it because we accept the RCEEMS.

In a few years, once everybody has got all of their CE approval cycles through, it will all be the same.

And I think this is the last part of, almost the last part. So on the course certificate, you actually have to print Category A. If it's approved by AART, of course, it's Category A credit. We approve -- we don't do A plus, which is for radiologist assistants. And if it's a hands-on activity, you actually have to list the course learning objectives on the certificate. Apparently, this is useful when it goes to other states, the other states or RCEEMS understands what they're given credit for.

And then the last one, go ahead, I challenge --

nobody -- do we have any lawyers in the group? Do we? Come on. You can admit it.

(Laughter)

JAMES FUTCH: No? All right. So everyone read this and tell me what you think that means.

REBECCA McFADDEN: Oh, my gosh.

CHARLES HAMILTON: You can get an amendment five years from now.

JAMES FUTCH: You don't count. You're a bureaucrat.

WILLIAM ATHERTON: You have up to five years to do so.

ALBERT TINEO: To make another change or amendment.

JAMES FUTCH: Yeah. So this is interpreted as a sunset clause by the bureaucracy. And this is something that has to be added, which I am told, means that five years from now, someone has to do some kind of review on this and --

CHANTEL CORBETT: Or it goes away.

ADAM WEAVER: See if it's still valid.

JAMES FUTCH: See, you're too logical. You've been too close to the physics and to the radiation and to the chemistry and all the rest of this.

CHANTEL CORBETT: I know. I should know better

by now.

JAMES FUTCH: You're like, what kind of review? What criteria does it have? And the answer is, there is no answer at this point. So we'll see in five years.

ADAM WEAVER: Don't they put that in a lot of them?

JAMES FUTCH: Usually it's in a statute by the legislature. It's a lot clearer then because it's the law and it says, unless we as the legislature act to continue this law, it will automatically be repealed as a law. That's pretty straightforward. This is -- this is a different kind of a thing. Anyway, it's in there.

All right. Let's see. Let's close that tab and let's go back here and the next page is -- all right.

So we, the Florida Department of Health, Bureau of Radiation Control, have been recognized for three years as a CE approver by ARRT and the National Consensus Group, which is ASRT and student medicine, ultrasound, all those other groups, because we, we have met the recognition criteria. This is basically accreditation for us. Fill out a whole bunch of paperwork, answer a whole bunch of

questions, submit a whole bunch of policies, explain how you do this, so on and so forth. It goes to ARRT's board of radiologists and other folks and they approved it in July three years ago.

So we were up for re-recognition this year, so we had to be reaccredited is the way I explain it. And we just submitted that application. It will be reviewed by ARRT's board again in July and hopefully, we'll continue to be accepted and recognized as a CE approver so that all the stuff that we do to approve CE's in Florida, you want to use it with ARRT, AART.

WILLIAM ATHERTON: Just curious, who is the one that approves the CE? Do you have people, an algorithm, people that sit there --

JAMES FUTCH: Yeah. No, there's a consensus.

So the rules that you saw, the ones that we just changed, that's a small part of it. That's kind of like the superstructure of a lot of it. There's a booklet full of little, here's how you handle this and here's how you handle that. And like, for example, one of the contention points for the upcoming meeting, they meet once a year, usually in Minnesota at the ARRT offices, is how much credit do you give a picture? How much credit do you give

a chart or a graph? Okay?

So if you wanted to figure out how much time it takes on something that's a video, okay. You've got minutes. You know how long it takes to watch the video.

If you want to figure out how long it takes to read text, I forget what it is. 1.85 minutes per X amount of, you know, words per paragraph or something like this.

But so we were running into, okay. Here's, here's a course. It's all text. There's no pictures. Here's a course that's half text, it's half graph, charts, pictures. Maybe there's labels on the picture, maybe there's just arrows pointing to things they want you to see with captions somewhere else.

Really, it takes the same amount of time to absorb it. If you read it all, it actually will probably take more if you tried to read it all in text. A picture's worth a thousand words, right? Not in ARRT's world. Apparently, it's an indeterminate amount of time. So we're trying to nail down some sort of mechanism by which everyone can agree on how you value these five charts that, you know, a technique chart, if anybody is still

doing that kind of stuff. Or here's several pictures of radiographs of, showing some aspect of poor positioning or, you know, poor exposure, something like this.

So it would be interesting to see what comes out of that. But that's still to come. But anyway, the application has been submitted again, and this time, if it's approved, we'll be good for five years, which is a good timeframe.

ADAM WEAVER: Aggressively getting longer each time you reapply.

JAMES FUTCH: I'm thinking, yeah. Five years ought to do it. That would be perfect. Clark will still be here.

All right. So that's, that's that part of it.

Personnel changes, I think we mentioned this already. So my staff is two -- two staff are dedicated to the Rad side of the world and the other four are wholly in IT programmers, help desk people or kind of a mixture of those folks and administrative assistant, purchasing, things like that.

And our CE coordinator position, Melissa Burns, those of you who know her, she's been in the job for, I guess a year or so. She has left to go up to

our division office to take another job, essentially doing project management. So we are -- we have one vacancy in that position. Kelly is again, for the fourth time in four years, covering, covering for -- as the CE coordinator. So if you know anybody who wants to come to work for the State for not very much pay, but lots of good, warm feelings -- he did it twice.

CHANTEL CORBETT: Bakes good.

ADAM WEAVER: Double dipping.

JAMES FUTCH: Bakes cookies, we hope. Hopefully you have another breadwinner in the family who makes a lot more than you do.

CHANTEL CORBETT: You want to retire.

JAMES FUTCH: You like the Tallahassee life. It's very much not like Miami, I'm told. People that come to Miami and say, I hate it up here. There's too many trees and too many wide open spaces.

CHANTEL CORBETT: Woods are scared.

JAMES FUTCH: Woods are scared. Woods are full of ticks right now.

ADAM WEAVER: There's a lot of bears up there.

JAMES FUTCH: So anyway, some personnel changes. That's it for us on that.

And then the last thing I wanted to show you is some, some various stats and insights into discipline complaint cases and things of that nature. Let me jump over to here and start out with -- this is -- let's start out with this one.

So this is current cases. Actually, let me show you this first so maybe some of this makes a little more sense.

So these are the discipline standards for this profession. Every profession has them. Most of them are fairly common across all professions. And these are, these are ours, A through, I think it's M or N now. Let's see. All the way down to, yep, N right there. Okay.

So being terminated from an impaired practitioner program. So you're in -- you got some sort of impairment program, drug related, and there's a state program that handles that. And you've been terminated from it because you're not complying. Being found guilty of any offense prohibited under this long laundry list, a bunch of criminal offenses, failing to report within thirty days after you had a certificate acted against, mostly by AART, but also another state.

Testing positive on any drug -- for

preemployment, employer required drug screen when you don't have a lawful prescription and legitimate medical reason for taking the drug. This one makes it easy to go after folks. You don't have to prove impairment on this one. The lawyers usually love this particular. You just show me the test result and we can go after, probably require an exam to make sure you're not impaired.

Employing, this is for people who use those uncertified operators. We used to call them NCO, non-certified operator. MQA calls them ULA. They have a big marketing program about that. This is not the person who is the unlicensed activity. This is the person who's employing the person who is taking x-rays without being licensed, et cetera, et cetera. It's kind of weird because it's in the Rad Tech statute, but it gives legal authority to go after the employer.

This is a catch all. Violating any part of this rule, any other rule of the department, et cetera, et cetera, et cetera. Failing to report somebody else you know is in violation. Being unable to practice, impairment or use of whatever drugs, mental, physical condition. Unprofessional conduct, paragraph F, which is also huge and

includes lots of different kinds of conduct, including tying into ARRT's code of conduct.

Making, filing reports, false report or record in your capacity as a certificate holder. So you go change the x-ray in some way, shape or form or you take an x-ray of yourself, or your own hand and then you modify the records so the boss doesn't know you've been x-raying yourself. That one happened last time around.

Being convicted or found guilty. Then we're back up to the normal stuff. You, yourself, being convicted of a crime against a person or a crime that involves the practice in some way, shape or form.

This is a big one. Having a voluntary or mandatory certificate to practice acted against by another organization, like a national organization like ARRT, et cetera, et cetera.

This is another one, good one, procuring or attempting to procure, basically, through various means, a license from the department. So you lied on your application or something of that nature.

So that's the bases for all the complaints that anybody ever makes against the technologist. It has to find a nexus in one of these statutes or you

can't act against them.

So we look at current case details. Here we go. And this is a spreadsheet. Very busy. Let me show you how many rows there are. So approximately 64 open cases at the moment. Each one of these is a case against a person. I've hidden the peoples' names and most of their CRT numbers and just left the case dates so you can see what year they were opened.

And these are the kind of things that the lawyers keep track of. Kelly keeps track of. They have all sorts of coding systems. Basically, this technologist is a CRT. It's currently under review. It was last acted on, you know, April 21st. It was opened some time in fiscal year 2023. And it really doesn't tell you anything at all about what the substance of the problem is, but there's 64 of them at the moment.

The case counts, well, let me show you this one. Here's a historical. Another application. This one, instead of having 64 rows, this one has 1,000 something or other. And this one goes back to 2006.

So these are all the cases that is we've had and these are sorted by incident type. So you have

various and sundry things that can happen. You have various kinds of conviction from other causes, how did it come to us? This is something, another agency does background checks on folks and we find people with convictions that weren't reported that way. Certificate not posted during inspection. That seems rather mundane compared to the rest of these.

A whole section for discipline by ARRT and another state. Again, this is from 2006, 1,000 records, roughly.

Let me show you how many of these there are. These are various uncertified operators. Various ways they come to us. From inspections. Somebody maybe gave an anonymous complaint. Maybe it's a disgruntled former spouse, who knows, former employee.

And then when you get down to the bottom of this, a lot of these uncertified operators not in compliance with the final order. So you did something, like you worked without a certificate. There was a discipline case. You were supposed to do a fine. You were supposed to do CE. Of course, you're supposed to stop doing what you're doing. And you didn't comply with some aspect of that.

Usually, you didn't pay the fine or you didn't do the medical errors course -- not medical errors. The ethics course so you don't mess up again.

So you come back through the lawyers again and we're going to go after you one more time for not complying. This time we're probably going to suspend your license until you wake up and do what you're supposed to do.

Let's see. Sometimes in old data, you have a situation where you create a case and there's no nexus for it, but you have -- you don't have any way to close it until it's finally acted upon through the whole system. These didn't have any incident recorded on them. But the biggest section down here is UPC, unprofessional conduct. Unprofessional conduct can include, as you'll see in a second, various kind of subcategories, if I ever get there. There it goes.

So these are unprofessional conduct involving misadministration of radiation in some way, shape or form. These are ones involving impairment. I think there's some impairment that's specifically related to prescriptions.

This is unprofessional conduct involving illegal activity. This is what we do when you have

a license that's still active. Maybe it's expired. It's not null and void. But you decide to continue working on a, on an expired license. So we come in and be categorized in this way, shape and form.

So that's kind of a 30,000 foot view of all the cases from 2006 forward.

Let me close this one and close this one.

CHANTEL CORBETT: So when you say disciplined like the ARRT, does that include CE violations or exclude CE violations?

JAMES FUTCH: It can include CE violations.

CHANTEL CORBETT: Okay.

JAMES FUTCH: ARRT and the other states, ARRT is pretty open about publishing when something has happened to a person and put them on the enforcement list. They'll send us the information. Their person, their discipline coordinator, enforcement coordinator talks to Kelly fairly regularly. They have a pretty good relationship; kind of keep each other aware of what's going on.

But they, they don't release records to us willingly. They'll just say, hey, this thing happened. So then we'll have to go to the lawyers and the investigators. We'll have to get a subpoena issued. We'll have to send them a subpoena and then

they'll give us the records. So they want legal cover of the subpoena in order to release the records to Florida so we can act upon them.

CHANTEL CORBETT: I wasn't sure on CEs since it's not required to have one of those to keep your license.

JAMES FUTCH: If you read the statute, it says that we will consider, theoretically, we're supposed to do the same thing they do. If they suspend the person, we should suspend the person. So we'll give very strong weight to what they did, but we'll also follow our -- I didn't show you one of those discipline standards. There's a recommended minimum, maximum penalty. First offense, second offense; that kind of stuff.

NCE is one that's, you know, kind of down here on the severity list.

This is, this is the report -- one of the first things I showed you was the open cases that we currently have. I think it was 63 or 64, something like that. And this is a weekly report that we do. In this case, it's covering a longer period of time. I asked Kelly to go from the beginning of the fiscal year to present.

So at the beginning of the fiscal year, we had

68 cases open. Over the past couple quarters, we have opened 44 new cases, we've closed 48. I don't know if that math works out. If it doesn't, it's only off a little bit. So the current case total is around 64. That doesn't represent -- they can open multiple cases against a given Rad Tech, so you can have, like, two cases against the tech. So the number of cases is always greater than the number of techs.

And here's how those incidents break down for this time. The current 64 open cases. This is how they break down in terms of how many for each of the various kinds of -- unprofessional conduct, uncertified operator and all the other ones that I just showed you.

And then the last thing I want to show you is, is this one. Is this one. Incident stats over from 2006, basically, from 2006 forward. This is how the stats break down. So it's got the incident type on the left. I've colored the ones that are basically the same thing, just different categories. You can see the ones that were involved and then the percentage, I guess 1013, that they've represented individually. I've added all the colors together. All the convictions are roughly 2.2 percent.

Uncertified operators, 31 percent. All these added together, these percentages. And then unprofessional conduct is 44.

So you can see between just these two categories, we've got 85 percent. So those are the two big categories. People working either on expired licenses, which I think is more common than people not working on any kind of license whatsoever. And all the various kinds of unprofessional conduct, which could be drug related, it could be, really anything else in the practice that you didn't do that you were supposed to, you did do that you weren't supposed to.

And that's it for, for Rad Tech update. Any questions?

RANDY SCHENKMAN: Okay. Well, I guess we're going to move on.

CLARK ELDREDGE: I'd like to go back.

RANDY SCHENKMAN: You have a question?

CLARK ELDREDGE: I've got a question. I've got a couple points I wanted to make.

So the one investigation that recently involved that, with MQA as well was we had a complaint against a physician who was instructing his non-Rad Tech employees to take x-rays. So his opinion was,

I'm a doctor. I can tell you what to do in my practice and I'm directing you to do this. You shall do this. And it was -- his employees complained to us. His Rad Tech had quit over certain similar activities. He was requiring the Rad Tech to train the front desk people and stuff like that to do the x-rays.

In addition, he was not maintaining his equipment. He was not getting it calibrated when the system kept popping up and saying it's out of calibration, get it calibrated now every time it booted up. And the coulometer, the light on the coulometer would not stay on. You had to hold the button on the coulometer, the light on the coulometer, it would stay on ten, fifteen seconds type thing. So you could position it, it would go out. You would have to hold on with one thumb and have to move it.

REBECCA McFADDEN: You mean they didn't have duct tape holding it down?

CLARK ELDREDGE: At least they had to hold it in position. That was good. But getting it lined up was the problem.

The other thing, we're currently involved with rule development for a security scanner. This was

part of statutes we passed a couple, passed a couple years ago. And one part of our statute says, you know, developing -- talks about explaining the justification of why you think you should be x-raying people to look for things hidden in and on them.

And that's something that when IASCORS, the Inner Agency Steering Commission on Radiation Standards came out with their guidance in 2008, they basically said, we're not going to touch that. Here's how you do the -- here's what you should do to set up a program, but we're not going to tell you how to justify, why it's a good or bad idea to x-ray people to look for things in them.

And then the ANSI HPS standard N43.17, 2009, which we've adopted rules for security scanners for inmates, it also says this is how you operate the equipment, but does not go into any justification of why -- what's the cost benefit analysis for doing it; that type of thing. Because, of course, all the rest of the human exposures in the medical field and where it's taking the assumption that the medical professional has determined that there was medically valid, the beneficial information outweighs the risk from the exposure.

So that was that group. And that was my two added things that I missed from the other two updates.

If anybody has any inspiration on --

(Laughter)

CLARK ELDREDGE: -- risk weighting, we've got some really rough stuff at this point. But when I went and contacted the EPPI group, and then the health, some public health graduate school and their toxicology folks and their EPPI folks and was referred to another professor at another college who does all hazards evaluations, they said, oh, that's an interesting question. Have fun.

(Laughter)

CLARK ELDREDGE: Yes, you can let me know if you have any inspiration or know somebody who might have some, because while we all are, all the physics folks in here can look and say, okay, I can take, you know, UNSCEARs or IAEAs or others risk of cancer from what dose using LNT, that's one side of the equation. The other side of the standard is what do we expect for them to say. Here's how I'm balancing the risk on my side to compare about the cancer risk in their, you know, versus how many people I plan to expose at what dose. That's it. We've got one

side, the other one is the --

NICHOLAS PLAXTON: You think it would be, sounds like it would be easy because you could -- I mean, the idea is let's stop drugs and weapons coming in to the prison, so you can imagine, I'm sure they have stats on how many people get --

CLARK ELDREDGE: Right. They just have to provide that and show data.

RANDY SCHENKMAN: For the safety.

CLARK ELDREDGE: The prisons isn't the hard one.

NICHOLAS PLAXTON: Okay.

CLARK ELDREDGE: Or the prisoners going in to the people. They're asking, of course, we want to x-ray anybody walking across the --

NICHOLAS PLAXTON: Threshold.

CLARK ELDREDGE: -- threshold, whether they're visitors or employees or things like that and that's where it gets a little different because they're not personally, usually personally at risk, because the prison just doesn't have one security line. I mean, because you've got the inner sanctum, so to speak, the center part, where everybody is in their cells and whatnot; then you've got a couple buffer areas involved.

RANDY SCHENKMAN: Yeah, but you could say it's for the safety of everyone in the building.

NICHOLAS PLAXTON: I mean --

RANDY SCHENKMAN: That's what it is. That's why you're doing it.

CLARK ELDREDGE: Well, you're also saying we're going to provide you -- we're going to increase your risk to offset the other risk for these other people. And so, are you actually receiving any particular dose? The statute actually links it to the individual's risk, not just the group risk. The statute actually says --

CHANTEL CORBETT: Even in the hospital prison units, you have to go through the x-ray units.

CLARK ELDREDGE: Excuse me?

CHANTEL CORBETT: They have metal detectors and x-ray units that they're wanting to put in some of the prison units and some of the hospitals.

CLARK ELDREDGE: Okay. Yeah. That's --

CHANTEL CORBETT: Yeah, because they're offsite from the prison, itself.

CLARK ELDREDGE: Yeah. And how much is that needed there versus when they come back, when they come back to the prison --

CHANTEL CORBETT: Yeah.

REBECCA McFADDEN: -- with cancer.

CLARK ELDREDGE: Yeah. There's plenty of data how many people behind bars actually get hurt by all these things. That's pretty straightforward.

NICHOLAS PLAXTON: Sure.

CLARK ELDREDGE: But then the question is the risk for the ancillary folks involved with it.

REBECCA McFADDEN: Right.

CLARK ELDREDGE: And you know, there is, there is something to be said about -- for the benefit of society as a whole. But the statute actually says everybody has to have their individual benefit as well, not just the societal benefit.

NICHOLAS PLAXTON: You can imagine there's got to be some, like, inmate attacks on some of the security in those places. But they also, I mean, sometimes the security people are involved in trafficking --

CLARK ELDREDGE: Right.

NICHOLAS PLAXTON: -- of drugs and weapons, which that's probably why they don't want it to be involved.

RANDY SCHENKMAN: There's visitors bringing drugs and weapons in.

NICHOLAS PLAXTON: Exactly.

CLARK ELDREDGE: Right. Visitors, they're still, if they're interacting with the guards, with the inmates together, is still another layer, the inmate has to go out of the building and back in. You can scan the inmate when they cross their threshold rather than the visitors coming in.

CHANTEL CORBETT: Yeah, but that's like no visitors trying to bring prisoners something.

RANDY SCHENKMAN: Have any of the visitors ever attacked any of the security guards?

CHANTEL CORBETT: Oh, I can guarantee that's happened.

CLARK ELDREDGE: That's what they need to demonstrate.

CHANTEL CORBETT: State prison? Yeah.

CLARK ELDREDGE: And were they hurt by their activities? Of course they were. Yeah, demonstrate the data. That's what we're working on. How to best demonstrate the data. So you've got data and not just want to do it. You actually thought it through. Some states have adopted standards and say you have to demonstrate why none of the other security methods will work for what you want to achieve, which is a slightly different standard.

But that would probably also be part of the

overall structure, is first why must it be this method? Show us why. And then second, you know, give us the data and what the risks are, what's actually happening, to show that there is something you're actually trying to prevent. And it's going to give a safety benefit, life safety benefit to everybody.

NICHOLAS PLAXTON: A cavity search versus scan. Cavity, might as well scan.

CLARK ELDREDGE: That's the other consideration of efficiency and personal --

WILLIAM ATHERTON: It seems like if that was a choice offered, that would eliminate a lot of the ethical things, if we give them a choice.

CLARK ELDREDGE: And the fact if you're -- if there's -- with the x-ray, the difference between that and a lot of other technologies, it's able to look into the body cavities. And so, if it's, you know, are your controls such that somebody can remove something from a body cavity, hand it to the person next to them, and have them insert it into a body cavity so they can go across the security line. What's the controls for that? How obvious, you know, versus, I'm going to take something off my body, out of my neck, hand it to this person.

They're going to stick it in their clothing and stick it through. You don't need an x-ray for that. You've got plenty of other technologies that can do a search of the -- between the skin and the clothing that doesn't require transmission of x-rays and it dose internal organs.

RANDY SCHENKMAN: They've got to get the info.

CLARK ELDREDGE: Yep.

RANDY SCHENKMAN: Okay. Brenda? Are you ready?

BRENDA ANDREWS: I am.

RANDY SCHENKMAN: Okay.

BRENDA ANDREWS: Since we've already started working with the travel documents, did everybody turn theirs in to me? I got some of them before we went to lunch. If you have not turned yours in to me and you have any questions, ask me your questions now so we can go ahead and get those picked up.

Some of them were completed because generally, you have ground transportation and there aren't any receipts. So I went ahead and this time, did a reimbursement so that it would speed up the process of getting your refund checks or reimbursement checks. The others were the signature pages where I am waiting for receipts and those types of things

and then I'll fill the reimbursement out once I get everything in.

So if anybody has anything to turn in to me, signed, go ahead and do that now. And that way, I can get that process going when I get back.

The other part of my update was the vacancies for the Council. We have more vacancies right now than we've had in quite a while. I think the last time we had about six, which was quite a few at one time. We now have seven. And that would be the basic x-ray machine operator. Mark Wroblewski was in that position before. Now he works for the Department of Health, so he would have a conflict of being on the Council.

So we have, in all of these, done a lot of due diligence to get the societies to send in nominees. And in some cases, we have been successful. And in other cases, we have not. I think I started with the one that Walser was in back in '21 and I still do not have a nominee for that position.

If you have any ideas or suggestions, I'm open.

CHANTEL CORBETT: Which position was that?

BRENDA ANDREWS: That was the lay position. That lone title.

I also have in your packets, an updated list of

all the Council members and showing all the vacancies, so you'll be able to see whose positions are vacant.

Now, four of the positions, we have an appointment package that's going through right now and it's in another stage. Since we talked this morning, it has moved. It is now with the chief of staff.

So that was the certified health physicist, which is Adam Weaver. We put a package through to reappoint him. The environmental radiation, environmental radiation matters expert, Joe Danek, we put his name in again to -- for the appointment. We have the Board Certified Radiologic Physicist, which is the one Mark Setton is in, and he has reapplied for that position as well.

And then the last one we have a nominee for is the Board Certified Podiatrist, and that person is Dr. Luis Rodriguez with Barry University. So we're hoping to get that package completed within the next week or two, if we keep our fingers crossed, and get these people on board.

The other ones are, like I said, the lay person or the person who's never been certified as a radiologic technologist or been a member of any

closely related profession. Matthew Walser was in that one. And then we have the basic x-ray machine operator or a licensed practitioner who employs same. That's the one I just mentioned that Mark Wroblewski was in. And then after that, let's see.

JAMES FUTCH: Radiologist assistant.

BRENDA ANDREWS: Radiologist assistant. Do I have that in here?

CHANTEL CORBETT: So there should be two, like, lay persons.

JAMES FUTCH: Yeah. The other one --

BRENDA ANDREWS: Yes.

CHANTEL CORBETT: Okay.

JAMES FUTCH: The other one we have a physician, Dr. Armand Cognetta from Tallahassee is the dermatologist that is doing the radiation therapy for, for skin cancer.

CHANTEL CORBETT: Skin, yeah.

JAMES FUTCH: And he has not been at the meetings for a while. We're not really sure if he's -- we don't really know if he wants to continue to serve, but he hasn't been at a few of the meetings. So there's a potential for another one that's currently filled. So we've tried some different things. On the basic operator, that's

always a tough one. We most recently tried the chiropractic associations with Dontavia's boss' help because she licenses the chiropractors, because so many of the chiropractors use the basics or were basics back when you couldn't take the chiropractic exam any time you wanted to. And it can be a physician who employs one, so, you know, it could really be either one. No help so far.

So if you know of anybody who's a doc who employs a basic or basics, themselves, you know, let us know.

The certified radiologist assistant, George knew of a person and I can't remember what happened to that one. Did they not respond?

BRENDA ANDREWS: We got a response from them. They did not support or endorse the person that George gave us.

JAMES FUTCH: Was that FRS?

BRENDA ANDREWS: FRS and they nominated someone else. But the person they nominated did not meet the qualifications.

JAMES FUTCH: Was it a radiologist assistant?

BRENDA ANDREWS: Technologist.

JAMES FUTCH: They turned out to be a tech and not a radiologic assistant.

BRENDA ANDREWS: Not an assistant. They recognized, when they got the letter, that they did not qualify for it. So we reached back out to them for them to give us another nominee or endorse the person. We put the language in there up to them but they did not take the bite -- the bait. Whatever you call it.

JAMES FUTCH: I don't think they realize how few licensed radiologic assistants --

CHANTEL CORBETT: Can we give them the Excel list?

BRENDA ANDREWS: James thought ahead and he gave me the list and that second time around, we gave them the list. So I have not heard. And it's been about three weeks now since I gave them that, that information, and asked them to suggest someone else. So we're still waiting.

JAMES FUTCH: Thirty-five active licenses. Something like that. Not 350 -- 35.

BRENDA ANDREWS: Yeah. So we're having, I'm not sure, it almost seems likes it's falling in line with everything else in this day and time, where people don't respond. But we're going to keep trying and pushing to get either nominees or suggestions or, you know, of someone qualified for

those positions so we can get them filled.

At least those four, we should -- we will have them filled, providing everything goes through and everything is approved, long before our next meeting. And when that happens, I'll send out updated lists.

JAMES FUTCH: On the position, two positions that Brenda calls the lay positions, the ones that can't have been a Rad Tech or a closely related profession, Matt Walser was a physician assistant and that's why he went to the physician assistant group. We also tried the nurse practitioners this time. And I think their thinking is Matt -- the lawyers look at the closely related profession. What's a closely related profession. Well apparently, it's not a dermatologist who does radiation therapy or a physician assistant who may do fluoro or something else for a radiologist who's, who's, you know, in the practice.

So I think it's safe to say if you know of any PA or a nurse practitioner in your facilities, and either your facility would like to nominate them or even better, if the society upon which the facility or yourself or part would like to nominate them, please let us know.

BRENDA ANDREWS: Yes. You can e-mail me. Copy James, either way, so we can go ahead, because that person has to complete the online DOH questionnaire and submit it. A resume'. And if you find someone that's interested, you can ask them even at that time, to go ahead and give you, to give you their resume' and get that to us and we can go ahead and start the process to get them on board.

In the questionnaire, we do look at their references and we do call the references. James does all of that. And he does have conversations with that person. So it's a lot of people. It's a lot of positions to be vacant right now.

CHANTEL CORBETT: How many basic operators are active?

JAMES FUTCH: Probably between 2 and 3,000. Those numbers have been decreasing as the --

CHANTEL CORBETT: That's still more than what I thought.

JAMES FUTCH: It used to be, like, 4,000 or something like that.

WILLIAM ATHERTON: Which society did you reach out to? FCA?

JAMES FUTCH: For?

WILLIAM ATHERTON: Chiropractic, to look at

those.

JAMES FUTCH: We kind of left it up to Dontavia.

WILLIAM ATHERTON: I was going to say there's multiple.

JAMES FUTCH: Feel free. Feel free because I mean, it hasn't worked. So -- if anybody has any other ideas, you could put anybody in the position. But the problem with that is, most people don't care about the Advisory Council on Radiation Protection, so they have to have some kind of connection to actually want to do it.

BRENDA ANDREWS: So that was, that was one of the main things. And then also in your package is, during this time, we usually vote for the next Council meeting for the fall. And so I put calendars in there so we can make those discussions with September through December as the months we're looking at.

WILLIAM ATHERTON: November 23rd. That's Thanksgiving. I was just kidding.

JAMES FUTCH: So the usual timeframe is the second or third week of September, somewhere along in there. This one is an interesting one because September is ending on a Saturday and October is

starting on a Sunday. Usually we have a little bit of crossover into the last week of September; has something to do with the first week of October. I only say that because that's the week that I'm at a timeshare. I need to be somewhere else.

CHANTEL CORBETT: What week did you not want to do?

JAMES FUTCH: That's a good question. Which week is the 39th? What week of the year, according to timeshare world. I have to go figure that out.

RANDY SCHENKMAN: You do or don't want to do it at the end?

JAMES FUTCH: I would say the week of the 18th would be okay.

BRENDA ANDREWS: September?

JAMES FUTCH: Yeah. We can do it.

CHANTEL CORBETT: That would be the last week of September would be the 39th week.

JAMES FUTCH: So that would be the one to avoid for sure.

WILLIAM ATHERTON: Yeah, September 26.

CHANTEL CORBETT: You want Tuesday or Thursday?

RANDY SCHENKMAN: Tuesday, the 19th, would probably be better for me.

JAMES FUTCH: It's up to you guys.

CHANTEL CORBETT: I was going to say the 19th or 21st.

RANDY SCHENKMAN: The 19th would probably be better for me. I'm not going to be here the 21st.

REBECCA McFADDEN: September 19th.

RANDY SCHENKMAN: Is September 19th good for everybody?

JENNIFER PETERSON: Yes.

KATHLEEN DROTAR: Yes.

RANDY SCHENKMAN: Okay. So why don't we go for September 19th.

KATHLEEN DROTAR: Sounds good.

BRENDA ANDREWS: That was easy.

RANDY SCHENKMAN: Okay?

BRENDA ANDREWS: And, of course, you know, I will check with the hotel here to make sure that date is available here so that we can have it here again. It seems to work out for everybody very well.

RANDY SCHENKMAN: Mm-hmm.

BRENDA ANDREWS: So if that date is not available, I will let you know immediately. Is there a second date you want to choose in case that one is not available?

KATHLEEN DROTAR: Do we need to go to October?

NICHOLAS PLAXTON: National Good Neighbor Day?

CHANTEL CORBETT: How about the 12th, the week before?

RANDY SCHENKMAN: You think you're going to be away the end of September?

WILLIAM ATHERTON: His starts the 27th.

REBECCA McFADDEN: Maybe that Thursday, the 21st.

KATHLEEN DROTAR: She's away. Randy's away.

CHANTEL CORBETT: She was saying the 21st she's not available.

REBECCA McFADDEN: The 14th then?

KATHLEEN DROTAR: Do we need to go to October for a second date?

RANDY SCHENKMAN: Do you want to go into October?

BRENDA ANDREWS: I'm going to check with Summerlin right now to see if that date is open.

RANDY SCHENKMAN: Okay. While you're doing that, do we have any old business to go over?

(No Response)

RANDY SCHENKMAN: Anybody have anything? Okay. Well then, as soon as we find out -- they usually get right back to you?

BRENDA ANDREWS: Depends. If they're right

there in their office. I know that Summerlin, I sent it to Carlos as well as Summerlin. So one of them may be able to --

RANDY SCHENKMAN: Are they right here?

BRENDA ANDREWS: They are at the Hilton. They are located across the street at the Hilton.

CLARK ELDREDGE: The guy at his office is here.

BRENDA ANDREWS: That was Eric. He's not part of it. Well, he could be. I could find out. I don't have his information. I have not dealt with Eric at all. I'm not sure what part of it he's involved in. Let me look his number up.

(Stood at Ease)

CHANTEL CORBETT: Should we have an official adjournment with an e-mail follow up on date?

WILLIAM ATHERTON: We're asking if we can be excused, mom.

RANDY SCHENKMAN: Okay. Well, thank you everyone, for coming and the meeting is adjourned.

(Proceedings concluded at 2:55 p.m.)

CERTIFICATE OF REPORTER

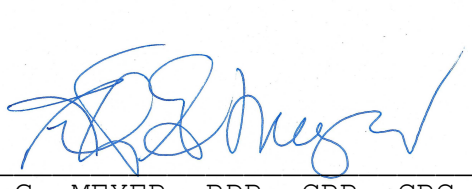
STATE OF FLORIDA:

COUNTY OF ORANGE:

I, Rita G. Meyer, RDR, CRR, CRC, do hereby certify that I was authorized to and did stenographically report the foregoing proceedings and that the foregoing transcript is a true and correct record of my stenographic notes.

I further certify that I am not a relative, employee, attorney or counsel of any of the parties, nor am I a relative or employee of any of the parties, attorneys or counsel connected with the action, nor am i financially interested in the outcome of the action.

Dated this 5th day of June, 2023.



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