STATE OF FLORIDA
BUREAU OF RADIATION CONTROL
ADVISORY COUNCIL ON RADIATION PROTECTION
MEETING

HYATT REGENCY - ORLANDO AIRPORT
Orlando, Florida

Tuesday, October 18, 2011

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ADVISORY COUNCIL MEMBERS:

DR. RANDY SCHENKMAN
DR. WILLIAM ATHERTON
DR. ALBERT ARMSTRONG
MS. CAROL BONANNO, CNMT
MS. KATHLEEN DROTAR, M.Ed., RT, (R)(N)(T)
MR. PAUL BURRESS, CHP
MR. MARK SEDDON, MP, DABR, DABMP
MS. PATRICIA DYCUS, BS, RRA (R)(M), RDMS

BUREAU OF RADIATION CONTROL STAFF:

WILLIAM (BILL) PASSETTI, Bureau Chief
JAMES FUTCH, Administrator
JOHN WILLIAMSON, Administrator
JANET COOKSEY, Management Review Specialist

MEDICAL QUALITY ASSURANCE STAFF:

BETSEY HINES, Rad Tech Licensing
GAIL CURRY, Rad Tech Licensing

(Whereupon, the meeting was called to order by Dr. Schenkman, after which the following occurred:)

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DR. SCHENKMAN: Dr. Janowitz is not here today, so I'm playing Chairman.Why don't we just go around the room and everybody introduce yourselves, say who you and what you do?

I'm Randy Schenkman and I'm a retired radiologist.

MS. HINES: I'm Betsey Hines and I'm in the certification office in Tallahassee.

MS. CURRY: Gail Curry, I'm also with certification.

MR. BURRESS: Paul Burress. I'm a health physicist and I work at Florida State University.

MS. DROTAR: Kathy Drotar. I'm with Keiser University. I'm the university department chair for radiology and radiation therapy.

MS. COOKSEY: I'm Janet Cooksey with Radiation Control.

MR. FUTCH: I'm James Futch also with the Bureau of Radiation Control.

MR. PASSETTI: Bill Passetti. I'm the Bureau Chief of Radiation Control.

MS. BONANNO: Carol Bonanno, recently retired, and I represent the nuclear medicine field in the state of Florida.

MR. SEDDON: Mark Seddon, medical physicist and RSO and chief physicist for Florida Hospital.

MS. DYCUS: Patty Dycus, I'm a registered radiologist assistant and representing the Board.

DR. SCHENKMAN: Okay. Well, welcome everybody.

Janet, do you have a copy of the minutes of if anybody needs them?

MS. COOKSEY: I do.

DR. SCHENKMAN: Okay. Does anybody have any comments about the minutes from the last meeting? Comments, corrections, anything?

Well, if anybody wants to see them at any point later on, Janet has them.

So can we take a vote -- do we need to wait for Bill to approve the minutes?

MR. FUTCH: We'll have to do it again when he gets here, so --

DR. SCHENKMAN: Okay. We'll defer our vote on that.

Okay. Now we need to discuss election of chairpersons, but – we need to wait for a quorum, Janet, do you want to get started?

MS. COOKSEY: In your packet in the pocket on the left side, I put your travel information, your documents, and some instructions, and I just need you to sign the white copy. On the peach colored one you can write in your time and date of departure and all the different things that are listed, and you can give those back to me at the end of the day or you can send them back in the envelope that's attached.

I also put your current contact information in the packet. I just need you to check that over and let me know if there are any changes. I brought the copy of the bylaws that were adopted in 2007, and they need to be signed by the Chair and the Vice-Chair, so when we do that election today we can get signatures. There are no changes since that time, so I don't know if anybody wants to look at them but I have a copy of them in case you do.

MR. FUTCH: Randy, with your permission I'll go over to Tab C and talk about the specialty technology.

DR. SCHENKMAN: Yeah, we'll wait for Bill to do the chairperson.

MR. FUTCH: You'll be happy to know that the specialty technologist issue which the Council has been supportive of for -- I've lost count of how many years. I think at least three, four, maybe more.

This year apparently we must have done something right or something different than we did in previous years because the Surgeon General supported the specialty technologist legislation, as approved by the Council and as written by the Department at the last meeting in October, 2010, and allowed that to go forward as one of the Department's initiatives to the Governor's office, who also supported it and allowed it to go forward to find legislative sponsors downtown this year.

We were fortunate to find two sponsors, Representative Oliva from Miami in the House and Representative Flores -- excuse me, Senator Flores also from Miami in the Senate. So we actually have two bills. They just came out of bill drafting about -- I think about two weeks ago. One of them is in front of you. It's underneath Tab C in your folders and this is Senate Bill 376, and the companion bill in the House as written in the upper right-hand corner, it's House Bill 309.

These are identical. These exactly match what we had submitted as the Department's proposal and it's almost exactly word for word what you all have approved in October 2010, with some minor grammar fixes here and there.

There are -- whenever we have a bill that goes through the Senate's offices especially, they like to fix grammar in existing law, and you'll see a little bit of that.

For example, if you look at the -- let's see where the first place is they do this. If you'll look at the bottom of page five of Senate Bill 376, you'll see a paragraph down there where they have changed the phrase, "...or the rules adopted thereunder..." to "...applicable rules...".

Further on, they've changed the statement that says, "No application for a limited CT certificate shall be accepted...". They've changed that to "An application may not be accepted...", and this is the kind of thing that happens. They usually take any statements that the current law has that are in plural form, they change it to singular. Anything that says "shall not", they try and say "may not"; so they try to apply their rules of grammar in the current, I

guess, bill drafting thinking.

But here's the important point: it doesn't change anything at all with regard to that substantive part of that law. It's just something that comes along for the ride. It usually causes heartburn among people who are looking at it, like what are you doing to that part of the law we didn't say to do that, you know, what are you doing over there? So, it's okay, it's all right. Calm down. It's the first thought I have, also, when I see it. They didn't do anything at all to that section.

But just to refresh your memory, what this legislation does is it fixes the current Rad tech licensure laws, which were first enacted in 1978 and are over thirty years old. Current law only allows us to certify Rad techs in the three primary areas of radiologic technology, which is radiography, nuclear medicine, and therapy. It does not allow us to license anyone in any of the advanced, post-primary or specialty areas that have developed as medical technology has changed over the past 33 years. So, for example, we could not license someone to do PET. We could not give them a PET license, we could not give them a CT license

or any of the other array of advanced or post-primary licenses.

So what this change to the law would do is it would allow the Department to issue those licenses in those advanced or post-primary areas, and it would do it in a very special way. It would do it only by endorsement of the person's national registry credential. So, for example, if you're with ARRT and you have a CT license from ARRT and you wish to come to Florida and have a Florida CT license you can get that by endorsement – if this law passes or legislation passes -- you can get that by endorsement from the Department and have that reflected on your Florida license. So it would be by endorsement only.

That does a couple of things. It saves the taxpayers a lot of money and the Department a lot of effort in trying to develop an examination for licensure. It also saves the applicant the hassle of trying to go through or having to go through a separate State exam if they have already done that for the national registry credential. So that's why exams are specifically prohibited; it's only by endorsement.

And let's see, what else -- let me look

through here.

The scope of practice and the title that's used by the person in Florida. The Department has the authority to write rules so that the title would essentially match the combination of letters that the person uses at the national level. For example, if it's CT then we're going to call it CT in Florida.

"The scope of practice would match or be consistent with..." is the phraseology here, "...would be consistent with the National Registry's scope of practice...", so we would not, you know, we're not going to give CT's the ability to do PET or something like that. Whatever they're doing nationally, whatever their scope of practice that they have qualified for and passed the test for, whatever it is nationally that's what it would be in Florida.

The last thing about it is that we are not requiring people to obtain advanced or post-primary certifications if they do not wish them. For example, if you're a radiographer in Florida you're currently authorized in State law to do anything with any kind of an x-ray machine unless it's prohibited by federal law. So, for example,

mammos is a special case for that.

For example, if you're a radiographer in Florida and you wanted to do CT, in fact, if you have been doing it for twenty years and this law passes you can still do it; you're not required to come back to us or come back to the National Registry and get a license in CT, okay. So nobody is being eliminated from doing the thing they're currently doing. I can't say that enough. That question has come up many, many, many, many times in this process.

DR. SCHENKMAN: So this is for people coming from out of state more than --

MR. FUTCH: Out of state or if you are in Florida and you are one of those radiographers who has gotten the National Registry CT license and you wish finally to have that reflected on your Florida license, you can give that to us and apply for endorsement, and we will put that on your Florida license. In some ways, this makes it easier, I think, after a number of years of having this option available. I think it will make it a little bit easier on the employers, also, because I think people will naturally start to gravitate to realize, oh, wait, I actually can put that on

my Florida license and maybe I'll even go get it now at the national level, and the employers will have more of what that person is qualified for reflected on their state license, so they don't have to look at all the different national registries and see what smorgasbord of titles they have out there.

Bill, did I leave anything out?

MR. PASSETTI: No.

MR. FUTCH: Janet?

MS. COOKSEY: No.

MR. PASSETTI: Any questions?

MR. FUTCH: Well, this is just the first step. With the legislature going through redistricting this year, they'll be meeting basically two months earlier than normal. They'll start in January and they'll be done, I think, by the end of February or the very beginning of March, one of the two. So the entire process is backed up. Meetings that we would have had downtown in committees to discuss this -- and I don't think it's been assigned to any committees yet the last I checked, but those meetings that would normally have taken place sixty days later

are taking place sixty days earlier. So we'll be very busy in November and December, I think.

Of course, the big thing is this has to actually get heard and voted favorably out of whatever committee it's in, and then of course be voted favorably by both houses to become law.

DR. SCHENKMAN: Is there any discussion about it potentially not passing?

MR. FUTCH: No. Kathy and some other folks and I have had discussions with ASRT. They have seen this language, they are supportive of it. The Florida Society of Rad Techs, I've given copies to the current president, Ginger Griffin. She has responded favorably to it, also. I've sent copies Duane and, in fact, if I forget, Carol, we need to give him a copy of this as it's written here. I think he's got the version we submitted to the legislature. So we've given copies to FNMT and they responded favorably to it, to what they've seen, which is exactly what we have here. So everyone who has seen it has responded favorably.

The sponsors like this because it is fixing archaic restrictions that basically are preventing

people from doing things that they want to do. For example, those nuclear med techs who have gone to the trouble of getting the full CT certification from ASRT have been asking us for years to be able to have that reflected so they could do full CT in Florida and we had been unable to; so the sponsors are very happy that they are able to describe this as a fix to bring the law up to date to modern technology and to assist in job creation as much as possible.

DR. SCHENKMAN: I also like the fact that it addresses any new technologies that may come up.

MS. DROTAR: So we don't have to ever do this again.

MR. FUTCH: Right. You may remember back in -- I think it was '04, we did that kind of partial fix to the nuclear medicine techs to allow them to do the limited CT if it wasn't a combination PET/CT machine; and in retrospect it probably would have been a good idea to do this back then because, of course, technology keeps changing and I don't know what they're going -- somebody told me there's a positron emission mammography machine which is not for, I guess, primary screening but it's for once something is identified. One of the

facilities was having questions about -- well, you know, it's a nuclear medicine procedure and they want the nuclear medicine tech to do it, but most of the people in their facility who have experience with mammography from the x-ray -- was it -- I don't think it was just you, Mark, I think it was somebody else, too.

MR. SEDDON: Yes. It may as well. The problem is that once you've injected the patient, positioning the patient on -- it's mammography positioning and the nuc med techs are not experienced in doing that, so it was making better sense to have a mammographer's support than the nuc med tech in the actual positioning, but I think the debate was is that considered doing the procedure.

DR. SCHENKMAN: Who's doing the procedure then?

MR. FUTCH: And one of the nice things about this is if this passes, you know, those radiographers who want to get involved in that area, if they were to go to NMTCB and get that PET certification, there would be no question at all at that point, you know. You could still use them

just for positioning, but at least there would be no question at all that they're doing some part of nuclear medicine and should they or should they not be. So that would help in that regard, too.

But, yeah, so this time around we put in some general rule making authority for the Department to be able to basically accept anything that comes out of medical GE Siemens' brain in the future.

MS. BONANNO: There is now a nuclear medicine assistant position, it's a master's degree.

A MEMBER: Really?

MS. BONANNO: Yeah. The first four people just graduated, so I don't know if this will include them.

MR. FUTCH: We'll have to wait and see how it comes out. Is it NMTCB?

MS. BONANNO: Yes.

MR. FUTCH: Not ARRT, the --

MS. BONANNO: Well, they worked together on the exam.

MR. FUTCH: We'd have to go and look at it and see if it was something that's intended for -- something at the level of, like a Rad tech or a

nuclear med tech, or is it something at the level like an RA?

MS. BONANNO: It's the same level as a PA.

MR. FUTCH: Oh, I'm not sure if it would in that regard.

MS. BONANNO: It might be tacked onto the RA.

MR. FUTCH: Oh, please. The way ASRT and FRS had the RA constructed, the RA is prohibited from doing nuclear medicine, so I'm not sure if it would work out over there.

MS. DYCUS: Unless there are already in nuclear medicine.

MR. FUTCH: I'm sorry?

MS. DYCUS: Unless they're already licensed in nuclear medicine.

MR. FUTCH: Oh, yes, unless they're already in nuclear medicine.

MS. BONANNO: With what's her name in Fort Lauderdale is a nuclear med tech and she's an RA.

MR. FUTCH: So that is the current description of this and the legislative planning folks in the Department were just overjoyed that we were bringing this actual legislation to show you, and when Bill gets here hopefully we can get

a vote of favorable support from the Council for this because it makes it easier for them to go to other legislators and say the Advisory Council on Radiation Protection has seen this exact legislation and have supported it and approves of its passage, and so forth and so on.

MS. DROTAR: James, could you let us know when it goes to committee so we could make some contacts?

MR. FUTCH: Oh, sure. In fact, if you're part of any facilities or individually or societies that would like to write a letter of support to, I guess, maybe Bill -- would that be the best place that we would give it to legislative planning people.

MR. PASSETTI: Yeah, that would be fine and then we can get it to the right people.

MR. FUTCH: Or, you know, I guess I don't want to be in the position of advocating for letters to legislators, but -- I can't do that. Wherever your heart may lead you.

So I guess when Bill gets here we'll maybe come back and take a vote.

Any questions, comments about this? I'll have to explain it all to Bill when he gets here.

Well, that's it, I think, on that topic.

DR. SCHENKMAN: Okay. We have proposed rule revisions. Here we've got the RA duties.

MR. FUTCH: Yeah, first on the list is the RA duties, which is --

DR. SCHENKMAN: In D1, and we have D1, D2 and we have D3.

MR. FUTCH: Let me -- since it's a little simpler, with your permission let me take the rule amendment for the definition of approved program first, and we'll have to repeat ourselves less when Dr. Atherton returns gets here. So that's Tab

Tab D2. You may remember this issue; this is one that I think we brought to you before and you asked that we come back with some specific language. But this issue is sometime a year or two ago -- Betsey and Gail, refresh if me I'm saying the wrong date -- we were very surprised as a department to learn -- we had an applicant apply to us who was a nuclear medicine tech it was a nuclear medicine technologist applicant and one of Betsey and Gail's application reviewers was very fortunately caught a kind of quirk in the person's educational history. This person was a radiographer already, licensed by the State, and had an NMTCB license, and did not have a diploma

from a nuclear medicine technology school, although this person was someone who had just recently taken the licensure exam. So you would have expected them to be a recent graduate.

Come to find out after a long, drawn out process of lawyer back and forth and discovery and et cetera, et cetera, they had qualified through a process that NMTCB calls alternative eligibility, which is a pathway where you have to complete, I think it's 8,000 hours of quote, nuclear medicine experience in a four year period, and then also complete a 45 clock hour class in certain nuclear medicine topics before being able to sit for the NMTCB exam. This person had done that and had passed the examination, and come to find out their 8,000 hours of nuclear medicine experience included never once having administered radio pharmaceuticals to a patient during that clinical experience. So we basically would not certify the person because they did not meet the definition of an approved program, which you have in front of you actually at the top of the page here on Tab D2. This is 64E-3.002 Definitions Current. This is the current definition of an approved educational and training program.

The means of program -- underline that word "program", which is recognized and accepted by ARRT or NMTCB, and fortunately for us NMTCB actually has a programmatic pathway for certification with identified programs with names of schools and addresses and stuff like that up on their website, and then this other thing which is alternative eligibility. And I'm not trying to knock NMTCB. When we talked to them about this, they mentioned that it was only going to be in effect for another few years. I think 2015 they repealed alternative eligibility so you can't qualify through that pathway anymore.

And we said, you know, how did this person's nuclear medicine experience make it through your process and qualify because most people that I've talked to, especially nuclear medicine techs, that kind of boggles the mind that somebody would have a clinical which does not involve the administration of radio pharmaceuticals at some point during their -- I mean, that's the whole point, right? You get to the point where you're educated so you can start doing this. Somebody watches you do it and makes sure you do it right. And the response was something along the lines of

there is a such a wide variety of what can constitute nuclear medicine experience, we've never been able to define it more than to just say nuclear medicine. In this person's case, we believe what happened through discovery looking at some of the documents that they just send like an affidavit to the supervisor of the person, and sometimes it ends up like the personnel, human resource liaison, and they have a checkbox. Basically, you tell them the dates of when they started and when they ended, how many hours per week they worked, and the checked box is like nuclear medicine or some other topic, and that's it.

So in response to that -- now we still think our current rule is fine. It does the job. It does say a program, and we do not consider alternative eligibility to be a program; we didn't have to prove this in a court of law. But if you go to NMTCB's website you can clearly see a distinction even on two separate applications -- here's one for people who go the program route, here's one for people who go through the alternative eligibility route, and they never, ever call alternative eligibility a program. But

the attorneys thought that it might be wise for the future if we go back and revisit the definition and perhaps add some additional clarification so that it's even more apparent that what we're talking about is not alternative eligibility.

My first thought was to go to the definition and say this does not include alternative eligibility.

DR. SCHENKMAN: But then they'll come up with something else, right?

MR. FUTCH: Yeah, so we were trying -- rather than writing it that way, we were trying -- we came up with these other alternatives down here, which are on the rest of the page we're looking at which again is Section D2. So we have two proposed additions and changes to the current definition, which are there and underlined.

So the first one basically is the existing definition plus an additional statement, which says the name, address, program director, and other contact information for such a program is actually listed on their website of ARRT or the website of NMTCB. Then the other method of doing it is to -- which requires a little more work --

is to separate out nuclear medicine program from everything else and say, basically, approved program for radiography or therapy is one which is recognized by ARRT, and then for nuclear medicine say it is one which is recognized by both ARRT and NMTCB because ARRT doesn't have this alternative eligibility pathway.

They use the same -- for actual programs, they use the same, as far as we can tell, accreditation requirements. So at least inside the US if you want to be considered an approved program by either group, you have to -- the Joint Review Committee on Education in Nuclear Medicine Technology is accepted by both groups, and then SACS accreditation for institutional programs like Florida State or, you know, big schools that don't have -- that are not solely programs. The whole school is not the program.

Now, folks besides me know a lot more about nuclear medicine, hint-hint, I don't mean to put you on the spot, Carol or Kathy; I was kind of hoping to have Dr. Janowitz here and also Alberto because his background is in this, also.

What do you think? Are we going to shoot ourselves in the foot with this or was this

actually helpful? Which one is more helpful?

MS. DROTAR: Question before we get to that. If we're going -- if specialized certification comes in, where is that going to fit in with these?

MS. DYCUS: They should be included -- those as post-primary concept.

MS. BONANNO: Yes, post primary programs necessarily.

MR. FUTCH: Right. Well, my thought on that was we're essentially saying whatever an approved program is whatever ARRT or NMTCB --

MS. BONANNO: Accept.

MR. FUTCH: -- accept it to be. So I don't think we're going to hurt ourselves with -- well, actually, the way the specialty technologists educational --

MS. BONANNO: Their requirements are left up to the two boards who do the certifying, and we're saying if the two boards certify them we're accepting them for the post-primary.

MR. FUTCH: So my short answer to your question is I don't think this affects that, but thank you for bringing it up and I'll keep that in the back of my mind as we move through this.

MS. DROTAR: Well, in case something gets changed along the way, then it might fall --

MR. FUTCH: Yeah, I never thought I'd have to change this program definition again once I --

MS. BONANNO: Well, you wouldn't if it were before 2016.

MR. FUTCH: Yeah, if it were 2016 or whatever -- I think it's 2015. Once 2015 is gone with this definition is 100 percent fine. I'll still say to this day if somebody asks me, I think the current definition meets the requirement of a program. I mean, what else can I say? I have to go say this in a hearing in a court of law.

MS. BONANNO: Just out of curiosity, what happened to this person?

MR. FUTCH: They eventually gave up fighting and withdrew, so we didn't actually have --

MS. BONANNO: They wanted to go to Georgia, I think.

MR. FUTCH: Actually, they were very close to Alabama to begin with. Maybe that's what happened.

DR. SCHENKMAN: That program -- not program, the alternative --

MR. FUTCH: Eligibility.

DR. SCHENKMAN: -- eligibility is approved by NMTCB.

MR. FUTCH: But it doesn't have -- which one are you looking at? The middle one or the bottom one?

DR. SCHENKMAN: The middle one, so even --

MR. FUTCH: But it doesn't have a name or a program director or an address. It's not a school.

MR. PASSETTI: Could they just move it on the website under 'Program'?

MR. FUTCH: If they did they would have to come up with an actual name of a school, an address, and a program director, and that whole thing.

DR. SCHENKMAN: They can't just put whoever, if they have one or two people that are running that alternative group? They can't just put them on and say that's who they are and they're working under them? I'm just --

MR. FUTCH: They could do -- I mean, theoretically, they could do what you're saying.

DR. SCHENKMAN: I'm looking at how they'll get around it --

MR. FUTCH: I don't think they want to.

DR. SCHENKMAN: -- if they need to.

MS. DROTAR: To be approved by ARRT, you have to submit a letter and signed and you have to send in your accreditation and everything else.

MR. FUTCH: But the question was about NMTCB, though, because they're the ones who have the alternative eligibility.

DR. SCHENKMAN: I think the second one would be more specific.

MR. FUTCH: Right, I think we could have brought, if we could have compelled them to do it, but we could have brought the director of NMTCB down to Florida to testify in that case and they would have been forced to say this is the program pathway, this is the alternative eligibility pathway. I mean, it's really -- I don't think that they're trying to say that alternative eligibility is a program in that regard; they're saying -- well, I don't want to put words in their mouth, especially on tape.

MS. DYCUS: It's a grandfathering thing.

MR. FUTCH: Yeah, it's a grandfathering thing and none of us really understand --

MS. BONANNO: Yeah, people are already like two years into it and you can't tell them, I'm

sorry, you can't do it, and you wasted two years of your career.

MR. FUTCH: They're acknowledging on their website that they're getting rid of it in 2015. I mean, it's got an end to it coming up soon. The only part I don't understand is why they still did it for so long.

MS. BONANNO: I don't know. They were supposed to do away with it three or four years ago, and that's why I was shocked when they extended it.

MS. HINES: We actually had a second applicant that we denied.

MR. FUTCH: Oh, did you? Thank you for keeping me out of that one.

DR. SCHENKMAN: Do these exclude anybody who should be included? Or is there anything in the language here that excludes anybody?

MR. FUTCH: Well, that's the hundred thousand dollar question. The key to the bottom definition is it says "and" between ARRT and NMTCB instead of "or".

DR. SCHENKMAN: Okay.

MR. FUTCH: So it has to be a program which both groups recognize. Actually, if I'm going to

say that I could just say ARRT and just forget about NMTCB, but then that causes a lot of eyebrows to get raised and that kind of stuff, too. So if someone could think of a shorter way of distinguishing a real school -- I mean, you ask somebody this and they say, well, I know what a school is. You know, I --

MS. BONANNO: It's a director with a desk someplace.

MR. FUTCH: Yeah, it enrolls students, it has financial aide -- well, actually, hospital-based programs don't. That's the other thing. We have to be careful not to exclude the hospital-based programs that are still out there in Florida because they don't grant -- at first they said he has to graduate, you know, get a diploma, but they don't really give you a diploma. You get a certificate.

MS. BONANNO: You wouldn't want to exclude the University of Miami.

MR. FUTCH: One of the easier things to do is to go back and say, well, it's accredited by -- and then you're back into the whole thing of why are you even saying recognizing except by ARRT, if you're going to go specify the accreditation mechanisms, which change with the -- eventually.

The national registries pick different accreditations that are okay even outside of the US, you know, the Canadian this and Australian that and so forth. I'm not saying either one of these is the best thing I've ever written or that Janet could correct after, right?

But I'm open to suggestions as to how to fix this or come up with something completely different or if not, if you like either one or neither one, let me know.

MS. DROTAR: James, just another question. Because ARRT have advanced placement standing but the student actually has to re-graduate from the program, so that's training for an educational program, right?

MR. FUTCH: If it meets the requirements for ARRT's program, yeah.

Well, don't everybody speak up at once.

DR. SCHENKMAN: Well, I think it would be a lot harder to get around the second one, the second proposal.

MR. FUTCH: The one on the bottom of the page?

DR. SCHENKMAN: Yeah.

MR. FUTCH: Okay.

DR. SCHENKMAN: I think that people could just put, you know, whoever they're shadowing that person will just put their name --

MR. FUTCH: We could actually do both of these. I mean, change the definition as on the bottom then stick the extra statement in there.

DR. SCHENKMAN: Would that make it easier for you when you're checking?

MR. FUTCH: I should ask --

DR. SCHENKMAN: That's right, yeah.

MS. HINES: We have to gather all that information. But if they give you a certificate that has the name, the address, and everything on it --

MS. CURRY: Which they do.

MS. HINES: We would have to change the requirement of what the schools are giving to the students so that if it was acceptable under this rule because right now we would get a certificate that says Keiser University, Orlando, such-and-such a date, nuclear medical technology. I mean, we don't have program director, the address. All that stuff is not on the certificate or diploma necessarily.

DR. SCHENKMAN: But it is on the letter. I

mean, but that is a choice whether you send a letter or whether you do a certificate or a diploma.

COUNCIL MEMBERS: (Over-speaking.)

MS. HINES: We also license EMT's and paramedics, so we're really busy with four processors for the whole state. So the easier you can make our process --

MR. FUTCH: Yeah, actually the next page talks a little more, Betsey, about what has to come to you. I want you to talk about that as soon as we finish talking about this one.

MS. HINES: Okay, well if I can interject one second; something that we are working on in like the next phase technology-wise, God forbid any more laws get passed before we get to it; for our online applications which really, truly are faster, we are working on a bid -- we already have it so that schools can be other payers and go in. So if Keiser, for example collects the application fee from their students near the end or whenever, then all the students can go on our site, apply for certification, and then they can put in Keiser's 1-2-3-4-5 number, and then Keiser can go in, affirm yes, they are our students, and pay for

them.

What we're working on next after that is that while Keiser's in there or any other school in Florida, they can go in and say this student in fact did graduate as a GR and this student, in fact, has taken a 4-hour HIV-AIDS course, which means we don't have to collect that documentation which right now is ridiculous. You have to get a piece of paper in, a lot of times by e-mail, we print it out, we put a scan sheet on it, enter it into our system, and then it goes to paper again. You know, so that will save a lot of work on our side and a lot of paper exchanges from schools to us.

MS. CURRY: It would just be on the front end. Kelly would have to approve the schools and get it in the system, which that --

MS. HINES: No, no, I don't think so.

MS. CURRY: Yes, she does. Somebody has to approve the schools in that. Kelly verifies that the schools are accredited and the schools for certification, correct?

MR. FUTCH: The school that approved this or the HIV-AIDS thing, okay.

MS. HINES: Well, they don't have to be in

the COMPAS system it's a totally other system.

We haven't all been trained in it, so we'll figure it out before we offer it to the public.

MR. FUTCH: Let's see if we can get some guidance on the actual definition of the program. Then we can talk about where to find lists of them.

So Randy has a preference for the one on the bottom, but you're not opposed to adding the other one to it?

DR. SCHENKMAN: No.

MR. FUTCH: In addition to that one. Any other --

DR. SCHENKMAN: Just so long as it doesn't make it so much more work for you guys.

MR. FUTCH: Yeah. Any other thoughts in that regard? Anybody?

MR. SEDDON: That makes sense. I mean, basically you have a second line that you add -- the second one onto the second definition there at the bottom. That way you're encompassing both.

DR. SCHENKMAN: There you go.

MR. SEDDON: As long as we're confirming that we're not excluding anyone, then --

MR. FUTCH: Except for the people who have never actually touched radio pharmaceuticals.

I don't want to cast aspersions on everyone who has gone through alternative eligibility. There may be perfectly fine folks out there who actually did, you know --

MR. PASSETTI: Or they did and they didn't want to tell you that they did --

MR. FUTCH: The problem is and NMTCB is -- the way they're handling this alternative eligibility, they're not requiring -- and this is my opinion, right, not the Department's, but they're just not requiring enough proof of the clinical education that something like this can slip through.

So I'd like to get a vote on that.

Do you want to get one now and if Bill comes we'll just reaffirm it, hopefully, unless he disagrees?

MR. PASSETTI: Well, we've held off on all the other votes. We may as well hold off on this one.

MR. FUTCH: As we leave this topic -- what I'm hearing basically, exactly what Mark said which is go for the second one and add the first

to it. Everybody's nodding their heads. So when Dr. Atherton gets here, we'll see if we can take a vote on that.

The next page is basically -- the page we just left is the definition of what an approved program is. On this page, which at the top it says Qualifications for Exam, this is what we collect so this has a little more bearing on what Betsey and Gail were talking about before.

I was going through this and realized it seems like there was a few things missing from what we're collecting. The first one is that right now the applicant has to have, of course, graduated from one of the programs we defined on the previous page, and verification of that graduation is described as a legible copy of an official transcript or a copy of the diploma must be provided with the application, or electronic. It doesn't mean on paper. It could be electronic, however it is you want to get it.

One of the things that I think folks had asked for was on the transcript that it not only have the courses successfully completed but actually grade achieved. So that's something I threw in. We had talked about that at some point

in the past.

DR. SCHENKMAN: That's misspelled, "I before E".

MR. FUTCH: Right. Reminder to Futch, spell check.

DR. SCHENKMAN: Sorry.

MR. FUTCH: No, that's okay. Then down below I was thinking about it, and this next line, a letter from the program director attesting the applicant's successful completion of all program requirements and should be accepted, that was written for the people who have just graduated from their programs. This was originally when it was written for, just graduated from their programs, they've already got their application with the Department. They want to take the test on the same day that they graduate and this is how we used to do it. I don't know if we still do it or not, but the program director basically sends a letter for everybody and says, you know, I'm the program director for this program, this person has successfully completed everything and graduated today, and go forth and they can be examined.

Then I got to thinking about in terms of alternative eligibility thing, which the person

who applied to it could have very easily done the same thing. They could have written a letter from the person they were calling their program director, which would have been probably the clinical doctor who educated them illegally some place in Florida. So I was trying to tailor this more toward a real program, as opposed to making it look like it was something that someone through alternative eligibility could comply with, if they wanted to. So that was the reason that I put the rest of this in here.

I changed the “will” to “may”, so it’s back to the Department’s discretion. Of course, there’s no reason why we would not approve somebody who came from a legitimate program and whose program director supplied the letter to us. Then the rest of this is in here because whenever we say we are going to do something at our discretion, we usually have to give the attorney some explanation -- it’s not the attorneys, but the Joint Administrative Procedures Committee who reviews what we do in rule tells us that we have to give some kind of guidance to the applicant. So what this is doing is saying if the applicant can show good cause to the Department that, for

example, they could not produce their diploma or their transcript -- not that they never had one, but it was 50 years ago and it died in a fire some place with the rest of the school records; or I just graduated and I haven't got my diploma yet and here's my letter from my program director. That's what this is intended for. So it's just trying to tighten it up with regard toward the proof that's coming to us to further distinguish the proof that would come from somebody who went to a real program from the proof that would come from somebody who didn't go to a real program. All right.

So, Betsey, Gail, anyone?

MS. DROTAR: Can you clarify that is just going to be for people that are taking the Florida state exam or is it for everybody that's making an application?

MR. FUTCH: Well, for the purposes of -- let's see, let's back up for a second.

MR. PASSETTI: It's under the examination section, so --

MR. FUTCH: It's qualifications for exam.

MS. DROTAR: For the state exam, it wouldn't be -- okay. Thanks.

The only problem that I might see is if it was somebody who was coming from, like the school, like Keiser, that graduated from the program and only wanted to take the Florida exam. They might not be able to get their official transcript because of finances, etc., and if there's not a diploma not until graduation because then the letter from the program director says that those things can no longer be obtained, and it's not that they can't be obtained but there would be a delay in it which would delay them taking an exam.

MR. FUTCH: So they can take out "no longer" cannot be obtained. Just leave it at that. Yeah.

DR. SCHENKMAN: Is not available.

MS. DROTAR: Yeah, or can't be obtained, or something.

MR. FUTCH: Okay.

DR. SCHENKMAN: Is not available at the time of the application.

MR. FUTCH: Mm-hmm. Any other comments, thoughts, revisions?

MS. HINES: I'm wondering if this can be adapted so the electronic verifications can be part of it.

MR. FUTCH: Yeah, if you have something

electronic-wise, you want me to put in a statement that says electronic submissions of -- electronic representations of the above paper documents will also be accepted.

MS. HINES: Because that is in the works.

MR. FUTCH: Right. Okay. Well, that's it for that one.

DR. SCHENKMAN: Do we want to talk about one or two?

MR. FUTCH: I guess we'll back up to one now.

DR. SCHENKMAN: Okay.

MR. FUTCH: We can talk about that one. All right. So Tab D1, Radiologist Assistant Duties and Supervision.

As you may recall, a number of years ago the radiologist assistant was added to the licensure types in Florida. This is actually 2006, I think. And the radiologist assistant I think of is kind of like a physician assistant light, can't write prescriptions for medications and do other things, diagnose diseases. Basically, the RA is -- well, Patti is one. I should let you explain what the RA is.

MS. DYCUS: I guess whatever they want it to be.

MR. FUTCH: Well, it's a physician extender and exists, I think, so that the radiologist -- has to work for a radiologist. The radiologist doesn't have to do all of the especially fluoroscopically guided procedures. The RA is a person who is educated at the -- what we call it? Is it a master's level?

MS. DYCUS: Well, there's Master's available. They're moving it to all Master's.

MR. FUTCH: So take a look at Tab D1, not the first page but the second page that says Statute and Constitution. This is where we get the authority to write rules.

In fact, it says:

"A person holding a certificate as an RA may perform specific duties allowed for an RA as defined by the Department by rule. The rule must be consistent with the guidelines adopted by three organizations: the American College of Radiology, American Society of Radiology Techs, and the American Registry of Radiology Techs with the level of supervision required by such guidelines."

Then the next part of it is the prohibitions. They can't do nuclear medicine or radiation therapy unless they are a currently

licensed nuclear medicine tech or a radiation therapy tech. They can't interpret images. Very important point that the Florida Radiological Society wanted to make sure that was in there.

DR. SCHENKMAN: And ACR.

MR. FUTCH: And ACR and everybody. Cannot make diagnoses and cannot prescribe medications or therapies.

So in 2007 right after this passed, if you back up a page, we adopted this current rule language which does several different things. In the beginning what it does is it adopted a document that ARRT and ACR and ASRT had, I guess, all agreed to back in '05, which the ARRT called the Radiologist Assistant Role Delineation. That document is also included in your packet; and in fact, if you turn ahead let's see how many pages -- three, four, five, six, seven pages in. I think it's the eighth page, the first stapled section of papers in this tab. That's the Radiology Assistant's Role Delineation January 2005. I went one page too many.

This document if you tab through these three or four pages here, you can see it actually has a numbered listing of clinical activities with the

level of supervision specified out next to each one. So that is what the rule we were just looking at in 2007 adopted.

And it made some caveats which is back on the rule, if you look at 1A, B, C, D, and E; it makes reference to specific number of clinical activities on this list that we were just looking at, and it qualifies them in some way, shape, or form. Basically, we had to qualify some of them so they would comply with the statute. And, of course, you never really have to do that in a rule because the rule can't supersede the statute, the statute always supersedes; but we did it so that the radiology assistant reading this would understand which parts of this thing might conflict with the statute. So we highlighted those for them.

Then the second part of the rule, paragraph two, this is how we come to find out who the supervising radiologist is and what the relationship is between the RA and their supervising radiologist; and it's just a requirement that within 30 days there's a document that comes to us that has the name of both people, the license number of both people, and signatures

and when the supervisor relationship began. That goes to the Department. So the rule accomplishes two things. It actually adopts what the duties are and the levels of supervision, then it also has that bottom part about letting the Department know who your supervisor is if you're the RA.

All right. So fast forward a little bit and now the document we were looking at, the radiologist assistant rule delineation January 2005 no longer exists. I mean, it exists in Florida law because we adopted it by reference, but what's happened since then is the next document which is the registered radiology assistant entry level clinical activities effective January 2011, affectionately known as the ELCA, yes, the ELCA, entry level clinical activities list. This document serves the same purpose for ARRT, I guess, that the other one did which is ARRT did a task analysis and they build their exam based upon what the practicing folks in the field say that they're doing in terms of procedures. That's really what this document does for ARRT.

So there are some differences between the old delineation and the new ELCA. One of them is

it clearly states that the ELCA is for entry level radiologist assistants, and it also -- you'll notice if you flip through it, it doesn't have a varying level of supervision for all of the individual tasks; and I apologize for all the scribbling on the pages. I started out thinking that I was going to try and track the changes from one to the changes in the other one, and I got lost after about the first page-and-a-half of that. There are some tasks that they pulled out entirely. There are new tasks in the new one. Most of it is they just changed and combined two or three of the tasks and the old one changed the wording around and the new one, so there's almost no way to actually track it explicitly from one document to the next.

But the big thing about the ELCA is that it does not have a varying level of -- it actually doesn't even specify a level of supervision out to the side like the old document did. The old document said general, direct, personal, et cetera. The new one just has a statement which is on -- if you're going from the front page of the ELCA document, if you turn over to -- it's page three there on the right-hand side. It says

somewhere near where I've underlined that ARRT test development and educational requirements for certification assume that the level of supervision for entry level RRAs, they call it -- they stick an extra 'R' in there -- will be at the direct level for clinical procedures.

So they assume at least the clinical procedures in this list are at the direct level kind of for the guy who just got his license and just started work. Then they go to some trouble to say a little bit later down that the actual level of radiologist supervision will depend upon the RA's experience, as well as state and employer requirements. So they're kind of saying you might start out at direct, but then you can go otherwise.

So here's the issue for me. I've got a statute that says I have to adopt specific duties that all three organizations have agreed to with a level of supervision required by those duties, required by those guidelines. There is a little more to this. I talked to ASRT. ASRT has a practice standard. I don't want to confuse you further, but this is probably going to do that. The practice standard which is the next paper

clipped set of pages after the ELCA is many, many, many pages long. It is written in a much different fashion, a lot more generic fashion, and it has more levels of supervision recommended in it at all. The standards, and we've only -- I think we produced about half of this for you. All of the even numbered pages are missing because we were trying to conserve space and not -- no, actually, we forgot the even numbered pages, but we have a complete document up here. But it's okay because we're not going through that one page by page because we would be here for a week.

But suffice it to say if you look at the format on each one of the pages of the ASRT practice standard, like, for example, their page RA 9, it starts out at the top. It has a section of clinical standards then it goes to quality standards then it goes to professional standards. Each one of those has a standard list at the top, like this one says standard 3, Patient Education. It has a rationale, has a general stipulation where it kind of describes what the RA is supposed to do at patient education. Then it has a general criteria and then a specific criteria. Now when you get down to the bottom to

the specific criteria, that's the kind of thing that was listed previously in the role delineation and is currently listed in the ELCA but not nearly as many and in a much more generic fashion.

So here's the question. I've got RA's calling me, one of 30 in particular who comes to mind, whose facility really wants her to be able to do something like lumbar punctures which currently under the existing rule and existing 2005 role delineation requires personal supervision. 'Personal' means at the elbow, in the room, at the same time. Well, none of the radiologists in her facility now that she's not an entry level person anymore, they understand she can do these procedures; they want to be doing it at direct level supervision which requires them to be in the building while she's doing it. But our role delineation currently says what the old one said which is personal.

MS. DYCUS: The role delineations were taken based on CMS guidelines for reimbursement. When everybody figured out that that was not going to fly or easy to change because we petitioned CMS to change those guidelines; they can't change those guidelines without an amendment to the Social

Security Act, a congressional amendment. So those guidelines, supervision levels were not designed because of competence or the need in the field. They were designed from CMS thinking that at sometime when we changed CMS they would just change right down the line for everybody. That's not going to be the case.

The issue regardless of what supervision levels we set in real practice, you're limited by what CMS will reimburse regardless of competence or what we set.

MR. PASSETTI: So why would people want to change the supervision when if they did it that way they're not going to get reimbursed for it, right?

MS. DYCUS: Correct, but we're in the process and there's been a bill submitted at the federal level to change that.

MR. FUTCH: So the national societies are trying to get CMS to change its guidelines to reflect what?

MS. DYCUS: To reflect general supervision. For a radiologist assistant to be effective or to be helpful to a practice they have to be able to practice somewhat independently from the

radiologist. I mean, with supervision but not hands on. He has to be -- he/she has to be able to read while you're doing procedures, and so regardless of what's set out by state law or what's set out through the ASRT or the ARRT, we're still bound by CMS in the end.

MR. FUTCH: Let me read something that Kathy just -- it says, "Radiologist Assistant" Bill introduced in House amending the Social Security Act to recognize RA state laws and allow Medicare reimbursement September 22, 2011. Today Representative Dave Reichert, Jim Mathison, Pete Olsen, and Bill Pasquel introduced HR 3032, the Medicare Access to Radiology Care Act of 2011. This bill would require Medicare program to recognize radiologist assistants as non-physician providers of health care facilities to Medicare beneficiaries. Then it goes into a long description of what they are and what they can do. So basically they tried to just change the levels, but they couldn't do that because they still viewed them as like a technologist?

MS. DYCUS: Correct. That meant that they would change it for all RT's because RA's weren't recognized. But they went in there and messed

with those levels that would allow RT's, RA's -- and would be non-discriminatory.

MR. FUTCH: Let me ask you -- and I apologize if you said this already -- once this happens, and I'm assuming it does happen, CMS guidelines are going to have a different category for RA than RT, and is it going to say everything's general supervision?

MS. DYCUS: No. What it's doing, what this bill is really doing is just giving us a category as an RA and then they will go through that or we'll petition different exams to be different levels, and there will probably be much discussion over that. But it's similar to the PA's and then whatever the RA does will be reimbursed at like 85 percent, I think.

MR. FUTCH: What physicians are reimbursed at, right?

MS. DYCUS: Yes. It gives us a category.

MR. FUTCH: One more document to throw at you here. I had some discussions with Christine Lung, the government relations person at ASRT out in New Mexico about this topic. In fact, everything you just heard me go through here I just went through with her. She submitted a

letter to us if you back up in the same Tab D1, you'll see a letter from ASRT dated October 10th. It's right after the statute. This is what Christine in the ASRT recommended that we do and I'll save you the trouble. The first part of this is just a general description of how all three societies are in agreement on this and she excerpts some of the pieces from that ASRT practice standard that we just left, and she started out at the bottom of her letter several paragraphs all the way through the bottom almost to page two, she describes in paragraph form basically what a radiologist assistant is and what they do and so forth and so on.

Then she gives her recommended actual rule revision starting on the bottom of page two of her letter, 64E-3.0032, and essentially what she's done is she struck through everything where we refer to the role delineation and the specific activities and substituted basically that the duties shall be delegated by the supervising radiologist and that there must be a written agreement between the radiologist and the radiologist assistant that describes the duties and the supervision levels, written and signed.

Now further on she actually asks that this document be submitted to the Department. Watch Betsey and Gail jump out of their chairs.

MS. HINES: We don't have anything to do with that.

MR. FUTCH: Well, you do with the document that says who is the supervisor.

MS. HINES: Right.

MR. FUTCH: But this down here she's actually asking for the signed delegation agreement that has the specific duties and the limits of supervision for each procedure to be sent to you by the doctor.

MS. CURRY: Okay, that would just be added to what they sent to --

MS. HINES: I don't know whether we can put, I mean, does the community want that delineation acceptable online? That's the question.

MR. FUTCH: Well, all the radiologists I know, and I'm not sure they would want to do that, but I don't want to speak for radiologists when there's one in the room.

DR. SCHENKMAN: I would highly doubt that they would want to do that.

I also think that there's a problem with

this because if you have somebody who just comes to you and you don't really know how good they are at what they're doing and especially how good they are with their hands or their image interpretation, 30 days may not be enough to figure out exactly what you're comfortable allowing them to do. So they're going to write something that's going to be a lot more limited and then every time they change it, they're going to have to re-submit what they're going to be allowing this person to do as they gain confidence in the person or lose confidence in the person.

MS. DYCUS: And, also, you're working for a group of radiologists with each one having different thresholds of what they'll let you do and not do. So it's very difficult to do it that way. There are things that --

DR. SCHENKMAN: But I don't think that this is very practical at all.

MR. FUTCH: Okay.

MS. DROTAR: Is there like a training record or procedures that you've done that you could say now this is showing that you've gotten more experience at those levels?

MS. DYCUS: The credentials board has, you

know, a number that they might watch and then --

MS. DROTAR: Is that something that you'd have to have at the facility? For instance --

MS. HINES: I was going to say does the Department need to get into the middle of that? I think we should have --

MR. FUTCH: We didn't even get to the part where she's asking with every renewal will a new one come in. Well, there are several parts to this. Do you think we should -- let me back up for a second.

In terms of requiring that there be a written document kept by the radiologist for their radiology assistants, is that something that you think we need? Is that required?

MR. PASSETTI: Is that something that's being done now?

MR. FUTCH: Yeah, what do you do now?

MR. PASSETTI: Between you and your radiology group.

MR. FUTCH: I'm not talking about the thing that says who your supervisor is, which goes to the State; I'm talking about the thing that would say what Christine calls the written, signed delegation agreement that contains the duties that

are delegated in the supervision levels.

DR. SCHENKMAN: That's just to say that they're more confident with you, they've allowed you to do more, basically?

MS. HINES: Is that in writing somewhere?

MS. DYCUS: Probably not, but see, I'm in an out-patient center where a hospital would have more of that documentation for their credentialing department.

MR. FUTCH: You know, me sitting up here in the ivory tower of Tallahassee, it sounds like a good idea to me, but I've watched so many of those never see the light of day because they're shot down as being too onerous.

MS. DYCUS: It would have to be and then specific probably to --

DR. SCHENKMAN: The other thing you could is just have a form that has all of the different procedures on it that the radiologist keeps, and as the RA gets more comfortable, gets more experience. They just check off when they're allowing that person to do that and they just keep it in their records and then if, you know, somebody comes by -- an investigator comes by, they have it in the records. If you could do something like that, that wouldn't be such a

difficult thing. I mean, each RA would have a sheet and if a radiologist felt you were competent and allowed you to circulate it, they would check off the sheet.

MR. PASSETTI: But you're in a situation now, right, where you have somebody submitting saying I'm your supervising radiologist, but you may be working for five radiologists.

MS. CURRY: We would have all five.

DR. SCHENKMAN: No, but that's what I'm saying, each RA has a sheet; so the radiologist just checks off on that RA's sheet when they're -- or just initials it when they feel comfortable for the --

MR. PASSETTI: But if you're a group of radiologists, do all five of you have to sign off on that sheet?

DR. SCHENKMAN: No, each time that the radiologist that you're working with feels that they're comfortable starting to let you do this, then they would initial that procedure.

MS. DYCUS: They might do that for an RA, you know, have you done this for any other radiologist? If Dr. A thinks you're qualified then I would trust his judgment and you can do my

procedure.

DR. SCHENKMAN: Because usually in a group, it's a group, you know; you're not working for 25 individual radiologists.

MR. PASSETTI: Well, that's what I'm asking.

Does she have to submit something from one radiologist in the group saying I'm her supervising radiologist, or do all five of them have to sign?

MR. FUTCH: Right now they all submit something to the Department, so that's what I was saying.

How many people do you have in your group?

MS. DYCUS: Three radiologists. We just added a fourth one.

MR. FUTCH: There are only thirty RA's in Florida, roughly. I've had this discussion with a couple of them, and what they do is they just, you know, everybody decides the same thing, I think, and sends it in from the group --

MS. HINES: And then we have entered the relationship in our system, which would show online.

MR. FUTCH: It was easier to do that than

trying to figure out who was supervising you this particular six month period day, whatever --

MR. PASSETTI: They're already taking responsibility for deciding what level of supervision they want them to have and --

MR. FUTCH: Yeah.

MR. SEDDON: How is this different from a PA?

MR. FUTCH: That's a good question.

Knowledge? I believe they have to have a written protocol --

MS. HINES: They have to send in a protocol or the supervisor has to --

MR. SEDDON: So they have to have all--

SEVERAL MEMBERS: (Over-speaking.)

MR. SEDDON: So basically we're mirroring identically what the PA's are --

MR. FUTCH: Yeah, so does it get down to the level of duties when you say it's a written protocol?

MS. HINES: I think that the Nurse Practice Act changed so -- because their protocols have to be reviewed by the Board of Nursing; and of course, we don't have that capability and that's their review. Since I've been gone from there, so for the last six years, and so those all have to

be reviewed but they have nurses on staff. As far as I know, the PA's are basically just a supervisory agreement like the RN's are.

MR. SEDDON: From my understanding how it works for PA's, it's anything that the supervisory physician is privileged for they can do. That's where we had an issue a few years ago, remember, with fluoroscopy. I remember there was an attorney general letter, remember about five or six years ago?

MR. FUTCH: PA's and nurse practitioners being considered licensed practitioners for the purposes of Rad tech, yeah. Which changed by the way, the PA part of it changed. We'll talk about that sometime. The ARNP's never did, but anyway--

Well, here's what I would -- what I'm thinking the more I hear folks talk about this.

(Whereupon, Mr. John Williamson entered the meeting room.)

MR. FUTCH: Well, hello there. There's a spot for you over there.

Everybody, this is John Williamson. He'll be later in the agenda after lunch talking about NASA and some other things.

What I was thinking when I first saw this,

and the reason that I didn't just cut out the role delineation and substitute the ELCA was that -- well, two things. One, the ELCA says it's specifically for entry level RA's whereas the rule needs to apply to everybody; and two, although it went from personal supervision to less restrictive supervision (on some things), it went the other direction on some things that were formerly listed as general, like review the patient record. If you take it at face value, everything for the entry level person should be a direct level supervision. So I was hesitant -- I liked the part that got less restrictive, but I was really hesitant to say, well, gee, everything else has got to also be in direct level.

So what I'm thinking is perhaps we should adopt -- still go ahead and adopt the ELCA for one purpose, which is at least it's got a list of activities. Excuse me. At least it has a list of activities on it so that if you're a radiologist who's employing an RA for the first time or an RA who's being employed for the first time by a group, you'll have a specific list here that everybody agrees is part of the thing that you can do. I mean, you can at least point to it and say

that's a list of duties that I can do.

As far as the level of supervision, we could write the rule to say something along the lines of, you know, for entry level radiologist assistance the beginning level of supervision is as listed in the entry level clinical activities, which is direct. Then for, you know, all other RA's, it would be as listed in the practice standards which are very vague and very general, which essentially means that the radiologists can delegate what they want at what level of supervision they want. Then I don't know exactly how to write that.

MR. PASSETTI: Then you have to define what "entry level" is and how long it is instead of just leaving it up to the radiologist to determine the supervision level.

MS. BONANNO: Because initially if you're starting into a procedure you've never done, you're entry level at that point.

MR. PASSETTI: You're entry level even if you're an RA for 10 years, right.

MS. HINES: But when a statute goes out can they enforce anything unless we say entry level is this length of time or this level, I mean, is

there a subjective way -- an objective way to do that?

MS. DROTAR: That I would think would be difficult because you're talking about keeping those things at entry level, then if you've never done a lumbar puncture and three years later is now when somebody is training you to do that, but you're at an advanced level. So it's going to be very subjective to the procedures that you've done.

MR. FUTCH: Yeah, maybe they could just adopt both documents and not specify in the rule anything about entry level and let the documents exist on their own as they're written.

MS. DYCUS: And correct me if I'm wrong on that on the ELCA because those are the requirements to graduate from the program or sit for the examination so that any of the ELCA have -- there's been a competency level to get to "achieved" in order to get there, right, with those procedures? You have to have done a competency in small bowel with enteric plexus in order to graduate from the program.

MS. DYCUS: And you have those documents when you take them to your first radiologist. As an intern, I've done 20 needle localizations without

any adverse events. You have all of that to take to help them determine where your level is for that.

MS. DROTAR: So they actually call that an internship where you're doing those things?

MS. DYCUS: Yeah.

MR. FUTCH: So the first time you work here you're an entry level person; the next day you're not?

MS. DYCUS: Correct.

MR. FUTCH: Well, I've been spinning around with this one for a number of months now. We told the one person who said their facility really wanted them to be able to do this lumbar puncture at the direct level, we said -- there's always, you can always ask for a variance from the rule.

I think we'd probably grant it given the, you know, the document that we can see for sure even for entry level people who says it's now at the direct level. It's not going to make a hill of beans of difference when you go to try to get reimbursed for it because you still have that issue that's out there.

MS. DYCUS: And there are some practices who think that even not getting reimbursed for some of

the procedures still warrants having an RA in their practice. So some are willing to forego that reimbursement on some things.

DR. ATHERTON: I have a question. The radiologist assistant, say they do something wrong, is ultimately the supervising radiologist responsible, also? So it's going to be in their best interest not to approve them or allow them to do things that they're not comfortable with.

MR. FUTCH: Well, I'm not an attorney but I would imagine that's how it would work. I don't think we've had a case yet.

DR. ATHERTON: So I don't know if it has to be that way.

MR. FUTCH: Well, let me say I don't think there's been a complaint filed against them. I guess it would probably come to me and I -- have you heard of it? Yeah.

Well, let me ask you this. Are you leaning more toward Christine Lung's approach where we kind of say basically whatever the physician delegates or whatever they specify in terms of duties and we have absolutely no adoption of ELCA or the practice standards? Or are you leaning more towards something that involves adopting ELCA

and the practice standards, one or the other or some combination of the two so we have some document that a person can reference?

MR. SEDDON: I think Christine Lung is following like how they handle the PA's in general, not directly, just in general, because that goes back to Bill's point of ultimate liability lies with the supervising physician or lies with the physician in all cases. So that's why I think they're taking this approach saying, I mean, for whatever reason for the RA's we have we're very specific and this is going to be constantly changing every few years because of the changes in the field and competency. So are we boxing ourselves in by adding five more years, it's going to be a change in this.

MR. PASSETTI: We boxed ourselves in the first time by adopting that document.

MR. FUTCH: Yeah, I think -- well, two reasons. One is it was brand new and we did not have anybody who was doing it -- but also, I think, you know, the society and the legislators who brought this together, they wrote a statute that's fairly prescriptive when it comes to what the Department must do. It says we must

promulgate a rule which, you know, it's in there, you all read it, which contains specific duties with the level of supervision agreed to by the guidelines of the national groups. In retrospect, I kind of wish that little section said nothing about the Department promulgating a rule and just reference the national groups in the standards that they had.

MS. DYCUS: Christine is also coming from the aspect that's a national organization and many of the states have adopted their RA laws through their medical board and not through their radiation board. So she's probably mimicking for the benefit of other states, too, how they're reflecting it.

MR. FUTCH: Partly, I'm not sure if I -- if I go to, for example, what Christine wanted; I'm not sure if JAPC would approve that, and not the part where she's asking that the thing be sent to the Department, but just the part where we don't have any specific -- see, the statute says -- where is that?

DR. SCHENKMAN: Does it have to be that specific? Can we do the entry level one?

MR. FUTCH: "...performs specific duties

allowed for an RA as defined by the Department by rule."

MR. PASSETTI: The word I kind of got stuck on was it must be consistent with those; it doesn't say it has to list specific procedures in supervision.

MR. FUTCH: Well, I think if I just adopted the two documents I think that would fly. I mean, I'd just say the 2011 ELCA and whatever the version the ASRT Practice Standards are hereby adopted to meet the requirements of statute whatever we're in here.

MS. DROTAR: In the ASRT practice standards, you've got the scope of practice outlined; and as that changes then that would just go back to refer to that document and what changes within the practice standards, too, if it gets narrowed or expanded in any way without having the change.

MR. PASSETTI: In the rule you have to adopt the date of the standard, so if it changes you have to go back and redo the rule and change the date on it. I mean, it's just -- you can do it; it's just you have to actually have a specific date on there.

DR. SCHENKMAN: Well, what I was thinking was

maybe you could adopt this entry level one but with another paragraph that says that the level of supervision is based on the physician's assessment of the --

MS. DROTAR: Skill level?

DR. SCHENKMAN: Yeah, skill level or abilities and can go from, you know, direct to general at the discretion of the physician.

MS. BONANNO: She said CMS; how is CMS going to pay for without the physician being there? He'll be there or determine that he doesn't want to be.

MR. FUTCH: Adopt the ELCA but then say the level of supervision and duties can vary as delegated by the supervisor according to the ASRT Practice Standards; because with that last statement in there with the level of supervision required by such guidelines, that's the only one that allows -- it specifically says the supervisor can do that.

DR. SCHENKMAN: Okay, so that would be fine. But then you're not limiting it so much to any one thing, and as the supervising radiologist feels that the level of competency is going up they can start giving the person more independence.

DR. SCHENKMAN: Right. That's the practical thing.

MR. PASSETTI: We can try to do that, be practical if we're going somewhere.

MR. FUTCH: Okay, so everybody seems to be nodding their heads that that's a good idea.

Do you want to take a vote on that one now that we have somebody to vote with?

DR. SCHENKMAN: Okay. Do we need a vote to approve that?

MR. FUTCH: Yeah, why not?

DR. SCHENKMAN: Does anybody have any discussion before we have the vote? The vote is to use the entry level as the base and then as the physician feels that the RA becomes more competent they can increase --

MR. FUTCH: What I would say, if I may?

DR. SCHENKMAN: Go ahead.

MR. FUTCH: The motion that somebody might want to make is to adopt the ARRT ELCA but add some language to the rule saying that the level of supervision and duties can vary, as assigned by the supervising radiologist according to the ASRT Practice Standards.

MS. DROTAR: I make a motion.

MR. FUTCH: What I just said?

MS. DROTAR: What you just said.

DR. SCHENKMAN: I'll second it. Okay. All in favor, aye?

COUNCIL MEMBERS: Aye.

DR. SCHENKMAN: Opposed? Okay.

MR. FUTCH: It is now 11:45.

DR. ATHERTON: I have one question that's not really related to the voting, but it says here the RA is prohibited from performing duties specified in this section. Give me an example of what those duties are.

MS. HINES: They can't read the x-rays.

DR. ATHERTON: Okay. That's the only thing probably?

MR. FUTCH: Yeah, and the statute has a few things they can't do.

MS. DROTAR: They can't prescribe.

MR. FUTCH: They can't do anything with nuclear medicine or therapy unless they're also a nuclear medicine tech and therapist.

DR. SCHENKMAN: Do you want to real quickly go back over so we can vote in the minutes and --

MR. FUTCH: Oh, yeah.

MS. BONANNO: We need it for a quorum.

DR. SCHENKMAN: Yeah, we needed it for a quorum.

MR. FUTCH: I think we have time to do just the minutes and then we need to get over to the other one.

DR. SCHENKMAN: Okay. We wanted to approve the minutes of the October 5, 2010, meeting.

Does anybody have any discussion about those minutes?

Okay, so all in favor of approving the minutes?

COUNCIL MEMBERS: Aye.

DR. SCHENKMAN: Any opposed? Okay. That's done. Election of chairpersons?

MR. FUTCH: Let's do it after.

DR. SCHENKMAN: After? Okay. Then we're caught up.

MR. FUTCH: I think Macaroni Grill. I have some stuff to set up here, so I think Bill or Janet know the way if you all want to go ahead.

(Whereupon, a lunch recess was had.)

DR. SCHENKMAN: So do we want to vote on those things first?

MR. FUTCH: Yeah, let's -- whichever one you

want, we need to talk about the Chair and the Vice-Chair and then the specialty technologist, get votes on those, too.

DR. SCHENKMAN: Okay. So why don't we start with the Chair and the Vice-Chair.

MR. FUTCH: Do you want to describe? Well, I can do it.

Basically, Dr. Janowitz is currently the Chair. Randy's the Vice-Chair. The terms are up this year, I guess we open for new nominations and see if anybody would like to do that? If not, accept discussion of just re-nominating you guys if you're willing to. Since Dr. J's not here, I'm pretty sure he would be.

DR. SCHENKMAN: I'm sure he would be.

MR. FUTCH: We just look for the meeting when you're not here and then we nominate you.

DR. SCHENKMAN: Is anybody else interested in being nominated for Chair or Vice-Chair?

Okay.

MR. FUTCH: You might have to sweeten the deal a little. I think they'll accept money.

DR. SCHENKMAN: Can we take a vote on whether to retain the current Chair and Vice-Chair as it stands?

MS. DROTAR: I make a motion to nominate Dr. Janowitz for Chair and Dr. Schenkman for Vice-Chair.

DR. ATHERTON: Second.

DR. SCHENKMAN: Okay. All in favor?

COUNCIL MEMBERS: Aye.

DR. SCHENKMAN: Opposed? Okay. Well, thank you all.

Now we're going to do the specialty tech.

MR. FUTCH: Right, and basically what the Department would appreciate is a vote on the bills as they're currently written, the Council approving them in their current form if that's the will of Council.

MS. DROTAR: So moved.

MS. DYCUS: Second.

DR. SCHENKMAN: Okay. So let's vote. All in favor of keeping the rules

MR. FUTCH: Proposed legislation.

DR. SCHENKMAN: Proposed legislation, excuse me, as it stands? Aye?

COUNCIL MEMBERS: Aye.

DR. SCHENKMAN: Opposed? Okay.

MR. FUTCH: And I think we're down to D3.

DR. SCHENKMAN: D3, we're already -- oh, we

didn't do fluoroscopy. Right.

MR. PASSETTI: I'll be doing that one. The folks from our x-ray department are not here today. I think a couple of meetings ago we went into a lot of details on this issue with the fluoroscopy. Just to refresh everybody's memory, there was some concerns with the registrants and some of the manufacturers of the equipment. A couple of reasons.

One is our rules were a little different than FDA, who regulates the manufacturers. They look at it as equipment performance of what they manufacture, and we look at the fluoro dose rate for fluoroscopy from the patient exposure point of view. So there were some differences on how we measuring the output of fluoro machines. It was causing some confusion with the manufacturers when they came in, if we would cite a registrant how they would get their machine back in compliance.

So we worked with several manufacturers, mainly one, and what we ended up doing is behind -- we decided we needed some rule revision and it's behind Tab D3. Basically, what we have here is proposed regulations and what it mainly does is that we clarified three definitions there on the

top of the first page. Mobile C-arm, a C-arm system, and a C-arm fluoroscope.

One of the problems that we were running into is that people that were using mobile C-arm systems, they were using them in the same room on the same table. They didn't move; they just stayed there and they were rooms that were used basically as a stationary fluoro. We were going in and measuring them the same way as we would a stationary fluoro. So a lot of times they weren't meeting the FDA requirements.

So after meeting with manufacturers, they agreed that if we clarified the definition of what is a true mobile C-arm, something that you move from room to room and use on different tables and patients, that would be mobile. Then under the C-arm system we clarified that it means a stationary or a mobile C-arm that's routinely used in the same room with the same patient support device. So we clarified the definitions.

Then the other issue is the way we were measuring the output during our inspections. What it came down to is we agreed -- a lot of the registrants agreed and the manufacturer agreed that if a particular facility has procedures that

spells out how they use that fluoro, how they set it up, how they position the patient, that we can measure that the way they use it, not necessarily in a standard, most conservative manner. So, hopefully, that makes a little bit of sense.

So really the only thing, the major part of the changes are the three definitions up front, and then on the second page at the bottom starting with number four, and that's where it basically says if the registrant has a radiation protection program that spells out how they will use the machine, then we'll measure the machine in the same mode that they use it. We found after working with the manufacturers that in most cases if we measure it how they're using it, they're going to meet those fluoro limits.

So we're getting ready to start the rule promulgation process on this piece. If you have any -- after you go back and look at it, if you have any comments, questions, or suggestions, we still have plenty of time to take those into account as we go through the rule making process. But if you have any questions now I'll try to answer it; I don't know if I'll be able to but will try to -- we'll get you the answer for sure.

DR. SCHENKMAN: Does anybody have any questions?

I have a question. When you say that they did not meet the standards, but when you measured them the way they usually meet the standards, aren't the standards supposed to be a strict measurement?

MR. PASSETTI: It came down to -- there were two standards. The FDA sets standards for how the machine performs and we were looking at it as how much dose the patient was receiving. So there was two different ways to measure that. What basically we did is we measured the worst case scenario where we went into a fluoro room, we set up the equipment where you're going to receive the very highest dose, and some of them were not passing that. But if you put it at actually the way they were using the equipment on the patient, they were meeting the requirement.

Does that make sense?

DR. SCHENKMAN: So when you put it the way they're actually using it, it's not worst case scenario?

MR. PASSETTI: Right, a lot of times, right.

So what we're saying is if you don't have procedures -- if you don't document how you're doing your thing, we're going to come in and do a worst case. But if you have procedures that tell us exactly how you set up your equipment and your patient, we'll use what you're using to measure that.

DR. SCHENKMAN: That makes sense.

Anybody else have any questions, comments?

MR. BURRESS: What are the dose limits? What's the range or what's the magnitude of them?

MR. PASSETTI: You know, I don't think I'm going to be able to answer that. I think the maximum one is 10 R per minute.

MR. SEDDON: So I know the issues we had in previous discussions with Don is to make sure that all the vendors could meet -- Phillips, I believe, is the one you guys worked with initially, and so I think the question was whether GE could also meet the standard because the problem is they're following the FDA traditional guidance which is 30 cm which doesn't fire to calibrate their systems, and now that it's all computerized you can't just go in and change things automatically.

I know Phillips said if they used this

criteria you have here, their systems would pass and they can calibrate them properly. I know GE had been telling us at one point a couple of years ago that they were having to, I think, cheat the system somehow to make it pass by using this criteria.

MR. PASSETTI: Yeah, we're getting ready, we haven't done it yet, to send this draft language to the manufacturers so they can look at it and make sure --

MR. SEDDON: What's happening now on a lot of those, especially for cath labs, they do special filtration, especially if they're constantly changing the type of filtration. So it's not the old days where you adjust the Max MA and that's it; now it's all very complicated and calibration occurs and how they actually go ahead and adjust the beam, harvest the beam and exposure rate. So it's not something you can just tweak down a little bit.

MR. PASSETTI: Like I said, if you have any comments or questions, we have time as we go through this process.

MR. SEDDON: I think the main one is to make sure you talk to GE and make sure they can pass

it. I don't really see a problem there, it's a very low dose; but GE is the one that we seemed to have the biggest challenge with.

MR. PASSETTI: Okay. Thank you.

DR. SCHENKMAN: Okay. So moving right along, proposed rule revision is continued. We're done with that now?

MR. FUTCH: I believe so.

MR. PASSETTI: I think we're done.

DR. SCHENKMAN: Okay. So now we move to introduce Mr. Williamson.

MR. WILLIAMSON: Good afternoon. I'm here to talk to you about the preparations for the Mars science laboratory launch.

I'm the administrator of the Environmental Radiation Program. I've been involved in planning for anomalies with the launch vehicle since late 2006.

Curiosity is what they're spending all their money in launching this. It's another rover like Spirit and Opportunity that were launched in 2003 only Curiosity is a much, much larger rover. Spirit and Opportunity were about two by two or so, little desktop-type size rovers. This one is actually large enough -- you can see some pictures

of it -- you could actually ride this one if you wanted to.

Just a little bit of detail about it. It's a rover that's going to assess whether Mars had water on it at some point in the past. It has a whole mess of different scientific instruments that they put on. The video I'm going to show shows one of them in action. It's going to collect rocks and soil, do analysis of them actually on board the rover, and do the chemical composition of the rocks as well as whether there's any signs that there was ever any water on it.

More detail about it. This is really -- they spent a lot of effort making this real cutting edge, and I'll go back to the video. From the way which they're actually going to land it on Mars to the whole design of it, it's a really cool design that they use for the whole thing. This actually moves a lot faster than the previous ones, too. I think this can move up to 90 meters an hour, so 1-1/2 meters a minute or so. So it's really racing along there.

The one thing about this is they're using an RTG, a radioisotopic thermal generator, on board

this one. Spirit and Opportunity were powered by solar panels, and one of the problems about Mars is it has a lot of dust and when those solar panels got covered with dust they greatly affected the amount of power that the rover could generate. At one point, they actually had a massive storm on Mars that actually served the opposite of what they expected; it actually blew all the dust off the solar panels, which is why you saw they had an extended life span on those two devices.

This one actually is going to have an RTG, radioistopic thermal generator, and it will probably have somewhere between -- a normally RTG's in space have a 10 to 15 year life span, so they expect to be able to get much more data on this one. I actually have -- it would probably help if you could see the video.

MR. FUTCH: It's an amazing soundtrack.

MR. WILLIAMSON: Yeah. Let's do it this way. I guess I'll have to stop. It never works.

PANEL MEMBER: How long did the other two last, the other two rovers?

MR. FUTCH: One of them is still going, I think. One stopped last year. I think Opportunity is still going after a fashion.

I'm glad to know it wasn't just me who was having problems with video today.

MR. WILLIAMSON: All right. There we go.

(Video plays.)

MR. FUTCH: A little different than the bouncing ball landing on the Spirit and Opportunity. It's got its own laser weaponry, we hope.

DR. SCHENKMAN: That's impressive.

MR. WILLIAMSON: Now that you saw the video, you'll have a test on everything that's going on.

This is not the first time that radioactive sources have been used to use power in space. All the way dating back to the Apollo missions, they had radioactive sources, the little more famous ones the Voyager series, the Pioneer series. The last one that was launched was Pluto New Horizons in January 2006. You guys may remember Cassini, the one that was launched in 1997. Cassini essentially worked flawlessly and is investigating the moons of Saturn right now. It's giving some really, really fantastic images of Saturn, and that was powered by three RTG's making it the largest amount of radioactive material that was ever launched on a single mission -- about 330,000 curies of Plutonium-238. You see a -- some of

them were actually launched on -- two of them were launched on the space shuttle and Cassini went up on a Titan IV and two of the New Horizons went up on that one, and that's five.

Just a breakdown of what the MMRTG is. MM is for the multi-mission, RTG is the new design that the Department of Energy came up with. It uses the same theory as all the previous designs only they made it a more modular system so that they can add additional power, like by adding additional modules to it. And I think on this one it's got -- an RTG essentially uses the decayed heat of an alpha emitter, Plutonium-238, to generate electricity using a thermo coupler. A thermo coupler simply uses two dissimilar metals; you have one that's really hot, one that's really cold, and the difference if you run a line across them you can actually generate electricity.

Obviously, if you're in space it makes it really easy to have the cold end of it and then if they're using the Plutonium-238 to produce the heat on the other end. It's actually got eight different modules inside with Plutonium-238 in it that make up a single RTG, and then it uses a lot of graphite shielding for the designs, 10.6 pounds

of Plutonium-238 approximately 59,000 curries of material. You probably didn't notice it, but in the video you can actually see a clear rendition of where this RTG sits on the back of the rover.

Here's another breakdown of it that shows a little bit more detail with the eight actual graphite blocks that have -- we're saying 10 pounds of Plutonium divided by eight, so there's about 1-1/2 pounds of Plutonium in each one of these graphite cylinders here.

Another cut-away of it showing the actual, some of the safety features that they've put into these things. This is a single one of the cut-aways, you know, I said there are eight of those on it and they actually have the Plutonium fuel in a ceramic pellet form on the inside and it's encapsulated by an iridium outer shell. Iridium is very, very hard and gives an extreme impact and heat resistance. Then it's got graphite covers around that and those form an impact shell as well as high temperature protection.

Some of the different safety features that are built into a power source, the graphite impact shell provides impact protection and ablation, so if it actually -- once the spacecraft goes up and

doesn’t get a complete burn, it starts to come back down and the graphite shell is actually helping to protect that Plutonium-238 from being burned up in the atmosphere. It serves as a great insulator, thermal protection; they have a graphite impact shell, an insulator, and an aeroshell which is the outer part of it. It’s a ceramic fuel which means that when it breaks up, typically it breaks up into chunks. It does not break into powder, that Plutonium Oxide powder is not considered something that is generally going to happen even in the most severe accidents. It has a very low vaporization rate on that fuel, so it’s not going to vaporize and spread all over the entire world and kill everyone on earth like a lot of the people who are against this will tell you.

It’s highly insoluble; when it hits water, it typically goes straight to the bottom and sits there. It’s not absorbed into any plants. Typically, when it gets into soil it just stays there. It’s not also absorbed particularly well in the human body. Because of that, the majority of it tends to move right through as insoluble material.

It is an iridium clad fuel, fuel containment

by its impact protection, 2400 degrees Celsius for the melting point, so it's going to help protect it in case of the worst accident. The actual worst accident scenario isn't actually a re-entry, but it's the vessel -- the spacecraft or the rocket going up, turning around and coming right back down, hitting the launch pad, and setting off all the rocket fuel. That's the worst accident case scenario that they can actually generate.

Why are we really so concerned about that? Well, you know, what they say about spacecraft. It's two million moving parts, each one of them built by the lowest bidder. The nice thing about this particular vehicle, and it's an Atlas V 541, it has a Centaur upper stage, and this is actually the ring that you saw that was attached to the actual spacecraft itself. That's considered part of the spacecraft and it is actually coupled to that upper stage. It's got four strap-on boosters on the bottom. The Atlas rocket has a 100% success rate so far, so it is a very, very successful launch platform. Obviously, the first time it will happen it will be less than 100%. It still is a very successful launch platform. It does have its inherent risks, of course, as any

type of space launch does.

MR. SEDDON: About how many launches?

MR. WILLIAMSON: Well over 100. I think 115 or so.

The actual spacecraft itself -- I just pointed out that ring, the ring is what holds it to the Centaur, then it's got the back shell which actually covers the descent stage, the descent stage which is what we saw during the retro-rockets and then using a sky crane to actually lower the rover and then it's got a heat shield on the bottom side of it.

When you're looking at the rocket on the pad, all of this is actually upside down because as it goes up and it goes through space and then it separates from this, and then that continues on and it flips over on the heat shield, and obviously the whole thing is upside down as you're looking at it on the pad.

The rover itself on the back end of it is an RTG, and the actual RTG is actually open to the atmosphere in Mars. It's got the vent fins on it to radiate any excess heat that builds up. This is, of course, the big instrument module that we saw, and of course, the wheels are actually quite

large. If you're familiar with the SUV that you can buy for your three-year-olds to drive around, this is about three to four times the size of one of those. The tires are about 12 to 14 inch tires. They are kind of expensive tires, though. I think they're $100,000 apiece or something, but of course, if it has flat tire on Mars it costs a lot to get the tow truck there.

The accident scenarios that they've actually looked at, the launch area, land impact, near shore. I tell you, the real truth of the matter is, for us who are sitting over at NASA all we want is to make it the first 50 seconds because if it makes it 50 seconds, we're done, okay. And that's actually a much shorter time. This one says it's actually blame-clear in 13 seconds. So after a very short amount of time, less than a minute, everything that the people in Florida have to worry about is over with, okay. So really that's the really crucial one.

The other accidents, of course, near shore then it becomes the Coast Guard and the Navy's responsibility. Sub-orbital means it doesn't make the complete burn in the orbit, it can actually drop part of it on the southern part of Africa or

even on Australia. They have contingencies about that. Orbital control where I can actually get into a vehicle -- it would take a number of days in order for it to actually come back down days or weeks. I think it's like 300 days, depending on how long the second stage burns. Then, of course, control orbit, the different configurations you could have for an accident.

The good news. This is the final environmental impact statement. The probability of a successful launch is 91.7%. This takes into account everything -- not just the spacecraft but everything else that could go wrong. Remember, you have 100% success with that particular spacecraft. You can have a completely successful launch of the rocket and you could still have a failed mission. That's part of the reason you see the 91.7. Overall probability of an accident is 1 in 220, and this really is based on figuring out the odds of the rocket going out, turning around and coming right back down, having an intense fire that actually fractures the RTG's itself. The probability of an accident in the launch area with release is 1 in 420, so about half of that probability of release would occur in

the launch area itself.

Mission risk accident probability, given the accident is 0.14. Fairly low probability. It is still something that we consider which is why we're doing the whole contingency planning.

By the way, in general, when we're all talking, we never refer to it as an accident. It is an anomaly. Some of the previous missions, the Department of Energy owns the radioactive material. Even when it goes up, the Department of Energy owns the radioactive material. We have been told that that RTG is actually considered a facility under the law so that the Price-Anderson Act indemnifies DOE if something happens. So you've got this thing that weighs 80 pounds that is a Department of Energy facility. Okay.

So what has the Department of Energy done in the past to make sure that they have preparations in case something actually happens? Dating all the way back to 1989, Galileo had two RTG's. Galileo was intended for Jupiter. It went up on a space shuttle and that's something that even if the space shuttles were still operating they would never do that again. For obvious reasons, the space shuttles don't have nearly the success rate

that they have going up on single use rockets. More than 300 DOE personnel on the ground in central Florida in preparation for an accident.

A year later Ulysses also went up on a shuttle. It had a single RTG. That was a mission looking at something to do with the sun. Once again, 300-plus personnel.

In 1996, Mars Pathfinder, with only 16, it had heater units, not RTG's to provide electricity but lightweight heaters used powered by the decay use as well. Many less people because, one, there weren't nearly as much material that there was in the RTG format.

Cassini, I mentioned earlier, was the largest amount of radioactive material ever used, 330,000 curies. DOE had 112 personnel. One thing to realize is that with each one of these launches you also had State and County personnel who were also involved. For instance, on the Cassini, you'll see 112 people. The Bureau of Radiation Control had between 15 and 20 people involved in that particular launch.

Spirit was the first rover, Opportunity was the second one. DOE only had six. The State of Florida provided personnel for

the laboratory and the field team as well.

Pluto and New Horizons had 68. On this particular one, they're cutting down to 38 people. Only 27 of them on the ground in central Florida, and the consequence home team in Nevada is going to have 11 people. You ask how in the world can you continue to cut down on your numbers here?

Well, part of it is that Cassini was three RTG's, there's one here. So, you know, three times as much material, three times as many people? Well, not necessarily. It has to do with the type of equipment that we're actually going to be using to monitor for. You guys know, obviously, there have been a lot of advances in electronics since 1997. I mean, you can carry around a cell phone that will do all kinds of things that you had to have a whole computer to do fourteen years ago.

Part of the deployed field assets that is really different about this is an ECAM. An ECAM is an environmental continuous air monitor, and it's basically an air monitor in a box that you deploy out somewhere. It breathes at twice the normal human rate, it pulls the air in about five or six feet tall, and it runs it through a cyclone

to separate out the respiratable particles and the non-respiratable particles and it coats those on a filter and then counts them on an alpha spec.

For those who are familiar with radiation, we have a term called the DAC, the derived air concentration. If you take the total amount of radiation that an occupational worker is allowed to have over the course of a year and you figure out how much of it -- if you got it all by inhalation, when you divide that value by 2,000 hours you get a DAC hour, how much radiation would you keep breathing in in one hour that will accumulate to be his annual limit of intake? Well, this particular item, an ECAM, can calculate one DAC hour of sensitivity in about 15 minutes of run time. So in 15 minutes it can tell whether the radiation there is exceeding what the annual occupational dose is. NASA has bought 30 of these at greater than $30,000 apiece. They will be deployed for the launch. They have all been tested for the last four or five months. We used some of them with the Pluto New Horizons launch in 2006, and they went out and bought a whole bunch more. There will be 17 offsite and 9 onsite and these are the pre-deployed ones. They've

already picked the locations where they're going to put them. In general, they're fire stations where they have security because they use a satellite uplink plus it's a $30,000 piece of equipment and they also run power to them.

Then we're going to have four mobile ECAM systems running around, two of them onsite and two of them offsite. What we have at the mobile one, we have a team of somebody who's in a pick-up truck and they've got this ECAM in the back of a pick-up truck and they drive somewhere and they get it out of the pick-up truck and they set it up. They set the satellite link up and they bring it online, so let's say the day of the launch we've got these 26 pre-deployed and you know which wind direction the wind is going, okay. So then they say, okay, if we're going to have a release, it will be blowing with the direction of the wind. So let's take our mobile ECAM and let's go put it right smack there where the middle of the wind direction is going to blow so that if something does happen, if we have an anomaly, we will have a person which is what the ECAM is who can tell how much radiation is there, sitting there breathing it in telling you what the results are.

James is actually serving on one of the mobile ECAM teams.

MR. FUTCH: You've got me on the onsite team, right? I want to be as close to the source as possible.

MR. WILLIAMSON: We have offsite field teams. We have three offsite field teams that are aside from the ECAM teams. They'll be going around setting up air monitoring stations and taking care of all those additional -- I think that there's about 30 total sampling sites that will be around all the way from Volusia County all the way down to south of Palm Bay area where we've got monitoring equipment set up. In addition to the ECAM's, we have large air pumps that will also be running. These three teams will be running around doing all that collection. The Bureau of Radiation Control has six they're providing the field team personnel for the offsite teams and there's a number of onsite teams as well, including a medical D-CON team on site, so if there is an accident and one of the field teams needs to have help in D-CON they can do that, or the accident actually impacts some of the NASA workers, we'll be able to do that. There's also

two couriers with NASA who run samples offsite or onsite to the laboratories, if necessary. Five-person regular D-CON teams who can do decontamination of equipment, not necessarily medical. So there's a large number of different teams that are actually working on this, as well as those 30 ECAMs.

MR. FUTCH: You didn't tell them the best part, when we're all supposed to be there.

MR. WILLIAMSON: You know, I'll think I'll actually get into that. Some of the contingency planning that we've actually done. I I mentioned the first meeting was in late 2006. I think I've been through at least 11 meetings. I think I'm actually missing one; I just can't figure out when it was. It just all sort of runs together. We had pre-meetings where we decided the best way to set up our contingency planning and we had five different contingency planning meetings. We've done additional training. Then we have one, two, three, four -- we have five additional days of training before the actual launch day, and then on Black Friday is the opening of the launch window. So while everybody else is out shopping for Christmas bargains, we're

going to be there at 6:00 in the morning getting ready to send something up.

DR. SCHENKMAN: We're proud to know you.

MR. FUTCH: We will be there.

I mentioned the ECAM. This is an ECAM, okay. You can see 30 of them all set up over at NASA. They were running them for three weeks to make sure that every single one of them was operational. They had their satellite uplinks packed. Some of these date back to the Pluto New Horizons Mission. They've been updated with the software and firmware, but it is a fairly well known system. They've also ended up using them over at Los Alamos National Labs when some of the fires took place earlier this summer to do monitoring for health contamination. Los Alamos had a lot of -- it was a weapons production factory and they didn't always care what they did with their waste in previous years, so a lot of the scrub brush out there, like the sage brush, actually has uptake radioactive materials, so when it burns it makes radioactive particulate. So they sample the air there when they have big fires.

DR. ATHERTON: So these are going to be placed around the country during the launch in

case there's --

MR. WILLIAMSON: Around Brevard County or Volusia.

DR. ATHERTON: In case there's a --

DR. SCHENKMAN: An anomaly.

DR. ATHERTON: Then they'll be there to detect the level? Okay.

MR. WILLIAMSON: Yes. It's like a person standing there breathing it in at twice the normal rate --

DR. ATHERTON: At first I thought they were going to be on the shuttle or the rover going to Mars, but now --

MR. WILLIAMSON: Every single one of them has a number of different things. They have a satellite uplink. They also have a point to point IP, so they also put them where they can do a direct link to a repeater, and then do radio communications back to NASA. So they've got at least two and I think they also were even looking whether they would use cell phones, so they have multiple redundant ways of communicating back.

MR. FUTCH: Notice the high tech anchoring system.

DR. ATHERTON: When was the first time that

these were used?

MR. WILLIAMSON: They were used with Pluto New Horizons as well, not as many of them.

DR. ATHERTON: So now it's the standard that these are used?

MR. WILLIAMSON: It appears that they're going to be --

MS. BONANNO: That displays radioactivity on board.

MR. WILLIAMSON: Previously, when we did monitoring you had to take an air sample and you had to take the air sample off and you had to count there and then after you count you had to rush it back to a laboratory. These do all that for you and they do it in 15 minutes. It's just they tend to be kind of expensive to have sitting around.

MS. BONANNO: I could see a really cool movie about all this, you know.

MR. WILLIAMSON: One guy sits and watches all of those ECAMS. This is Steve Holman. He's the senior scientific advisor for NASA. He works at Lawrence Livermore National Labs out in California. He's one of the guys who's so scary smart it's hard to talk to him at times. He's

also very approachable which is nice, but on the screen here you see most of them are agreeing; when they actually reach a level of alert which is above that DAC-hour sensitivity, they start turning colors. He's the guy -- he's worked with Canberra who's the manufacturer of the ECAMS. Canberra as the manufacturer is actually going to have a team onsite who can go out and run trouble shooting if we have one of the ECAM's go down to make sure that we have as many as possible up and working before the launch.

We had mobile classroom training back in late March where they actually went through and showed the field teams what they're going to be doing and learned how to set up an ECAM. Somewhere in there is a picture of James.

MR. FUTCH: I'm underneath the smudgy thumb print in the middle of the picture.

MR. WILLIAMSON: They went out and practiced setting one up so they know how to do it. They'll be running the mobile systems, of course.

MR. FUTCH: That came in handy with that satellite alignment when I had Direct-TV installed. I thought we had fancy equipment; you ought to see those guys' signal meters when they

hook up a dish.

MS. BONANNO: Are these going to be in public places just around or no?

MR. WILLIAMSON: The majority -- 26 of them, well, the ones onsite are easy. That's nine of them because they have controllers onsite. The offsite ones are generally located at fire stations. They already have security and power.

But the mobile ones we'll be setting up, I don't know whether they're using -- actually, they can't all be fire stations. They go set those up wherever they have to. That's the idea is that they'll, you know, it will be a single ECAM in the back of the truck. They'll go set it up and then they'll be able to go run for cover and then get there in a very short amount of time.

What they also did, the RAMS is a DOE-run database. I can't remember what it's called now. I have it on one of the later slides where they actually -- they can collect information on the readings in the field then they can use a tablet, a GPS-enabled tablet that has multiple forms of communications back, so it automatically relays the kind of information they collected in the field back to a database so they can then check it

in the RAD's you see and then start seeing where you're seeing high areas come in.

The RAM's MPCD is a multi-path communication device. It's another DOE item and uses -- this is a satellite dome here. It uses three separate means of communication. It can use a satellite dome, it also has cellular, and it also has a wide area network. So whatever area network by the wireless, so whatever it defaults, whatever there, and then it just keeps moving up. If it doesn't have the wireless then it goes up to -- if it doesn't have computer wire or network wires, then it goes up to cell phone. If it doesn't have cell phone then it goes to satellite.

You were asking where the stations, where these are going to be set up. If you look at this map here, it's not a really great picture of it, but you could see all the different locations they're going to have pre-deployed ECAMs and air monitoring systems.

DR. ATHERTON: And these have been deployed before the launches, have there ever been any abnormal readings before the launch?

MR. WILLIAMSON: No, this is one of the great things about Plutonium. The background levels of

Plutonium are almost zero.

DR. ATHERTON: That was my question.

MR. WILLIAMSON: Yeah. So if you see something, there's something seriously wrong going on. And that's one of the great things --

DR. ATHERTON: And they've all been tested?

MR. WILLIAMSON: Yeah, they've all been tested.

The other thing that's really great, because the background is zero, that's what gives you the ability to detect a DAC hour at 15 minutes. You know from doing counting of anything that if your background is very small it's easy to see any signal, so that's one of the nice things about working with Plutonium.

There's bad things about working with Plutonium, but that's one of the nice things about it.

NASA went out and bought a whole bunch of new equipment enough to run all 16 of their field teams and then have back-ups for each one of those. They bought FIDLERS, that's a field ionization detector for low energy radiation. It's essentially a really big sodium iodide that's really thin so it can see with low energy stuff.

Plutonium, you typically are looking at the peaks at like 17 KEV, which is a fairly low energy case. So you need a really thin detector. They also have alpha meters because of course

Plutonium obviously has alpha and then radiogen which are the Canberra meter that can take a whole bunch of different probes. So they bought a whole bunch of those. They updated some of the ECAM's.

I mentioned that they had loaned ECAM's out to DOE for the Los Alamos fires, but you see some of that equipment here. This is a FIDLER here, okay. It's got a little stand with it and this is the field energy that's active for low energy radiation. This is how -- if you have to walk around and detect where you might have a spill of alpha, you're going to be carrying the FIDLER walking around very slowly hoping that you're going to be able to get those radiations to the bottom of that detector. The only problem about FIDLERS is that because they have such a thin window if you set them down on a rock or something, you probably just punched a hole in it and that's a $6,000 detector you just ruined.

We had on August 30th, we had the Department

of Energy come down to our facility in Orlando and they provided field team multi path communication device training to the NASA people and also each one of our personnel, who is going to serve on a field team, and part of the field team training obviously has to do with learning how to use the equipment. But it's also just as simple as learning how to collect various types of environmental samples. We know we will be collecting vegetation, food crops, things like that, as well as soil; and there are specific protocols that you would use to collect these types of samples to make sure that when you take them to the laboratory that you can analyze them and know what the answers are correctly. So the guy in the blue are typically the DOE people, except for this guy right here, who seems to be in all the pictures.

DR. SCHENKMAN: Camera hog guy, yeah.

MR. WILLIAMSON: Learning how to collect vegetation here. This is talking about using some of the GPS equipment, I believe.

You asked about the training for the month of November. Okay. Not only are they going to ruin our Thanksgiving holiday, but for some of our

personnel they'll be traveling on Thanksgiving to be here, but our friends from the DOE will be arriving on the 8th of November and they won't be leaving until it goes up. The 8th is the travel day, the 9th is we're starting to get fitted for respirators, and then we actually start our training on the 10th.

Now does anybody remember what November 11th is? It's a holiday for most of us, although those who volunteered to work this, it's not a holiday. We're all going to be working as well as on Saturday; and Sunday we're actually having a full deployment drill. Then on Sunday night or probably Monday morning State people get to go back home and rest, but the DOE people, they're actually taking the MMRTG and they're integrating it with the spacecraft. So the DOE has to have field teams on standby the entire time before it goes up. So the DOE people get to spend pretty much the whole month of November here.

MR. FUTCH: So it's out on the pad from the the 15th or 16th?

MR. WILLIAMSON: Then the opening of the launch is the Black Friday and extends until, I think, December 17th so it's possible that we could be waiting around until December 17th. We

hope not because Janet's -- she's thinking of the money, too.

The worst case scenario is that it goes up and it comes right back down, then we're never going to leave. Then not only did we lose those two holidays, but we lose Christmas and New Year's and Martin Luther King and everything else afterwards.

I actually -- NASA provided some of the pictures at the end of MMRTG actually arriving onsite at NASA. These are REM balls, they're neutron detectors. This is the actual shielding around the RTG when it came in and it came in one of the DOE's -- I think they call it the SST or something safe transport. It's their armored vehicle that they use to transport very sensitive material. The great thing about these particular trucks are they have deterrents built into them so that if somebody tries to break into them the truck actually can get them.

DR. ATHERTON: Where does it come from? Where do they store this?

MR. WILLIAMSON: That was made -- I believe it was made in Idaho National Labs. Ironically, and I can't resist this, the material for the RTG

is from the former Soviet Union, sometimes known as FSU.

A picture the side of the truck opening up and using just a big forklift, taking it inside the facility, doing additional surveys on it. They're actually starting to pull the cover off and that's it. That's the RTG right there. The fit check, they actually took it and took it over to the facility where they're actually going to make sure that it actually fit and that all the connections fit as well, make sure that it will actually power up the rover. Once again, you can see in the clean room, the RTG itself, then of course they're using survey equipment the whole time.

This is the actual spacecraft. We saw that earlier. Here's the heat shield, this is the back shell. When they put the RTG -- this is now -- I think this will be made together. When they actually have to work on the RTG, they have to work through this tiny little window here after it's assembled. So if they have to do additional work on them, they don't want to split the spacecraft apart, they go through there.

DR. SCHENKMAN: And it already has the

radioactivity in it?

MR. WILLIAMSON: Yeah, the RTG is loaded. They've actually got it hooked up to an electrical cooling apparatus to pull the heat off. It's like anything else; if you don't remove the heat you could damage it.

This is the spacecraft again. This is a rover. This is one of those lights you can buy at Home Depot. You can see the size of the rover; it's actually a fairly large item there. The RAD CC, that's the Radiation Control Center. This is the command center for the radiation emergency contingency planning and operations during the launch. NASA went through and they re-did it all. This area here is where all the big shots get to sit and then this area is where the rest of the little guys get to sit. You know, the ones who actually do something. This is a conference table where the little guys tell the big guys what the maps actually mean.

MR. FUTCH: This is where John will be.

MR. WILLIAMSON: Yeah, that's where I'll be. I get to watch out -- actually, these windows right here, my desk is the third one down, and these are the windows and I get to turn around and

watch the launch going up. That's the one benefit of what I get to do.

Then, of course, the whole point of the whole thing is a successful launch. That's Pluto New Horizons.

MR. FUTCH: Is that where Space X built their launchpad or close to there?

MR. WILLIAMSON: I don't know.

(Applause.)

DR. SCHENKMAN: That's great. Does anybody have any questions for him?

MR. FUTCH: So if the news media calls and they want to know how concerned we are in Florida, we can all say you've received the instructions on how well prepared we all are for why this is not going to happen.

DR. SCHENKMAN: What happens to it however many years from now? It just stays on Mars?

MR. WILLIAMSON: It'll move around and get the Martians.

MR. FUTCH: Yeah, unless they throw it back at us it's going to stay there.

MR. WILLIAMSON: If any of you guys saw the first Transformers movie, they had transformers -- the decepticons stomp people they built a laser to

get rid of that guy.

MR. FUTCH: It really does have its own -- I'm kidding when I say it's laser weaponry, but all the scientific instruments are designed like John said to figure out if there's water and perhaps life. So when it's driving around, it can take a core sample from a rock, go up there, or something else, soil, and bring it on board; but to figure out if it wants to do that it's got the laser. It can use a laser, for example, from across the room to vaporize a little bit of the rock and look at the gasses coming off and decide whether or not it's an interesting enough rock to go actually take sample from. So it's got a Class 4 laser on it, which is laser weaponry in my book. I don't know about you.

DR. SCHENKMAN: Thank you so much.

MR. WILLIAMSON: You're welcome.

DR. SCHENKMAN: Okay. Are we going on to radioactive materials update?

MR. FUTCH: Yes.

MR. PASSETTI: Yeah, John and I are going to give you a little presentation or information on an interesting situation we've been dealing with in the last few months in the nuclear medicine

area. About -- I can't remember when exactly it was, but we got a call at the office in April 2011, customs and border patrol between the border of the United States and Canada, they have radiation detectors there and some people were going through and set off the radiation detectors. The first one -- after doing some evaluation and some isotope identification, they determined it was strontium. They did some more research, talked to the people, and they determined that they had a PET scan a few months earlier so they started looking into that.

And a few weeks later, they had another patient that was going across the border set off the detector. The first one, they called and said they received a heart scan in Florida. The next one, I think the second one -- they saw the same thing and said, yeah, I had a heart scan in Nevada a couple of weeks ago or a couple of months ago. Then a third person came along and they detected it again in a similar situation. Yeah, I had a PET scan a few months ago.

So we started looking into it and it kind of developed from there. Most of you, most of the people here are familiar with nuclear medicine but

just a little bit of a background. The radio isotopes they use in nuclear medicine typically or most of the time come from -- it's produced for what's called a generator and it's a device that has a column of an isotope in it and it's called the parent isotope. When that decays, usually it decays to a daughter isotope that has a short half-life, and that's what they use -- they take the daughter out of the generator, they inject that into the patient and do their imaging with nuclear medicine. So you have a parent, that decays, along with the parent it decays to the daughter, short-lived it's used in the patient. Typically, you'll hear of molybdenum technetium generators. That's what you see in 90% of the cases. But there's also a generator that they use in patent imaging and that's what this generator was; it's called a strontium rubidium generator.

So the long-lived column is strontium, it decays to rubidium, and they inject that into the patient to do heart studies with.

Now with these generators there's always the potential that that long-lived isotope that is the column that's decaying can do what they call break through and come out with the short-lived isotope.

So in nuclear medicine facilities every day before they administer an isotope they do a breakthrough test. So, you know, on molybdenum technetium generators they do what they call a moley breakthrough test to make sure there's not too much of a longer-lived isotope in there. They do the same with this strontium rubidium generator. They want to make sure there's very little strontium breaking through.

So when they started detecting fairly high amounts of strontium in these patients crossing the border and they found out they had heart scans, the questions started coming up. Well, obviously, there's been some breakthrough with these generators that's getting into the patients. So a number of things happened.

The FDA got involved. Of course, one concern is, is the generator working properly? I think they were first manufactured 20 years ago?

MS. BONANNO: Twenty-two years ago.

MR. PASSETTI: Twenty-two years ago. So has there been a change in the manufacturing? Is there a change in use? Are they using it a lot more often than they used to? You know, obviously there's some breakthrough getting through. Of

course, the other question is if the facilities are doing breakthrough tests, every morning before they put this into the patient, they should be detecting the breakthrough and not giving it to the patient. So all these questions came up.

The first thing that happened was FDA recalled the generators across the state -- across the world, nationwide and internationally. They recalled the generators and started doing an investigation. So I think we had 30 facilities in Florida that were licensed to use this generator and knowing that two of the patients crossing the border had scans in Florida, you know, we were a little concerned. So out of the 30, we sent inspectors out and did inspections at 21 of the facilities just to see what we could find out.

At the request of the FDA, you know, they asked us to assist them because they're looking at the generator. They're doing tests on the generator to see if they can find any problems with the generator, but they wanted us to look at the use of the generator, so we visited 21 facilities and behind, let's see, Tab F there's a two-page summary of kind of what we found in our 21 inspections, and under "Findings" I'm just

going to briefly give you just a brief overview at the first bullet there.

At nine of the facilities when we did the inspections we were recording zero values for the breakthrough test, which tell us immediately that they probably weren't doing the test properly because you should see something. They were just documenting all zeros. So right off nine of the facilities from our inspection appeared to us that they weren't doing the test properly.

Then we had 12 facilities that were doing the breakthrough test correctly for a majority of the time, and we were also looking at the type of dose calibrator they were using. About 12 of the facilities were doing it properly. Of those, five facilities detected strontium over the breakthrough level but still went ahead and used it on the patient, anyway.

We also had three facilities -- there were several facilities that recorded at the breakthrough level or above and didn't report it, which is a requirement to report it to us. So we had a number of facilities that did it properly, were over the limit and they didn't report it.

A number of the facilities reported the

breakthrough to the manufacturer but again didn't report it to us, so it wasn't looked in to by us.

Then there were 18 facilities that -- the manufacturer recommends that if you get to one-tenth of the breakthrough level you should repeat the procedure before you administer it to the patient. We found -- let's see, in 18 of the facilities out of the 21 had days where they were above the one-tenth of the limit and they did not repeat the test. So it's a little concerning what we found out of the 21 facilities; quite a number of them were not doing the test properly or were doing it properly and it didn't slow them down, they were doing patients, anyway.

Just as an aside, the last bullet there kind of gives you an idea of the patient throughput, five of the licensees are doing 200 or more patients a month for, as you can see there; so there's some concern, I think, too, that the generators are being used more often. They're being polluted more often than they normally were. So we're still in the middle of the investigation, but John's going to cover the second part. The FDA asked the CDC to do what they call an epi-aid basically to kind of look at what kind of scope

there is to this nationwide. You know, how many of these things are failing, how many patients were over-exposed from strontium, kind of the scope of the issue.

So there's a number of states working together. They're calling patients back in that had the scan between a certain time frame and we're looking to see if they have strontium in their systems.

MR. FUTCH: Still?

MR. PASSETTI: Still, and a lot of these scans were done like in February. So here we are in October. We're still seeing strontium.

MR. SEDDON: What's the half-life of strontium?

COUNCIL MEMBER: It's 120 days.

MR. PASSETTI: No, it's 64 days. Strontium-85 is 64 days; strontium-82 which is the daughter is 20 or 25 days. And the rubidium that they use in the heart scan is 75 seconds?

DR. SCHENKMAN: Seventy-five seconds.

MS. BONANNO: No, you elude the generator directly and the patient --

MR. WILLIAMSON: This is actually a picture of the fusion device. You can't see it,

but actually it does have tubes in it. You hook it directly up to the patient, with a 75-second half-life obviously you're not going to bother to do anything else on them, 22 years of use. The letter from BRACCO recalling them.

They actually asked all of the licensees to send their generators to Los Alamos National Labs for testing. Thus far, Los Alamos has not been able to duplicate the breakthroughs that were discovered. What this means, it really makes it even more interesting is it's possible that it's not the generator but what you put into it to get the stuff out. The problem is if you're looking at the ionic solutions because obviously it uses a saline rinse, and I don't know who makes the saline rinse. Do they allow anyone or do you have to buy it from BRACCO? Does BRACCO have samples of the saline?

MS. BONANNO: No, they use whatever normal saline that they have there in their facilities.

MR. WILLIAMSON: Okay, is the normal saline higher in salt concentration and that's what stripped it off. There's an awful lot of variables that you can have on this. These are generally -- the parent is cross-linked to a

column. If you put too high a concentration on it, it can start to strip the it off.

The letters from BRACCO to their patients explaining everything that went on. In general, I'd say BRACCO seems to be somewhat on board towards letting people know. Sometimes I think that they're convinced the best means is to delay it as long as possible knowing that this stuff is radioactive and has a half-life and eventually won't be detected anyhow.

Short timeline. January to July, 2011. That alludes to the patients. We know that two of them testified to custom and border protection were from the same facility in Florida in Sarasota, another one from Nevada.

DR. ATHERTON: The same facility?

MR. PASETTI: Two of them from Sarasota at the same facility. Not only the same facility, but almost the same day, the same time frame.

June 2011. There were some in April and some in June. Patients stopped at the US border crossing in Canada due to high levels of radiation detected, two and four months. April was the two, June was that one. Four months after this

individual's scan, obviously if you're finding something put in for a PET scan four months later, something went wrong. They did whole body scans at Oak Ridge National Labs, the strontium isotopes were still there. The indexed patient from the Nevada graded out at 4.9 REM the whole body scan for what his initial dose would have been. The Florida patients were less than that.

There's another patient in Nevada using the same instruments that they used for the initial detection and germanium portable detector, based on a comparison of that value to the other value, he could have as high as a 12 REM of exposure. You're still not talking about things there are that are probably going to -- you're not going to see any acute -- someone was talking about long term risk from cancer, most severe, and as we found from the majority of the people that we looked at, when you start getting a heart scan in general you tend to be a little bit older. We tell them 10 to 20 years and most of them are, like, well, I'm not going to be here in 10 to 20 years anyhow.

But any time you give somebody more radiation than they were supposed to get, there's

kind of a question mark.

July 25th, voluntary recall at BRACCO, the cardio-82 generators. In late August the FDA requested studies from the Center for Disease Control. The Center for Disease Control went to the states where they had good working relationships.

We did a population exercise with them earlier this summer, they came to us first to see if we could actually do an FDA study. We contact patients from facilities in the state of Florida and had a look at them.

Nevada had already been doing one on their own, so we were the second state to do it. In early September, CDC requested our assistance, we started working back and forth trying to find the right protocol, we got who were going to go with. But late September, the first week of October, we actually started making the phone calls, setting up the patients, and the first week of October the 3rd through 6th, we had three practices in the Orlando area. We actually did surveys of 123 patients in the Orlando area.

Sarasota we wanted to do, but because BRACCO was already doing Sarasota, CDC made the

determination that trying to bring the same person in for an additional study probably was going to be problematic. We do have some concerns about BRACCO's method; we chose to do a 10 minute count using an isotope identifier. We're not quite sure what BRACCO's protocol is. Theirs was -- they count you using a GM detector. If you're more than twice background then they send you to a -- RIID or gamma radioisotope identifier to identify. How long are they counting the GM detector? We counted everybody for 10 minutes no matter what.

This is what the set-up is. What we have here is a portable intrinsic germanium detector. This is a very, very high resolution detector and also a very, very high priced detector even for medical equipment; that's about $75,000 for that detector. We strapped it down to the table because we didn't want to bounce off the floor. We had it hooked up to a laptop computer, we have it set for a 10 minute count. We have somebody come in, the study participant comes in; they sit down facing it and they simply roll the chair up and the detector is as close as possible to their chest. Oh, look who our victim is.

MR. FUTCH: I want you to know, I asked

your staff to sit there while I took the picture, they refused. The only reason you've got a picture of a pseudo patient is because I sat there.

MR. WILLIAMSON: We obviously weren't going to take pictures of any of the real patients for privacy, but basically they just sit there. We try to make them as comfortable as possible. They just have to sit there for 10 minutes.

DR. ATHERTON: So the strontium deposits in the heart mostly or liver or where?

MR. PASSETTI: Bones.

MR. FUTCH: Bones.

MR. PASSETTI: This is supposed to be -- I guess you can't see it on the screen, but the center line there is where you see strontium-85 and there's actually a peak there of about 600 counts of strontium-85 of one of the people that we counted. For the background we used some of our staff and we also had 123 people go through and we had five people who were twice backgrounds, so we had a good selection of what a background looks like for somebody who serves none. The background is about 50 counts in a 10 minute section, so this person was about 620 counts. So you figure about 12 times what the normal

background is for somebody. Now the big question is, when did they have the test?

I got the data today. I think this person had the test in early March. So here we're sitting on October 3rd, they had the test on March 3rd, five months, strontium -- obviously, they got something they weren't supposed to.

DR. SCHENKMAN: Were these facilities that the patients came from, were there more patients from facilities that did higher numbers of scans?

MR. WILLIAMSON: Not necessarily. On these, they chose three facilities in the Orlando area to expedite the process because the environmental lab was located in the Orlando area. Now all these practices tend to do large volumes of patients. I believe that the Florida one was doing 200 to 300 -- each one of those was 200 to 300 patients a month. If you look at a six month period where those generators were used, you know, 1200 patients per practice. Thirty-one practices in the state of Florida, you know, maybe as many as 35,000 people. It would have been nice to have thought that the Sarasota facility was the only one that was going to have any issues, and we see at least some issues in another facility, at least one

other facility. I don't know which one of the three facilities that we have.

DR. ATHERTON: And out of the -- how many did you say?

MR. WILLIAMSON: One hundred twenty-three.

DR. ATHERTON: Out of the 123, how many did you find?

MR. WILLIAMSON: Five with twice background.

DR. ATHERTON: But you expect that to be zero?

MR. WILLIAMSON: Yes.

MR. FUTCH: CDC decided how many patients per state for the study, and then theoretically will have some sort of an idea based on the results of this whether or not it's really widespread around the country.

MR. PASSETTTI: We're still in the middle of it and that's what we know here today. Maybe the next meeting we'll have a little more information.

DR. SCHENKMAN: Okay. Thank you very much.

So what do we have next?

MR. FUTCH: The last thing.

DR. SCHENKMAN: Well, we have a request for reviewers.

MR. FUTCH: That's it. This is, if you turn

to Tab G, you may recall we have a basic x-ray machine operator category of licensure in Florida, and the education required for the basic x-ray machine operator before they sit for the state exam is a self-review of the State's study guide. A number of years ago with some assistance from the Council and specific Council members, we actually changed from a study guide the State had produced back in the 1980s to the one you see in your Tab G which is a commercial textbook published by Elsevier called Radiography Essentials, 4th Edition. It's currently in its third edition, and this book is used around the nation by different facilities in states to help the basic operator prepare for the ARRT limited scope exam. All the states purchase these for the ARRT limited scope exam that have state level licensure.

Long story short, they're working on the 4th edition of this book and we had a request first from Elsevier and then directly from one of the authors of the textbook, Eugene Frank, to see if any of our folks would like to participate in reviewing the 4th edition of the textbook this time around. Last time I think it was --

MS. DROTAR: Myself and Tim and --

MR. FUTCH: Dr. Armstrong?

MS. DROTAR: Yes.

MR. FUTCH: I've already talked to Tim about it and he mentioned that he would like to participate again. I think -- and I haven't talked to -- I thought everybody would be here, so it didn't work out that way. So I'm going to pass along Tim and Kathy's name and I guess contact Dr. Armstrong and ask him if he wants to participate again.

And that was very useful because Tim and Kathy and Dr. Armstrong are still involved with schools, so it's particularly useful for Gene Frank and the rest of them to get that input. So that was a quick one. I don't think there are any questions, are there?

All right.

DR. SCHENKMAN: Okay. Any council member issues? Anybody have anything they want to talk about? No?

MR. SEDDON: I have one. It's for the authorized user preceptorship requirements under the revision to chapter 6. The current requirements for authorized users that they have,

the preceptor signs off on their credentialing whether they are ABR certified or whatever their certification is. I know that the ACMUI recently changed that or is in the process of changing, they recommend that that be changed under the C regulations, and I'm wondering are we looking at doing something similar here in Florida?

MR. PASSETTI: For not requiring to have --

MR. SEDDON: Not requiring to have a preceptor statement signed off. The problem has been --

MR. PASSETTI: Oh, when they're board certified.

MR. SEDDON: Yes, so they're board certified and do we still require them under the new rules, they're required to have a preceptor sign off that they are board certified. The argument is that who exactly would that person be to go back to somebody from the residency program or who exactly is qualified to sign off that they are certified? And the -- I know from the NRC's advisory council point that if they're already certified they already had to have statements signed by their program.

MR. PASSETTI: I think we got in trouble with

the NRC because we went ahead and adopted that rule before they did. So I need to go back and double-check on that, but I think we moved forward or are going to move forward with it even before NRC does. So I think we'll be in good shape, but let me check with Paul on that to be sure.

MR. SEDDON: Okay, because that's an issue --

MR. PASSETTI: Yeah, it doesn't make a lot of sense.

DR. SCHENKMAN: Any other issues?

MS. DROTAR: Just a point of information. The ARRT for radiography, the content specifications are changing; starting January of 2012, they get implemented. So what it's going to affect are the competency requirements based on the standard of practice, so it's not -- I think programs are going to be making changes to the curriculum to adjust for that. But because of the types of exams that we're doing that where barium enema and GI were mandatory now only one of them is. You have to do one or the other because they're not done as frequently as others.

MR. FUTCH: Okay. I think --

DR. SCHENKMAN: Betsy, do you have an MQA update?

MS. HINES: Vicki Grant, who's been our executive director for the last four or five years, is retiring at the end of January. And DDC -- drugs, devices, and cosmetics -- has moved from MQA back over to DBPR which left a very small office of pharmacy so they have physically moved the eight of us --

MS. CURRY: No, there's 11.

MS. HINES: -- whatever, over so that we are under a new executive director, Mark Whitten, who could not come this time. He is at a pharmacy meeting. We've been there about two weeks.

Vicki still works for the Department but she's doing lots of annual leave. She has like 15 more days to work between now and the end of January, so she's not working with us directly at all. So the Rad tech crew and the EMT paramedic crew came with us. We have half of an employee that did medical physicists that came to us from the board office that has chiro and chemical labs and she has moved back under that. So if anybody has a need for anything that has to do with medical physicists then they would be found there. We could lead you to them. If you need to call me, I could get you over there. They're really

right across like a hall from us. That's it for now.

MR. FUTCH: Betsey, do you know if they updated any of this on the website yet?

MS. HINES: Yeah, it's updated -- I don't know if we updated our website yet. I bet we have not yet.

Our phone numbers have not changed.

DR. SCHENKMAN: That's good. Just everything else.

MS. HINES: All our moves we've made the last six years, our phone numbers have not changed.

MS. CURRY: I just wanted to let you know that our online applications are going really, really well; and Kathy and a group of her students came and did testing when we were fixing to go put that online. So they were really very valuable to us in testing that for us, but right now our online applications we're getting processed within three to five days from the time we get them in to us. The only reason we can't get them down to one day is because the money doesn't post.

But if the money posted we would be at one to two days on applications where it used to be 20 to 25 days.

MS. HINES: Actually, people that apply for the basic x-ray machine operator and have no criminal history in their background, we don't even see them. They're automatically approved which is awesome, which leaves us to be able to handle more complicated applications more easily because they don't have education requirements. They affirm that they've done the four hours of HIV-AIDS. But the online EMTs and paramedics are probably about 60 or 70% of applicants are using the online system the first time.

For re-exams, it's not available yet but that's coming. But I think we're only at 25% or 30% for Rad techs and I don't know why that it's not issued last for radiologic technologists as it is for some other, and I don't know whether we need to publicize it more -- we put out to the schools.

MS. DROTAR: I'm not sure; it's such an easy and quick system to use and I would think maybe part of it might be having -- people just not realizing that it's there and that it's as easy as putting in your credit card number, and it's very easy and user friendly system. It's wonderful.

MR. FUTCH: Kathy, do the educators have a

society or association with an annual meeting that Betsey or Gail could attend --

MS. DROTAR: Not really. I think probably the easiest thing is probably putting a letter in email out to the program directors themselves, maybe a notice on the website where you go in to get the application. It's on there but I think maybe something that's a bigger notice, if you don't have a positive -- if there's not a positive background, when you have a positive background you still need to do the paper one. But the students love it. With the system that we use, we have a credit card that we have for the campus and they just come down one at a time and just put them in. The students just line up and I think the last group we had 15 students and we had them done within half an hour, so it's really quick and easy. So thank you.

MR. FUTCH: Okay.

MR. SEDDON: Another thing that's come out recently was the Joint Commission alert last month for radiology. Did you guys review that at all? It's a similar event alert that came out from the Joint Commission regarding the use of radiation and radiology excluding

therapy, excluding interventional fluoroscopy. It applies to everything else and has, I think, 20-some guidances or recommendations as far as giving you the right dose for the right reason. They have that whole criteria of things that they have in there that they're recommending facilities go through and apply to their -- as far as requiring physics evaluations, procedure reviews.

It kind of goes hand in hand with some of the CT stuff that we were working on. I'm still working on that with some folks, but basically similar to what we did with our information notice a year-and-a-half ago. We required procedure reviews, verification of dose, education of staff, things like that. So it's something you probably need to review by next meeting because there are some recommendations to regulatory agencies as well.

MR. FUTCH: Okay. I guess I could mention a meeting or two ago I had brought to you an issue about the nuclear medicine techs being told by their facilities that they couldn't administer the interventional or any non-radioactive pharmaceuticals even if they were used in procedures. I took you through a fairly detailed

and exhaustive list of what the Society of Nuclear Medicine said, what the two big registries tested for on their exams, and showed you the list of pharmaceuticals and got a recommendation from the Council that in fact the use of those drugs is considered to be part of the practice of nuclear medicine in Florida, and I've actually used that a few times in that motion for everybody in the case of a couple of facilities who were doing that with their nuclear med techs. So that helped a great deal and I wanted to thank you for that.

DR. SCHENKMAN: Any other business? Okay. So we have to pick a date for the next meeting.

MR. FUTCH: Yeah. So we have May 8th, 15th, 22nd. Do we have any society meetings, CRCPD meetings, retirements?

MR. PASSETTI: We need to check that because CRCPD's meeting is in Orlando this year.

MR. FUTCH: Oh, really?

MR. PASSETTI: And it's always in May, so we need to check that. Maybe we can do it the same time.

MR. SEDDON: The 7th through the 10th.

MR. FUTCH: Okay, the 7th through the 10th. Okay. So we'll skip the 8th. Anyone have a

preference for the -- and we don't have the legislature this year interfering with -- because they're not going to be in session in May. So May 1st, May 15th, May 22nd.

Does anyone have a preference or care one way or the other?

MS. DROTAR: No, whatever works.

DR. ATHERTON: The 22nd sounds good.

MR. FUTCH: Okay. I hear one 22nd and nobody else cares.

DR. SCHENKMAN: Does the 22nd work for everybody at least at this point?

SEVERAL VOICES: Yes.

DR. SCHENKMAN: Okay. So why don't we set it for the 22nd and if anybody has issues when they check when they get home, we can adjust.

MR. FUTCH: Do you want to say anything about May of next year?

MR. PASSETTI: No.

MR. FUTCH: Well, that's it for me.

DR. SCHENKMAN: Okay. Thank you all for being here and we are adjourned.

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(Whereupon, the meeting was adjourned at 2:55 P.M.)

C E R T I F I C A T E

THE STATE OF FLORIDA,)

COUNTY OF WAKULLA,)

I, Suzette A. Bragg, Court Reporter and Notary Public, State of Florida at Large,

DO HEREBY CERTIFY that the above-entitled and numbered cause was heard as herein above set out; that I was authorized to and did transcribe the proceedings of said matter, and that the foregoing and annexed pages, numbered 1 through 140, inclusive, comprise a true and correct transcription of the proceedings in said cause.

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

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my seal, this 31ST day of October, 2011.

SUZETTE A. BRAGG, Notary Public
State of Florida at Large
My Commission Expires: 2/21/2013