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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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PUBLIC MEETING

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RULEMAKING TO ESTABLISH A REGULATORY FRAMEWORK FOR THE EXPANDED DEFINITION OF BYPRODUCT MATERIAL ESTABLISHED BY THE ENERGY POLICY ACT

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WEDNESDAY,

NOVEMBER 9, 2005

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ROCKVILLE, MARYLAND

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The public meeting met at 9:00 a.m. in Room T-2B3 of the Nuclear Regulatory Commission, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, Francis Cameron, Facilitator, presiding.

PARTICIPANTS:

FRANCIS CAMERON, Facilitator

EDGAR D. BAILEY

TERENCE BEVEN

ROY BROWN

JAMES A. CASE

LEE COX

PARTICIPANTS: (CONT.)

GARY L. DILLEHAY

LYNNE A. FAIROBENT

RICH FEJKA

BONNIE GITLIN

BARBARA HAMRICK

MARIA D. KELLY

LESLIE KERR

FELIX KILLAR

RALPH P. LIETO

RUTH MCBURNEY

GEORGE MILLS

MARY E. MOORE

SCOTT MOORE

ROGER MORONEY

ALAN B. PACKARD

ALSO PRESENT:

DOUG BROADDUS

CHARLES MILLER

THOMAS CARDWELL

MARK DELLIGATTI

SALLY SCHWARZ

CINDY FLANNERY

JENNY TOBIN

ALSO PRESENT: (CONT.)

RICH GIANATTI

JUDITH JOHNSRUD

JOE DeCicco

THOMAS ESSIG

RICHARD BLANTON

LYDIA CHANG

DEREK WIDMAYER

ROB LEWIS

SCOTT LEWIS

P R O C E E D I N G S

(9:13 a.m.)

MR. CAMERON: Okay. Thank you very much, Jill. Good morning, everybody. My name is Chip Cameron, and I'm the Special Counsel for Public Liaison within the Office of General Counsel here at the Nuclear Regulatory Commission, the NRC, and it's my pleasure to serve as your facilitator this morning. And in that role, I'm going to try to help all of you have to a productive meeting.

Our roundtable discussion this morning is on the rulemaking that the NRC is required to do on NARM issues by the Energy Policy Act. And I just wanted to say a few words about meeting process before we got to the substance of our discussions today. I wanted to talk about the format for the meeting, some very simple ground rules to allow us to have an effective meeting, do some introductions around the table, and do an agenda check with all of you.

In terms of a format, we are using a roundtable format today, and the objective is to encourage a dialogue among all of you, representatives of the affected and concerned interests. The

objective today is to try to get a different form of data information than we usually get where we have single comments all coming into the agency. Both types of input are important, but we have an opportunity today for perhaps some cooperative problem-solving.

The focus of the discussion is going to be at the table, but we know that there are those of you in the audience who might want to make comments or ask questions from time to time. We also have people on the phone with us, and you heard Jill turning those lines open. We also have people in the TV conference room, which is somewhere in Maryland, I guess somewhere in this building, so we're going to go to all of those three sets of audience periodically throughout the day for comment and questions, so we have a lot of people around the table. There's a lot of moving parts to the meeting, but hopefully it'll all go smoothly.

In terms of ground rules, the first thing is that what I'd like to do is to use these name tents to organize the discussion. If you during the day want to say anything, please just turn your name tent up like that, and I have two name tents which I'm going to lend to Ed Bailey. But at any rate, turn

your name tents up, and that will relieve you of having to always be signaling that you want to say something. Okay? And I'll keep track of that. Since we're trying to have a dialogue on the issues, I may not take the name tents in the order that they're turned up because we'll want to follow the discussion threads on that.

I would ask that we only have one conversation at a time, which is most importantly because we want to give our full attention to whomever has the floor, so to speak, at the moment, but also because we are taking a transcript. Lindsey is here. She is our court reporter, stenographer, and she's going to be taking a transcript, so if we only have one person speaking, then she'll be sure of who that is. At least in the beginning for those of you around the table, just say your name after you're recognized to talk so that Lindsey will get that. I think as we go on through the day, she has a chart of people at the table so that she'll know who it is. And when we go to those of you in the audience in the TV conference room or the phones, when we get there, also please introduce yourself to us, your name, and if you want to provide your affiliation, that's fine. And we have a lot of people around the table. Perhaps some

complicated, controversial issues, so I would just ask you to be succinct, economical in your comments. We want you to say what you need to say. That's the most important thing. That's why you're here, but if you could keep a weather eye towards the time, the length of your comments, then that will help to make sure that we give everybody an opportunity to participate.

In terms of ground rules for the audience, when we do go out to you, and I'm sorry I can't give you a specific time, we're going to see how the discussion is going, if you just raise your hand, I'll recognize you, and we do have a microphone right there. I'll also try, perhaps, to bring this Lavalier mike out to some of you. We'll do that. On the phones, when we go to the phones, I'm going to tell Jill that's what we're going to do, and then she's going to coordinate the people on the phones. And then we'll go to the TV conference room for any potential questions from all of you in there. Are you guys okay over there? Well, I'm not sure they're okay, but at any rate we know that they're tuned in to us.

SPEAKER: Yes, we can hear you. Can you hear us now?

MR. CAMERON: Yes, that's great. Thank

you very much.

SPEAKER: We'll keep the mute on until you come to us unless someone has a question.

MR. CAMERON: Okay. Great. Thank you. There's going to be a lot of issues that may not fit within the particular topic we're talking about, and we'll come back to later on in the day. I'll keep track of all of those. I'll also use these flip charts to try to keep track of the major points of discussion, not as a set of minutes, but so that that can help us to organize the discussion. And in a couple of minutes we're going to go to Charlie Miller, who is the Division Director here at the NRC of the Industrial and Medical Nuclear Safety Division within our Office of Nuclear Material Safety and Safeguards. He's going to say a few words of welcome to you. And I also just want to give you a brief agenda check to see if we're all on board with that. But before I do that, why don't we just go around for some brief introductions. If you want to give us one, just three sentences of what your interest or concern with this particular rulemaking is, that would be helpful. And I'm going to start with one of our guests. This is Mr. Ed Bailey, and we need to -- I think these microphones pick up pretty well, but we do need to

make sure we're using the microphone, so if you pull it towards you, that would be helpful for Lindsey. Ed.

MR. BAILEY: Okay. As Chip said, my name is Ed Bailey. I'm with the California Department of Health Services Radiological Health Branch, and here today as a representative of the Conference of Radiation Control Program Directors.

MR. CAMERON: Thank you, Ed. Felix.

MR. KILLAR: I'm Felix Killar from Nuclear Energy Institute, and I'm here today primarily representing the industrial users of accelerated produce materials.

DR. BEVEN: I'm Terry Beven, the Government Relations Chairman for the Society of Nuclear Medicine and the American College of Nuclear Physicians. We're pleased to have the opportunity to participate today, and we are here primarily with concerns about unintended consequences of the regulations that might affect patient access to vital studies, diagnostic studies and therapies.

MR. BROWN: I'm Roy Brown. I'm with the Council on Radionuclides or Radiopharmaceuticals, CORAR. Our principal reason for being here is that CORAR has been very supportive of NRC getting

jurisdiction over NARM material. However, we're concerned about some of the inconsistencies between the states, and we want to ensure any rulemaking going forward has as much harmonization as possible.

MR. CAMERON: Thanks, Roy.

DR. CASE: My name is James Case. I'm with the American Society of Nuclear Cardiology, and I'm here today representing their memberships and their concerns about access to radiopharmaceuticals, both in SPECT and the PET arena.

MR. CAMERON: Thank you, James.

MR. COX: I'm Lee Cox from the State of North Carolina. Today I'm here representing the Agreement States as a member of the NARM task force.

DR. DILLEHAY: I'm Dr. Gary Dillehay. I am a Radiologist Nuclear Medicine Physician practicing at Loyola University Medical Center outside Chicago, representing the American College of Radiology. I am currently the Government Relations Committee Chair within the Nuclear Medicine Commission the college, and we are also concerned about ensuring that there's continued access to these materials to our patients.

DR. MOORE: I'm Mary Moore from the Philadelphia VA Medical Center representing the American Association of Physicists in Medicine. We

are pleased to be represented here today, and I want to make sure that any technical support or clarifications that we can provide, that everyone knows that it's available.

MR. CAMERON: Thank you, Mary.

MS. FAIROBENT: I'm Lynne Fairobent, and I'm the Manager of Legislative and Regulatory Affairs for the American Association of Physicists in Medicine.

MR. LIETO: My name is Ralph Lieto. I'm the Medical Nuclear Physicist Member of the Advisory Committee on the Medical Use of Isotopes, and I'm here representing the ACMUI.

MS. GITLIN: I'm Bonnie Gitlin, the Acting Director for the Environmental Protection Agency's Radiation Protection Division, and I'm here to help assure consistency and coherence between all of the regulations that we share with NRC to govern this material, and make sure that the definitions are appropriate and consistent.

MR. CAMERON: Thank you, Bonnie.

MS. HAMRICK: I'm Barbara Hamrick. I'm with the State of California, but I'm here today as the Chair of the Organization of Agreement States, representing Agreement State interests.

DR. KELLY: I'm Maria Kelly. I'm a Radiation Oncologist at the University of Virginia, and I'm Government Relations Chair for American Society of Therapeutic Radiology in Oncology. And like the other physicians here, I'm representing the interest of patients and diagnosis and treatment, and how these rules will affect them.

MR. CAMERON: Thanks, Maria.

MR. FEJKA: My name is Rich Fejka. I'm with the FDA's Radioactive Drug Research Committee Program, where we have a lot of reporting of use of research with PET radiopharmaceuticals.

MR. CAMERON: Thanks, Rich.

DR. MILLS: Good morning. I'm George Mills. I'm the Division Director for Medical Imaging in the FDA. In my role, I oversee the approved products, the INDs, and the RDRC activities with these materials, and we've just come forward with our recent regulation that we're in public comment for for CGMPs, for PET products, as well as guidance with it. We're here today to make sure that we can get good harmonization development going forward with the NRC as they make their rulemaking.

MR. CAMERON: Thank you, George.

MS. McBURNEY: I'm Ruth McBurney with the Department of State Health Services in Texas. However, I'm here today representing the Health Physics Society, and the interest of the Health Physicists and Radiation Safety Officers, and what we have been pushing for for several years now are uniform standards for safety and security of radioactive material. And also, that there be better regulations or opportunities for disposing of the waste, as well.

MR. CAMERON: Roger.

MR. MORONEY: My name is Roger Moroney. I'm with Corporate Radiation Safety Officer with PET Pharmaceuticals. We operate 46 PET Radiopharmacies throughout the world, 42 in the United States, and each one of these has a cyclotron with it. We're here again to ensure consistency across regulation. Again, we're in 37 different states and we've seen the inconsistencies. Thank you.

DR. PACKARD: My name is Alan Packard. I'm a Research Chemist in Nuclear Medicine at Children's Hospital in Boston and Harvard Medical School. I'm representing the research community in nuclear medicine, the people who develop the radiopharmaceuticals as some of the other people have

mentioned earlier, and I'm here to see what we can do to ensure access and availability to these radionuclides so that this development can continue.

MS. KERR: My name is Leslie Kerr. I'm a Project Manager in the Division of Industrial and Medical Nuclear Safety here at the NRC.

MR. MOORE: I'm Scott Moore. I'm the Chief of the Rulemaking Guidance Branch in the Division of Industrial Medical Nuclear Safety, and my branch has the responsibility to write the rule.

MR. CAMERON: Okay. Great. And Charlie.

MR. MILLER: Thank you, Chip. On behalf of the Nuclear Regulatory Commission, I want to welcome everyone here today. I see we have a great turnout, and I'm really appreciative of that because this is an area that the NRC has not regulated in the past. As most of you know, Congress has given us a very aggressive schedule to have to promulgate rulemaking in this area through the Energy Policy Act, so this meeting today is an attempt to seek as much input as we can for the very aggressive schedule that we have to use in promulgating this regulation.

I appreciate everyone's attendance today. As we've gone around the table, one thing that struck

me is, obviously, there's a large usage of radioactive material generated as NARM in the medical applications, but I'm also very interested in hearing from anyone here who may have other applications that they feel that this material is used for, so we want to make sure that we get all perspectives today so that we can seek as much input as we can to try to promulgate what would be a logical regulation.

With that, I'm going to turn it back to Chip. I hope we have a very productive day. Thank you.

MR. CAMERON: Okay. Thank you, Charlie, for that, and for being with us. And I want to do an agenda check in a minute and get off to let you guys go, but it may be useful to have some of the other key NRC Staff and others introduce themselves at this point. You're going to hear from the Chair of the Task Force on the Energy Policy Act implementation, and I would just ask Doug to just introduce himself to you at this point, as well as if there's any other members of the Task Force here, please let me know and I'll bring this over to you. Doug.

MR. BROADDUS: Yes. My name is Doug Broaddus. I also work in the Division of Industrial Medical Nuclear Safety. I'm the Team Leader for the

Task Force for the Energy Policy Act, and I'll be talking about that in just a minute. We do have several members of the Task Force here today; Lee Cox already mentioned earlier, Martha Dibblee also from the State of Oregon, Joe DeCicco in the back, and then there's a couple of others that I think are in the video conference room, as well. Dick Blanton is over there, as well, I believe, and he's going to be giving a presentation later on today, as well.

MR. CAMERON: Okay. Thank you, Doug. And I would just encourage everybody during our breaks and lunch after the meeting to talk to people that are on the Task Force, or the NRC has a working group that I think Leslie is chairing, and are there members of the working group in the room?

MS. KERR: Yes, there are.

MR. CAMERON: All right.

MS. KERR: If they could hold their hands up, please.

MR. CAMERON: Okay. Why don't you just introduce yourself.

MR. CARDWELL: Thomas Cardwell with the Texas Department of State Health Services.

MR. CAMERON: Okay. Thanks.

MS. TOBIN: I'm Jenny Tobin with State and Tribal Programs.

MR. CAMERON: Okay. Any other working group? And, Martha, you're on the working group and the task force.

SPEAKER: Correct.

MR. CAMERON: Okay.

MS. KERR: There are others in the video conference room.

MR. CAMERON: And others over there. And thank you for helping us by being over there. Mark, do you want to introduce yourself.

MR. DELLIGATTI: My name is Mark Delligatti, and I am Section Chief of Rulemaking Section B, and Leslie is in my section, and we are responsible for carrying out this rulemaking.

MR. CAMERON: Okay. Lydia.

MS. CHANG: I'm a Project Manager within the Rulemaking and Guidance Branch.

MR. CAMERON: And just give us your full name.

MS. CHANG: Lydia Chang.

MR. CAMERON: Okay. Thanks, Lydia. And, Sally, do you want to introduce yourself to us.

MS. SCHWARZ: I'm Sally Schwarz. I'm

actually here representing ACMUI and the Nuclear Pharmacy Section.

MR. CAMERON: Okay. Great. And as you'll see, we're going to have NRC Staff tee up the agenda items for us when we get there, to just give you an idea of what the scope of the discussion is going to be. And we have one of our golfers, I guess. Please introduce yourself.

MS. FLANNERY: Hi. I'm Cindy Flannery. I'm the Team Leader for the Medical Radiation Safety Team, and IMNS, as well.

MR. CAMERON: Okay. Great. Are we missing anybody that should be introduced at this point? And, of course, those of you who have questions, comments, we'll get to know you as we go on. Just a quick agenda check - we're going to start out with a context piece for you to give you some background. Leslie Kerr is going to talk about this particular rulemaking, and the Act. We're also going to hear from Doug Broaddus about the larger task force, the task force on the larger issues. And after they're done, we'll go out to you for clarifying questions. I know that sometimes these clarifying questions are wrapped in a comment, that's fine, but we don't want to get off on a discussion of the

comments at that point. We just want to keep it to clarifying questions.

Next we have a couple of overarching issues, and one is that what I've heard from people is what's the best way we should leverage state experience? We, being the NRC. Don't reinvent the wheel, comments like that. Well, we're going to have a discussion on those issues. And, obviously, the suggested state regulations are going to be an important part of that discussion. There is a tie-in with a second over-arching issue, which is implications for radiopharmaceutical availability. We already heard Terry and Roy, and some others talk about that. Well, we're going to go into that issue. Obviously, uniformity is a larger issue than just NARM and concerns the broader byproduct set of materials. There's implications on fast track, I think, that we're going to be hearing about.

I have a question for you, or suggestion. It seemed like those two issues are going to be - that there's going to be a lot of discussion on those, perhaps more so than any of the other specific suggestions or agenda items. And I thought it might be useful to extend that discussion towards lunch rather than jump into the discrete source definition

at 11:00. And I want to open it up to you around the table to see if that -- does that make sense to you? Okay. Good. So that will be that one agenda change.

After lunch we're going to come back and talk about discrete source definition issues, which obviously includes Radium-226, and are there any other things that we should be dealing with? We'll go to the accelerator issue. Waste disposal and transportation is on your agenda. We're going to have some resource people here on both of those issues. In my conversations with people in preparing for the meeting, it didn't seem like there was a lot of dispute or controversy over the waste disposal issues since they're set forth clearly in the Act. And that's why we don't have someone from the Waste Disposal community here. I may be wrong about that, and we're not taking it off the agenda. We're going to discuss it, but that's what I heard.

And we have other issues in there, and some of the -- there are some procedural issues, like the fast track that I mentioned earlier. Obviously, compatibility runs through this whole business, and I'm sure we'll hear that in our over-arching discussion. But that's sort of where we are for the day. Are there any questions or comments about the

agenda before we get started? Do we need to adjust anything? Are there issues that you don't know where they might fit on the agenda, because this is your meeting. It's a valuable source of information for us, but if there's things that you think we should have on here that you don't see, either bring them up now, or just bring them up during the discussion. Anybody? Yes, Mary. And I'm sorry, I violated the rule. Okay, Mary.

DR. MOORE: What I was looking for was transition and implementation methods and time lines. We've already in our introductions addressed consistency and uniformity of the regulations, which would be step one. But once you establish that --

MR. CAMERON: Okay, good point. As we go through the discussion, let's make sure that we don't neglect issues of transition and time lines, because they're going to be very important. So I think that that's something that's going to run through the whole day's discussion, but we also may want to revisit that at the end of the day under other issues to make sure that we have gotten everything. So thank you, Mary. Anybody else at this point?

Okay. Well, thank you again, and I'll try not to be too intrusive with you today. And we heard

from Charlie, and I guess we're ready to go with Leslie for the first presentation.

MS. KERR: Again, my name is Leslie Kerr. I'm a Project Manager in IMNS, and I'm going to try to provide some context for the rulemaking, and also talk about the schedule. As you know, the Energy Policy Act is what kicked this whole effort off. It was signed into law August 8th, and the section that we're particularly concerned with is Section 651(e), which if you weren't able to pick up handouts earlier, the actual text of the act is at the back of the room. But basically what that section did was amended the definition of byproduct material in Section 11(e) of the Atomic Energy Act to include accelerator produced radioactive material, discrete sources of Radium-226, and discrete sources of other naturally occurring radioactive material that the NRC determines in consultation with other federal agencies pose a threat similar to Radium-226.

I'd like to point out now, and we'll discuss it later on the agenda, but the legislation did not define discrete source. And, in fact, it directed the NRC to define discrete source in its regulations, so that's one of the agenda items today, and we're looking for your input on that.

The Act provided for waivers that basically allows the Commission to grant waivers, allowing current programs to continue regulating the new materials for up to four years after enactment for domestic sources, for import and export sources there is only a one-year waiver granted. The NRC issued that waiver on August 25th, and the waiver was published in the "Federal Register" on August 31st.

The amended byproduct material definition is applicable to materials produced, extracted, or converted after extraction before, on, or after August 8th, 2005. Now that's a long-winded way of saying pretty much any time it was produced, then it comes under NRC jurisdiction. The materials have to be used according to the legislation in commercial, medical, or research activities.

The amended definition is not applicable to accelerators. The NRC will not be regulating accelerator use, only the material that's produced by accelerators. It's also not applicable to diffused sources of Radium-226, or other naturally occurring radioactive materials. There are some additional provisions of the legislation, and I guess maybe you all know, but when we talk about NARM, it encompasses both the naturally occurring and the accelerator

produced materials, so all of the new material is how the term NARM will be used today.

For Agreement States, Section 274(b) of the Atomic Energy Act was amended to include the new byproduct material, so that the Agreement States can regulate that material. As far as radiopharmaceuticals go, the Act requires NRC to consider the impact of the availability of radiopharmaceuticals to physicians and patients.

The Act also requires the NRC to seek stakeholder input from states and other stakeholders, and to the maximum extent practicable, the NRC is to use model state standards. And again, that's on our agenda to discuss today, as well.

As far as the rulemaking process goes, there is a working group that is led by IMNS. We have representatives from headquarters, from the regions, and we also have state representation on that working group. There's also a task force that is providing some of the key input for the rulemaking, which Doug will talk about next.

As far as the rulemaking schedule goes, the Commission is in the process of -- we sent a memo off to the Commission, and they are in the process of letting us know if the schedule in that memo is okay.

But basically, we have a very aggressive schedule that was dictated by the legislation. We have to have final regulations in place by February 7th, 2007, which is 18 months after the original enactment of the legislation. In order to do that, and to meet all of our other review requirements, we have to have draft proposed rule text to the states by January 3rd, 2006, which is not very far away.

Then after that review, we have to have a proposed rule to the Commission in March, 2006. And then we're hoping to publish a proposed rule towards the end of April, 2006. And all of that very tight schedule is dictated by having to have final regulations in place by February, 2007.

Now I think Doug is going to talk about the task force. And then after his talk, then we're going to take questions about the process.

MR. CAMERON: Okay. Great. Doug, here's the chair for you.

MR. BROADDUS: Thank you, Leslie. Good morning and welcome to you all. I'm here today to talk to you about the Energy Policy Act that was created in part to address specific provisions of the Energy Policy Act applicable to the materials and waste areas, and to describe the role the task force

will play in the NARM rulemaking that we're here to discuss.

The Task Force was chartered to address two significant recent NRC activities, each of which involves new programs and responsibilities. The first involves issuance of orders to certain licensees for increased control over certain radionuclides of concern that they possess. That activity is outside the scope of the discussion today. The Task Force's second responsibility is for developing a regulatory framework under which provisions of the Energy Policy Act applicable to the materials and waste arenas will be planned, and managed, and implemented, and for providing technical support to the NARM rulemaking effort.

Task Force membership is comprised of technical staff from multiple organizations, including the NRC Offices of Nuclear Material Safety and Safeguards, State and Tribal Programs, Nuclear Security and Incident Response, and one of our regional offices, and it also includes members from the states representing the Organization of Agreement States, and the Conference of Radiation Control Program Directors.

The expertise provided by the state

representatives on the Task Force is key to ensuring that we meet the intent of the legislation, to cooperate with states and use existing model state standards to the maximum extent practicable when developing the NARM regulations.

As Leslie indicated earlier, the proposed schedule for the NARM rulemaking is very aggressive to ensure that we meet the legislated requirement to issue the new rules within 18 months. A consequence of such an aggressive schedule is that it does not allow the working group established to develop the rulemaking package, time to research and develop all the technical issues related and needed to support the rule. It is in this area that the Task Force working in parallel with the working group will provide the most significant support to this rulemaking effort. The specific activities of the Task Force that are applicable to the NARM rulemaking include developing the technical basis for the rule, developing a proposed definition for discrete source to be included in the rule, determining whether any other discrete sources of naturally occurring radioactive material would pose a threat similar to that posed by a discrete source of Radium-226, developing the supporting guidance for the new rule, and developing

the transition plan that's required by the Act for the orderly transition of regulatory authority with respect to natural occurring and accelerator produced radioactive materials now included in the new definition of byproduct material.

As part of this effort, the Task Force will be evaluating options for this transition, including identifying potential options for establishing new agreements with states for the regulatory oversight of the new byproduct material.

One last thing that we will also be doing is identifying other needed programmatic changes as a result of the NARM rule and other provisions of the Energy Policy Act. We appreciate you all making the effort to be here, as the insight that you will provide will really help us to appropriately address these key issues.

MR. CAMERON: Okay. Thank you, Doug. Thank you, Leslie. Clarifying questions about schedules, how the Task Force enters into the rulemaking. Roy Brown.

MR. BROWN: I have a couple of clarifying questions, maybe not about the rulemaking process, but about maybe NRC's interpretation of the Act, I wonder if you could address. First of all, under the

material that's been made radioactive by the particle accelerator, is your interpretation that everything made radioactive by the accelerator is under the new definition of byproduct material; for example, even things that are not produced commercially for medical or for research use, like for example, copper target backing on our target that has no commercial implications?

MR. BROADDUS: That specifically is an issue that we will be discussing later, but I'd like to just make a comment on that; which is, the legislation requires or the definition in the legislation only applies to those materials produced or extracted for a medical research or commercial activity, so anything that was created outside of that would not be under the new definition.

MR. BROWN: I guess that's why I'm asking, because that may be a dichotomy where the state right now, even if it's not for commercial use, the state would take jurisdiction over, for example, that copper target backing, but it sounds like the NRC may not.

MR. CAMERON: Scott, do you want to amplify on this?

MR. MOORE: Yes. What Doug said is very important. The legislation gives us authority over

commercial, medical, and research activities, so that's what we have jurisdiction for legally. Okay? On top of that, we want to hear your input on what we should do with respect to the rule, and so that's something we're looking for input from you all on as part of this roundtable discussion.

MR. CAMERON: And there may be, when you get into was is commercial, what is medical, what is research, there may be room for debate on those. You also may be identifying gaps, clear gaps in the coverage, but we are going to do that. Before we go to your - we're going to discuss that later on - before we go to your next question, Roy - Felix, did you want to just say something here?

MR. KILLAR: I have a quick question on the timing of the comment period. You indicated that it will be out for proposed rule in April, but you didn't indicate how long the comment period is going to last. We encourage a minimum of 60-day comment period, maybe even a 90-day comment period. I realize that makes it very difficult for you to get your schedule and your work done, but there is a lot of people who are affected about this rule, who right now don't even know it exists, and so I think there's lots of education that's going to have to be done to make

people aware of what's coming here. And I think we need an extended time period for comments to get those people on board to understand the impacts.

MR. CAMERON: And, Leslie, what is the -- this entire meeting is designed for you to give us comments and suggestions on things like that. But, Leslie, is there a suggested --

MS. KERR: Yes. I would like to point out that another handout is a background information document, and there is a more detailed schedule in that document that reflects the memo that we sent to the Commission on the schedule, as well as other issues.

Basically, right now we are proposing a 45-day comment period. However, we intend to have posted the proposed rule text on the NRC website concurrently with it going to the Commission as of March 10th, 2006, which would give a full 75 days, so that it will be in the public domain.

MR. CAMERON: So that even though the comment period might be 45 days, and obviously you need to consider what Felix has suggested, as well as others. There will be a long lead time for people to become familiar at least with the basics of it. And, Scott.

MR. MOORE: Yes. I'd like to say something about the schedule at the start for everybody. The schedule is a very, very aggressive schedule. And we haven't had to work with a schedule that's this aggressive really for years. And what's driving the aggressiveness of the schedule is the publication date of the final rule that Congress gave us, which is February, 2007. It was 18 months from the point that the legislation was enacted, which was in August. Now we're down to I think about 15 months, so we're working to the February `07 date to get the final rule out. And to do that, we're finding ways in the schedule, and we're having to be creative with the schedule to get it out within the requirements under FACA for public comment, and ways within our process to work it with the states and with others within the Commission.

We have to give the states plenty of opportunity to comment. We have to give others within the Commission, the Commission itself time to comment, so we're trying to do things within a 45-day comment period, also put it up on the web, as Leslie mentioned, to give while it's with the Commission time for the comment to see it while the Commission is also looking at it. The Commission hasn't approved that

process yet, but we're about to release a letter that we gave to the Commission, the Staff gave to the Commission on October 31st, and we'll make that letter publicly available today to all of you. The Commission decided they wanted it released to you all this morning, so we got information to give it out to you all today.

MR. CAMERON: Okay. Thank you. Before we go to George and then to Lynne, we're coming back to Roy. Just let me note, when we get to the other issues part of the agenda, we'll not only revisit, as needed, Mary's comment about transition issues, but also process issues like the 60 to 90-day comment. Okay? That's where we're going to discuss those types of process issues. Let's go to George Mills.

DR. MILLS: Thank you. First of all, I want you all to appreciate what they're talking to you about. I had to write the radiopharmaceutical reg participation back in 1997 with the same type of time frame. There is a heroic march. They've got a lot of work to do to try to do this in that type of time frame. We were successful in that one within 18 months. We just came out with our GCMP reg, which was supposed to be done in two years. We were about six years late. So again, we made it on one, and we

didn't make it on the other, but that's part of the focus that I see in terms of this discussion, where from the FDA and the NRC we're going to need to work very closely together to get the language right and the wordsmithing right, because from that standpoint I see us with one, with approved products, I see us with license products, and I see us with regulated products. And so the wording and the wordsmithing that many of you in the audience may have some feel for is very key in terms of what we're going to be developing here. And my concern is to make sure that we're not going to affect the regs that we have, but necessarily indigitate and interface with the NRC in a very productive way. So as we look for that, we may well want to have channels that can be opened up between the two organizations in a productive way to interface those two, especially when we have the CGMP reg out currently in comment, which is going to close at the end of the year, so we've got to crossover at that same time for you with guidance at the same time.

MR. CAMERON: Okay. Thank you, George, for those words of advice. And I'm just going to put another issue up in the parking lot. We heard from Bonnie before about coherence, consistency with EPA and, obviously, FDA. There may be process issues

there that you want to talk about later on when we get to the other issues, if that's the approach place. And it at least is one appropriate place, so we'll keep that in mind. And I don't know if our heroes will still have their jobs if they're six years late, but at any rate, Lynne.

MS. FAIROBENT: Yes. Lynne Fairobent, AAPM. On the schedule I see that you've got end of the 30-day state review period that it's going to the states. Doesn't it also have to go to ACMUI, or shouldn't it also go to ACMUI at the same time it goes to the states for their pre-review? And I don't see that on either of the two schedules presented.

MR. CAMERON: Okay. Good question.

MS. KERR: We do plan to coordinate with the ACMUI. The schedule you have is an abbreviated version. But yes, we're aware that we will need to do that.

MR. MOORE: The ACMUI is an advisory body to the Commission, and when we go out to the states, we internally go out to all NRC offices, including the ACMUI. And to the ACMUI is provided copies, as are all key NRC offices, and so we coordinate with ACMUI simultaneous with the states.

MR. CAMERON: Okay. Lots of coordination

issues coming up here. Roy, you had some other issues, questions.

MR. BROWN: Yes. Thanks for circling back. Roy Brown with CORAR. The second question was on the exclusion language for low level waste. There seems to be a lot of confusion because in the Act it talks about low level waste does not include the new byproduct materials defined. Can you explain NRC's interpretation on that, because there's a lot of confusion, what exactly that means, and what the purpose is?

MR. CAMERON: And if we could do this one briefly, also, because when we get to waste, we'll have a discussion of that, I think. But, Leslie, go ahead.

MS. KERR: Well, I was going to say if it would be okay, we have a whole section of the agenda on that, if we could just parking lot that issue for now.

MR. BROWN: That's fine.

MR. CAMERON: Okay. Great. Other questions around the table? Felix.

MR. KILLAR: Yes, one other clarification. It's obvious to me but maybe that's why I need to ask the question because it's so obvious. When you talk

about research, we're not limiting it to only medical research. We're also including research for industrial applications, for animal, plant growth, tracer studies, things along that line is all captured as part of research.

MR. CAMERON: Okay. A good example of how many things could fit under the definition of research. And again, the NRC Staff is here to listen to your comments today, your suggestions on that. But Scott or Leslie, any preliminary things you want to say on that?

MR. MOORE: We would take it that way, but we're looking for input, so that kind of input from you all is important. We don't have any preconceived thoughts on that, but my thought is we would interpret research to be broad research, not just medical research.

MR. CAMERON: Okay.

MR. MOORE: But it's important to hear from you all on that, so when we're looking for comments or public comments, those are the kinds of comments we need to hear from you.

MR. CAMERON: Dr. Case.

DR. CASE: A number of the clinical groups here, our concerns were throwing the baby out with the

bath water type questions, and is it my understanding from what the schedule is looking like, that the first time the clinical community is going to see the proposed rule will be in March of next year? Because that really truncates the comment period for the public and the user community of these. Is there any way that they could have access to the proposed rule, given the fact Congress gave such an abbreviated time schedule?

MR. MOORE: The first point that the clinical community will see it is March. We go through the Advisory Committee on Medical Use of Isotopes before then, but the first point that the public sees it is March when it gets posted on the web, presuming that the Commission agrees to that. And even that is an expedited schedule. Normally, it would be after the Commission approves the SRM for publishing, which would be April or even May, but it would be March when we post it on the web.

MR. CAMERON: Okay. That's another issue that we need to come back to when we get to the other issues, is what's the most effective way to give people early access to this? And we can talk about when you do presentations and give material to the ACMUI, what are the Federal Advisory Committee Act

rules that might make that available, if any, to a broader audience, et cetera, et cetera. But let's make sure - we'll parking lot that, and we'll come back to it for discussion.

Okay. Those of you on the phone and in the audience, what I'm going to do is get us to the first over-arching issue at this point, and when we're done with that discussion around the table of the first over-arching issue, we'll go out and we'll do audience, phones, TV conference room. And if you have any questions at that time, we'll fold that in. So right now I think we've identified a number of issues for discussion.

Right now, we're going to go to the first over-arching issue, which is listed on your agenda as the role of state regulations as starting point for NRC regulations. Jenny Tobin is going to come up and Doug, if you could just give Jenny your seat. Thank you very much. And thank you, Doug. Okay. This is Jenny Tobin from our Office of State and Tribal Programs. She's going to do a tee-up for you, and then we'll get into the discussion.

MS. TOBIN: I'm Jenny Tobin from State and Tribal Programs, and I've been with the NRC not too long, but I'm very happy to see all of you here. And

with the Office of State and Tribal Programs, we have a lot of interactions with the Agreement States, many of which have regulated the material in the past. We work closely with the Organization of Agreement States, OAS, and CRCPD, and we seek their input in all kinds of matters. They have a lot more experience with many of these issues than what we do, and we learn very well from each other, I think.

One program that the CRCPD has used in the past or has explored is the licensing state, and they developed this about 15-20 years ago, and the original intent was to offer resources to the states for NARM material, but the concept didn't receive funding, and 17 states went through the process to become licensing states. And the program kind of tinkered out, we shall say.

Originally, it was intended for non-agreement states, but it was the Agreement States that chose to go this route. And the licensing states are states that are mandated by their legislatures to regulate the NARM material. So in our office, we've kind of looked at the licensing state program, and that might be one type of option that we could pursue and see if that's an option at this point, if that might be something we want to look into.

When we looked at the regulation it says "use state regulations to the extent practicable", and in our rulemaking group we took that to mean looking at the suggested state regulations that the CRCPD has drafted, and we found correlations to Part C for other CRCPD folks in the room, that means kind of that that's their general licensing. And so what we did was we looked through Part C, which is currently under revision, and we identified the areas that specifically regulated the NARM material. And most of the states that have regulations for the NARM material, we think that they use these suggested state regs, but that's part of what I want to get a feel for in this room.

I don't know to the extent that states actually use these or enforce them, so they are out there as guidance, but it would be very helpful for us to know if they're used and if they're successful in their use. And so another method that we've been using to get input, we have Martha Dibblee who's on the Task Force, and Lee Cox are getting on the phone with the representatives from each of the states, all 50 of them, and asking them if they have programs for regulating NARM. And they have a specific list of questions, and they're constructing a big matrix for

us to get some idea of where we're coming from, the history and the background. And so I could read through some of the questions that we've been asking them - if they have statutory authority for NARM, if they're a CRCPD licensing state, if they have specific licenses for NARM, if they regulate TENORM, if they exempt any NARM from their regulation requirements, and another question, do they license discrete and diffuse NARM or just discrete, do they allow NARM waste disposals in their state, and do they allow APRM disposals in the state, if they license PET facilities, and the number of NARM licensees, as well as APRM licenses, and if they -- I guess that's it. And so just getting the comments and the questions from all of the states on what they're doing, and if they have any advice for us here at the NRC.

MR. CAMERON: Okay. Thanks, Jenny. And Jenny gave you an idea of what our methodology is to try to get to some answers. And she mentioned two words, "history" and "background." And it may be useful before we get into the thicket of this to have some discussion, perhaps, of well, what's the philosophy behind this to the extent practical? What's the general foundation for why we're doing this? And I'm going to go to Lynne, and then Mary,

and then Ralph first. Lynne because she gave me a pretty concise description of what the issue was here when I talked to her. Lynne, do you want to start us off? Then we'll go to Mary, and then to Ralph, and then over to Roy.

MS. FAIROBENT: I'll see if I can. When I had chatted with Chip ahead of the roundtable on some of the potential issues that could come up today, one of the things is, obviously, this leveraging of the existing state regulations that are either ask an SSR suggested state regs in the CRCPD parlance, or in fact the states who have had aggressive programs for a number of years.

The thing that I think the community is most concerned about is the reinventing of the wheel. And I don't think, one, we don't have the luxury of the time frame to try to do that. And two, obviously, this material has been regulated, and it may vary from state-to-state, but it has been regulated by the states for a very long time. I'm not so sure the whole issue is broken, but we have direction now from Congress that we need to do something that appears to be some of a fix for whatever purpose, whether it's just to bring it under the federal umbrella system. But in doing so, I think we need to be sure that we

extract, pardon the pun, extract the relevant regulations that have worked to-date, and if there have been problems, identify those problems and mitigate them as we go forward with a federal umbrella system in order to, perhaps, resolve some of the inconsistencies from state-to-state, and the variability that has existed there.

From the medical community side, our concern is that we provide an awful lot of technical resource and support to the Conference of Radiation Control Program Directors and the suggested state regulatory process. And we fully want to continue to do that, and we think that this is one of the best vehicles for bringing in the medical community and the users groups' technical input to the development of the regulations. It's not as limited in the SSR process as it is in the federal rulemaking process for doing so. And I think that that technical input can be leveraged as we move forward into this regulation that has to be developed under the Energy Policy Act. Chip, is that good?

MR. CAMERON: Yes, that's great. Thank you, Lynne. And I guess I'd like to follow the thread of this, the broader issues at this point. I would just note that Lynne mentioned problems, the statutory

language is to the extent practicable, so it might be useful during this discussion to also to identify what potential downsides there are, for example, to using SRRs, or using states that have aggressive programs, so that the Staff can anticipate that.

Mary, did you also have sort of a broader point for us? Okay. Great. Thank you.

DR. MOORE: First, I commend the approach. I think the dual approach and the suggested state regs and the efforts of the CRCPD and other professional societies in development is excellent. But one of the hats I wear is a Commission Member for the New Jersey Commission on Radiation Protection, and we draft the regulations in New Jersey with statutory authority.

I would encourage you to continue surveying all of the states, because we do not automatically adopt the suggested state regs. We use them as guidance and a reference, and they are an integral part of it, but I think you're going to find among the individual states we're rather independent. And in New Jersey, we have an outreach not only to the medical physicists, the health physicists who get involved, and drafted, and are willing very graciously to participate and spend a lot of their time developing along with the physician groups, the

pharmacies, the nuclear pharmacies. We have an outreach for that. Again, to see what's going to work in our state.

And some of us were discussing the variability among the state regs. I think you need to identify what those variabilities are, reference them against the suggestions because the states have the purview, they have this ball of wax. I think the new regulations and the interface will cause confusion if this is not clearly defined. But I think your approach is good to keep comparing it to and have maximized your input from these two groups.

MR. CAMERON: The approach is good in terms of doing the survey to find out where the variability is, just wholesale adoption of SSRs may not be just the only source here. And the states being independently minded, so we're going to I'm sure get discussion on those issues. We have a lot of cards, a lot of tents up. Let's go to Ralph and Roy and see where we are then in this discussion.

MR. LIETO: Well, I had a question, and I think it's gotten answered a little bit. But to NRC Staff, the question would be that if states had or adopt the suggested state rules, that there is a high level of compatibility between those suggested state

rules, and current NRC regulations. Is that an accurate statement? Okay. Specifically, the parts that I have in mind that I think apply to the issues that we're addressing here today would be the NRC Parts 19, 20, 35, 30 and 32. Are those parts all addressed in the suggested state rules? Obviously, I'm not familiar with all the SSRs, but are all those parts addressed in the -- okay.

MR. CAMERON: Okay. You're getting an answer to that. I want to make sure that it was clear what we said about compatibility, though. Your general question was, what's the relationship between compatibility categories and the SSR. And I heard - I couldn't hear the shaking of heads, but I guess I saw the shaking of heads. Can we be --

MR. LIETO: Just point of clarification. Maybe compatibility is a wrong word to use here.

MR. CAMERON: Okay.

MR. LIETO: Because with the states, not coming from an agreement state, sometimes you're not as sensitive to what that word means with agreement states. But mainly, that if we use the SSRs is that they provide a template that would provide an easy flow from going from NRC regulation into state regulations, and vice versa.

MR. CAMERON: Which is sort of -- it's a broader question. And, Scott, you may - I don't know if you want to comment on that, but the compatibility issue is eventually going to have to be addressed. And I don't know if you want to just lay out for the people who are not familiar with our compatibility process what that's all about. Can you do that?

MR. MOORE: I can say something real quick about compatibility.

MR. CAMERON: Okay.

MR. MOORE: When we do a rulemaking, as part of the rulemaking, we have to address compatibility as part of the rule - we, the agency, have to address compatibility as part of the rule, so each part of the regulations gets assigned a compatibility rating, which means that agreement states have to adopt the rule at some level of compatibility; meaning that they have to adopt it with essentially identical standards, which is a certain level of compatibility, or they have to meet the intent of the rule, but it doesn't have to be essentially identical, which is a different level of compatibility. So there are different levels of compatibility, and when a rule is drafted, compatibility levels are assigned and identified on

what the rule that the Commission adopts. I guess that's how I'd explain that.

I want to address something that Ralph said, but I think it would be fair to let Barbara address compatibility to you, and add anything else to that.

MS. HAMRICK: No.

MR. MOORE: Okay.

MR. CAMERON: And I would just say, keep in mind that compatibility is going to be an important issue here. And, obviously, there's no proposed compatibility category in front of you, so that all of the policy issues about does it need to be exactly uniform, can the states be more creative, the types of things that Mary was bringing up - all of those points that you think are important about where it might fall, you don't need to know the categories, necessarily, but we'll be listening for that. Scott, another --

MR. MOORE: Ralph asked about suggested state regs, and SSRs in this area. We're learning, NRC is learning about the SSRs in the area of accelerator produced material and naturally occurring material. And we're very familiar with SSRs in our areas already of the Part 30 series, but what we're

finding is that while there are some SSRs in the area of naturally occurring material, what we really need to know is what SSRs exist in the area of accelerator produced material. And there aren't all that many. If there were, and if everybody had them, it would make our job very easy, if everybody had adopted them. Otherwise, we could just adopt them, so to get back to Ralph's question, there isn't just a consensus standard out there that everybody has adopted that we can just --

MR. CAMERON: And I don't want Barbara to blow a fuse on us.

MS. HAMRICK: Well, either Ed or I, but the point is the reason there's not a special part for accelerator produced material is it's just radioactive material. So the Thallium-201 in the nuclear medicine lab is treated the same as the Technetium or the other reactor produced material. We don't have to call it out separately, because it is just radioactive material. So Part C covers it for the licensing, the SSR for Part 20. There's no special regulation that would cover that. And, in fact, that's one of the things I wanted to say to get on the table here, is that in reality what I see this rulemaking doing is (a), you've got to amend the definition of byproduct

material; (b) you need to add a definition of discrete; (c) you need to somehow define where that extraction point is, but really other than that, you don't need to create a new regulation.

MR. CAMERON: Okay. And that's going to be very important in terms of what should be that exact -- how do you translate this into rulemaking language? I want to go to Roy, and then to George and Ruth. But why don't we get the regulators in right now, and go to Ed, and to Lee. And then we'll go around the table. Ed Bailey.

MR. BAILEY: Yes, I would like to clarify a little bit the SSR process. When we do an amendment to a part of the SSRs, those amendments are sent to three federal agencies for concurrence. They're sent to FDA, they're sent to EPA, and they're sent to NRC. So at least in theory, when we send a regulation to NRC, and they concur in it, which they do most of the time. I think we may have one outstanding example of where that hasn't occurred. The idea was that a state could simply take those suggested state regs, know that they were already concurred in, and put them into their regulations.

Now NRC goes ahead and reviews them again, I understand, and sometimes that causes some problems.

But in general, the only things that we add or have historically added, are things in the NARM area. And some examples would be that we do have some exemptions for certain levels of NARM products. We do have the concentration limits for emission, which uses same methodology for calculating that are used in Part 20. We do roll the dose rate or annual dose into one big bundle, and actually throw in x-rays. So as Barbara has said, we don't see the big deal. The big deal is where do you draw the line on the floor, if you want to call it that way, in a PET production facility. And once it crosses that line, it becomes NRC's. And I think that's where it's going to take some fine tuning of words, and maybe little turf battles here and there.

The problems that have been alluded to of states doing different things, and it's primarily, I think, because of these things and our say in the in PET process. And the big problem we have is we can't separate out what is new and what is the old traditional byproduct material. I can't tell you - well, I know `83 licenses certainly include NARM. That's the real problem we have. We don't treat it any differently.

MR. CAMERON: Okay. Let's hear from Lee,

and then go over to Ruth, who obviously, is a state regulator longstanding here representing Health Physics Society, but she may give us her views on that. Lee.

MR. COX: I just wanted to address some things that Mary said, and assure her that as part of my job as a member of the Task Force, I am looking at the differences of the state regs and not just the SSRs. And Martha Dibblee is behind me has done a lot of the work looking at the SSRs in the non-agreement states, so that is being looked at by the Task Force.

MR. CAMERON: Okay. So that's good. Great. Thanks, Lee. Ruth.

Ms. McBURNEY: The Health Physics Society certainly supports using the suggested state regs as a starting point. In fact, I think that was pretty much the intent of Congress in putting in this part of the bill. When we visited with Congressional staffers on this issue, they were excited to hear that there was already some consensus standards among the states out there, and this is one way that NRC could meet that aggressive time line, is to use those suggested state regs as a starting point.

As Ed mentioned, there is already a regulatory framework similar to that for existing

byproduct material on the NARM side. There is exempt concentrations, exempt items, a generally licensing part, manufacturing of general license products that are accelerator produced and naturally occurring. The sealed source and device reviews are very -- I mean, there's no difference. And also, medical uses and industrial uses, the states regulate them the same, so using those as a starting point, as Barbara mentioned, is just pretty simple, except for those over-arching issues of how do you define discrete source, and how do you define produced for commercial, medical, and medical activity, just to define the scope of what you're going to be regulating.

MR. CAMERON: So, Ruth, what you're saying and others around the table, is that once you set these definitions, is that the approach should be well, let's just use the SSRs as a starting point. We also heard Lynne included a different, I think you termed it aggressive state programs, and that's another consideration. Let me go to George, and then over to you, Barbara. George from the FDA perspective on this.

DR. MILLS: Several things, as you're touching in, I'm concerned about making sure we get these definitions looked at, as you push the

rulemaking forward, because again, we've got three approved sites in the United States now for producing FDG, and we've got an active program with the CGMPs coming forward to look for more of these sites to actually become approved. So from that aspect, as we have inspection programs working here, we've been in in terms of doing for approvals, for licensing, also for inspection for cause, and we've actually shut one PET Center down this year on a temporary basis because of a misadministration practice. So be cognizant that we're there on the same area and affecting both agreement states, as well as NRC states, so you want to take a look at that very carefully with the definitions.

MR. CAMERON: Okay. Thank you. And we'll get to those definitions. Barbara, did you have a quick comment?

MS. HAMRICK: Yes, it's very quick. I just want to emphasize again when we talk about taking the state regulations as a starting point, what we're -- the only thing we're really talking about is taking the, for example, the exempt concentration or the exempt quantities, the exempt concentrations, just taking those specific nuclides out of the tables that aren't already in Part 30. And that's what we're

talking about.

MR. CAMERON: Okay. Good. And I know people understand what you just said better than I do, but we'll go back to that in specific. Now let's go to --Roy had his card up for a while. We don't we go Roy, James, Felix, and then over to Roger. Okay, Roy.

MR. BROWN: Thanks. There's been a considerable amount of coordination prior to this meeting between a lot of the nuclear medicine communities. CORAR has been working with SNM and ACMP, and ACR, and we're clearly in agreement that using SSRs would be a great way to go, or finding a model state to model the new agreement states after would be a great way to go. But it really troubles me when we get into issues of compatibility, because that's where have a lot of problems, we've had a lot of problems in the past. Prior to the new definition of byproduct material, one state previously defined Fluorine-18, Carbon-11, and Agent-13 as byproducts, even though they're clearly accelerator produced before the new definition.

We have another state that has a 10 milligram per year criteria for release criteria, license termination criteria rather than the NRC's 25. I mean, we have one state that has very state-specific

labeling requirements that potentially conflicts with FDA, so we have this hodgepodge of different states doing different things, so we would really, really like to see a high level of compatibility, not just start at the SSRs, and then the states kind of wander off any direction they want to go in. That really creates a lot of operational problems.

MR. CAMERON: And that, I think, squarely fits into our next subject, too, which is the uniformity issue, so we'll get to that one. And Roy not only identified the problem, but gave his view that there should be a high level of compatibility. So we'll get to a discussion of that. Let's hear from James, Felix, and Lynne. Ed, did you have --

MR. BAILEY: Just a quick comment there. You know, we as states are going to be looking, as Lee has indicated, but I think the users who are operating in many states need to make a list of where these things are different, because to us, they may be transparent. I mean, when we talk, we think we're saying the same thing, perhaps. But we need to, I think, a list of those differences and identify where they are. Not today, just --

MR. CAMERON: And I think Roy is going to give some examples of that. Right?

MR. BROWN: Yes. Can I respond to Ed's comment? Is there some way we can do this as part of the rulemaking process? I mean, is there some way we can -- the industry can get together with CRCPD or OAS or NRC like now, rather than wait for the proposal to come out, because we're allowed to come up with a list of those differences and share that with you.

MR. COX: I think for the agreement states, I --

MR. CAMERON: Yes, you've got to talk into the microphone.

MR. COX: I'm sorry. Lee Cox, North Carolina I would be glad to meet with you and talk with you about those differences.

MR. CAMERON: Okay. And let's hold this. Thank you, Lee. It sounds like there would be enthusiasm for this, but let's hold a further discussion of this process until we get to the next segment. And we might ask Jenny how her survey of the states, it ties into all of this. But let's go to James, Felix, Roger, Lynne, and Ralph. And I think we probably have to go to the phone, so to speak, at that point. James.

DR. CASE: Okay. I have a bit of a concern about when I was looking at the template

states that were being proposed, states like Texas and California, where I work is in Missouri. We get I-123 from Canada. We get Thallium from across the state in St. Louis, we get F-18, FDG from Omaha. We've talked about getting Ammonia from across the state line over in Kansas. And really, in Kansas City, Missouri there is no cyclotron. Transportation issues become a very important issue for the practicing community to be able to do this. So if we say oh, we're just talking about the material just after it's extracted from the cyclotron, and when it enters the patient, yes, it could be being produced up in Montreal, and then coming through customs, and then dah, dah, dah. So when looking at a state like California and its regulations, I think the practicing community is going to be very interested in how a state like California could practically be a country, it's so big, how it relates to those of us out in Missouri and Kansas.

MR. CAMERON: Okay. Thanks, James. Another example of differences that need to be addressed. Let's go to Felix and George, and then we'll come back over this.

MR. KILLAR: I just wanted to touch on this briefly. We did an informal poll of some of our members on this issue, and basically what we found is

that the states are all over the boards, that they are certainly not created equal. We found states that basically had zero program, and states like California and Texas had a very good and very elaborate program. The concerns members have is that as we look at the states as a model, I think we want to limit it to what Barbara has suggested, is that we're just looking at the Section C to establish the waiver level, exemption levels, things on that line. And then as far as the actual regulations, we're more inclined to move toward the agreement state program approach as regulational type concept of compatibility because of the differences we see in the states. So that's the main thing that we're concerned about, is how this all is going to work together.

The other thing that hasn't been brought up yet, which is a concern that a couple of members have raised, is that in some states to change a level for regulation of radioactivity, they have to go to their state legislature in order to get that change done. How is this going to impact that, or how is that going to be impacted by this, because it really causes some real grief when we start talking about uniformity and compatibility, where we run into these type issues.

MR. CAMERON: Okay. That's a good point of consideration when we're doing this, is that how many states are going to have to go back to their legislatures to make these changes. Scott, did you want to make a point on that?

MR. MOORE: I can just answer the question on the legislature side. As part of compatibility, oftentimes agreement states are typically given three years to adopt regulations, even under the regulations where agreement states are required to be essentially identical, which is compatibility Level B, to give them time to go back to their legislatures and get them adopted. So under Compatibility Level B, which is essentially identical - pardon me?

SPEAKER: A and B are both --

MR. MOORE: Okay, A and B. Agreement states are typically given a three-year time period to adopt those regulations. And it's specifically for those reasons that they need to be able to go back and review the legislative processes.

MR. CAMERON: Okay. Thank you. My plan now is to, and usually my plans don't work, so don't worry about it. But it's to go to Roger, Lynne, and Ralph, go to the audience, our people in the TV room, and the phones, and then to take a break and come back

and talk about the implications for radiopharmaceutical availability. Roger.

MR. MORONEY: As a customer of many of your state programs, I just had a couple of comments here. First of all, we do agree with Barbara and Ed that there is nothing special about NARM and we would just like to see it rolled into the existing regs, add some isotopes and move forward.

As far as the comments on the independence of the state, I guess one of the things with PETNET that we've tried to find out or understand is where are these differences coming from. Is there a technical basis, is there a reason? We're willing to comply and work with all your regulations and your processes, but sometimes what we have found is the words may be the same on the page and what's in the regulations, but it's the implementations that's different. And I'm wondering if there's a linkage here to resources, where one of the things that perhaps the NRC can bring greater resources in depth and technical. We all operate under budget constraints, myself included. I'm getting this real well with our recent acquisition by Siemens, so that's something I just wanted to throw out, perhaps we could set up some resources within the NRC that could help.

MR. CAMERON: So it sounds like that you might support Roy's suggestion that there be some type of collaborative process to try to do this.

MR. MORONEY: Yes, very much so.

MR. CAMERON: Okay.

MR. BAILEY: I have to respond just real quickly.

MR. CAMERON: Go ahead, Ed.

MR. BAILEY: I think what you mentioned is exactly why the agreement states have, as long as I've been involved, wanted a federal agency to regulate NARM or NORM. And it was to a large extent the genesis of the licensing state program, was try to bring some uniformity to the process.

MR. CAMERON: Okay. Thanks, Ed, for that perspective. Lynne, and then Ralph.

MS. FAIROBENT: Yes. I just want to caution us to be careful on the terminology we're using. Ruth earlier used consensus standard in terms of the SSRs. They really are not a consensus standard. They're an example or an agreed to approach, and regulatory consensus standards have a very different meaning and a lot of other terminology, and I just want us to be a little sensitive to the use of terminology.

MR. CAMERON: And I think we know where you're coming from with that, and I think the use of the word "consensus", though, tied back into the fact that CRCPD does seek the concurrence of FDA, EPA, and NRC. So small "C" consensus, rather than -- and other stakeholders. Okay. Ralph.

MR. LIETO: Well, this might be, I guess, sort of a lead-in into the next conversation after the break, but I wanted to emphasize, and I can't remember if it was Barbara or somebody else that mentions this, or Dr. Case, but the biggest, or one of the biggest areas of impact is going to be on the non-agreement states in terms of NARM regulation. And especially where you have had, to a large extent, nothing more than a registration process with minimal inspection enforcement actions. This is going to be like going from the Dark Ages to the 20th Century, and so it's going to have a - I know I'm going to pay for that statement - it's going to have a tremendous, I think, impact in those states coming up to speed, I think, or I should say those registrants or licensees, if you will, in non-agreement states coming into this process that many of us have either just as NRC licensees with byproduct or agreement states have been involved with for years.

MS. TOBIN: Can I respond?

MR. CAMERON: Okay. Thank you. Go ahead, Jenny, and then we're going to go to the audience. Go ahead.

MS. TOBIN: I'd just like to respond to that with some work, the calls that Martha has made to some of the non-agreement states, and out of those 17, she's found that 14 have NARM regulations on their books, and 7 of the 17 register NARM material, and 4 license NARM material, so it does look some of them do have pretty good programs. And some states like Michigan have over 600 licensees.

MR. CAMERON: Okay. Thank you, Jenny, for that information. And Ralph.

MR. LIETO: This is Ralph Lieto. Jenny, I really caution you guys on that, because I come from Michigan. The rules were written in 1972 and have not changed. So yes, they have rules on there, but nothing refers to accelerator produced.

MR. CAMERON: Okay. We're going to go to the audience, but our next discussion is going to look at so-called dysfunctionalities that might have an effect on availability of radiopharmaceuticals, access as Terry pointed out to us this morning. And Roy brought up the idea of a collaborative process to

identify differences. Roger talked about well, there may not be differences on paper, but there might be differences in terms of how it's implemented, what are the implications of resources? And Ralph's point is that there's going to be a big impact of whatever we do on agreement states, which I think --

MR. LIETO: Non-agreement.

MR. CAMERON: Non-agreement states, which I think fits in with this discussion. I just put it up here because I guess are you increasing these dysfunctionalities, when you have to keep an eye out for that. But let me to go audience now, and then we'll go to phones, and then the overflow room. Anybody out here want to say anything about the discussion that they have just heard, and let me -- do you mind if I --

MS. ROMANELLI: Gloria Romanelli with American College of Radiology. George Mills had discussed the distinction between approved products, licensed products, and regulated products. I was hoping at the beginning of the next discussion he can discuss that paradigm and how the federal agencies, as well as the state SSRs would be coordinated under George's thinking.

MR. CAMERON: Okay. And let's try to tie

that into the topic that will be discussed. That's obviously important, and when we do go to that discussion, if George and others can context where that fits into our scheme of discussion. Thanks, Gloria. Okay. And, George, you understand what Gloria was asking. All right. Other questions out here in the audience? Yes. This is Sally Schwarz. Go ahead, Sally.

MS. SCHWARZ: This is Sally Schwarz. I'm from Washington University in St. Louis, Missouri. And again, the whole issue of the non-agreement states, I just wanted to state even though there are regulations on the book in many of these non-agreement states, again as Ralph mentioned, they're antiquated often, and there's no infrastructure in these states, or not none but small, I mean, compared to the agreement states. So I'm just curious as to funding, I mean, as to thinking about how this process will be evolving in the non-agreement states, because I know everyone is under budgetary constraints, thinking about NRC essentially taking on the non-agreement states. I mean, regulating NARM. I'm just concerned about the overall picture of how this will proceed.

MR. CAMERON: Okay. In terms of what are the implications for the non --

MS. SCHWARZ: Right, for the states. I mean, as far as if there isn't personnel now, how will this be progressing, how will this actually be regulated?

MR. CAMERON: Okay. We need to discuss that. That's related to Ralph's point. I'm not sure it fits in necessarily with our next discussion, but maybe we can start off with that. Barbara, did you --

MS. HAMRICK: Just quickly, I think that is addressed, or is supposed to be addressed through the transition plan that the Task Force is going to be developing. That transition plan is being developed in order to move non-agreement into either agreement status, or for the NRC to start regulating. That's what that transition plan is for. That's not developed yet.

MR. CAMERON: Is that correct?

MR. MOORE: That is correct, and the transition plan will address that. And actually, that scenario I think we'll have a fairly good handle on. We'll have to pick up the licensees in the non-agreement states, but we will have resources to be able to deal with non-agreement states as an agency. If those non-agreement states want to become agreement

states, we'll have to address that part through the transition plan. And there are policy issues to deal with under that. But I think in terms of resources, we'll be able to deal with non-agreement state users. They'll just remain non-agreement states if they want to remain non-agreement states, and we'll pick up accelerator produced material, and Radium, discrete sources of Radium under our jurisdiction.

MR. CAMERON: And there's two issues here. One is the transition plan, once you decided what's in the rule. But in establishing the rule, you need to also consider transition issues, such as the implications on non-agreement states. And we need to have a discussion of that, and maybe the best point to save that for, is to save that for the other issues at the end of the day, and start off with that. But it's not just once we have the -- is that your point, Sally, is that your concern?

MS. SCHWARZ: Yes. And one of the things, too, I mean, is that there are a lot of freestanding facilities that aren't licensed, and so you're talking about a large number of potential licensees that, again, will have to be submitting licenses. I mean, I know it comes into compliance but they're all time--

MR. CAMERON: Okay. Thank you. And,

Mary, I'm going to go to the phones now, but just keep your card up. Jill.

JILL: Yes, Mr. Cameron.

MR. CAMERON: We're ready to hear from our phone pals.

JILL: Okay. If anyone out there would like to ask a question or make a comment regarding today's conference at this time, please press Star 1 on your touch tone phone. Once again, if you would like to ask a question or make a comment regarding today's conference, please press Star 1 at this time.

MR. CAMERON: Okay. Jill, it sounds like people are okay with questions, comments now, and then we'll just go back to them later on. Is that okay?

JILL: That is fine.

MR. CAMERON: Okay. Thank you, Jill.

JILL: You're welcome.

MR. CAMERON: In the TV conference room, are there any comments/questions about what you heard this morning, anything at all? Okay. We don't want to ask what's going on over there, but all right. Thank you. And, Mary, final comment, and then we're going to go for a break.

DR. MOORE: This may be covered as transition for our next section, but Sally and Scott

both identified focusing to me on the three areas needing attention, the non-agreement states, the producers, nuclear pharmacies be they large companies or independent operations, and interfacing compatibility, or compliance, consistency, whatever word we want to use with FDA and EPA. But in the point that was just raised, and one earlier, for the states that don't have any regulations, or they're antiquated, whatever in the non-agreement states, and the NRC is going to then take oversight. According to what we discussed this morning, you only will have oversight over part of it. And this is what I was talking about for not only transition, but implementation, and confusion, is the states right now have jurisdiction over the NARM, so they license it, they inspect it. The regs address it. Now another agency is going to be coming in who is going to need to interface, and I know that's what everybody's struggling with, and I'm stating the obvious, but have to interface with the state programs. There may not be a state program, so now you're going to come in and oversee what I'm addressing or pointing out is a conflict that you folks are going to end up with. You're going to look at part of an operation. You may see there's serious issues with the rest of it, but by

regulation you're prohibited from taking care of it. And I think you need to address that, at least think about it.

MR. CAMERON: Okay. Thank you, Mary. And I think we're going to have a fuller discussion at some point of these types of issues that Ralph, and Sally, and others have raised. I have 10 to 11, and to allow you to get coffee and everything, why don't we take 25 minutes and come back at 11:15. Do we need escorts, Leslie?

MS. KERR: Yes.

MR. CAMERON: If you want to go to the restrooms, you're free to go without an escort. But if you want to get coffee, you need an escort.

(Whereupon, the proceedings went off the record at 10:52 a.m. and went back on the record at 11:23 a.m.)

MR. CAMERON: Okay. Here's Leslie.

You know, there are a lot of people in here. I don't know if you want to be informal and take your coats off, whatever, please do that. We're going to go to the next overarching issue, and we have Cindy Flannery here who in a minute is going to do the tee-up for us.

I just want to go over a couple of things

that we were discussing before lunch to try to put them in context. One of the things is that someone mentioned since this is sort of a rarified atmosphere here or group, when we do use acronyms we might want to explain them since there are people like myself who might not know. So that would be helpful.

We really tuned in on the differences in the state regulations as sort of an introduction for this particular discussion. Gloria Romanelli asked George Mills a question about the FDA framework, and that FDA and EPA framework are also going to be very important when we get to definitions, but obviously inconsistencies can develop not only because of differences in state regulation, but also because of the differences in the federal approach.

So I think that we might want to have a limited discussion of those differences of the framework, hear from George and hear from Bonnie, and then get more in depth when we get to the definition.

Roy Brown in connection with this subject talked about, well, it would be nice if we could have, and I'm using the term "collaborative process," okay, because that's what it sounded like to me, is that maybe a group of people can get together and help the staff. Roy mentioned Sierra CPD, others with effort

to identify some of the differences and how those might be dealt with.

I think Scott Moore is going to -- we're going to put this in the other issues category. Okay? Because it's a process issue, and I think Scott will address that at the time. The more information, the better, and the staff just has to evaluate what schedule issues there might be from doing something like that, as well as, you know, if there are any legal issues, there's the Federal Advisory Committee Act, which we all know and love and we have to live within the constraints of that.

So there's issues like that. We spent a lot of time on implications for non-agreement states, and I think we know that there might be more than transition issues there, but I'm going to put that in the other issues category. We'll go back and talk about those transition issues there.

And here we go, Cindy. Cindy Flannery.

MS. FLANNERY: Well, good morning. I'm Cindy Flannery of the NRC's Medical Radiation Safety Team in IMNS, and the next round table discussion is on the availability of radio pharmaceuticals, and as we can see by the representation here at the table, the signing of the act and the expansion of the

definition of byproduct material to include NARM is of particular interest to the medical community, you know, given that the many different rate of pharmaceuticals are produced by accelerators.

And one area that's getting a lot of attention lately is the area of radiopharmaceuticals produced for PET. The Section E(4) of the act requires NRC to consider the impact of the availability of radiopharmaceuticals to patients and physicians from promulgating NRC's regulations and programmatic changes.

At the October 26th meeting of the Advisory Committee on the Medical Uses of Isotopes, two different stakeholders, namely, the Society of Nuclear Medicine and CORAR, presented their positions on NRC's new jurisdiction over NARM and the impact that it has on manufacturers and distributors of radiopharmaceuticals and the nuclear medicine community.

So at this time I would just like to open it up for discussion.

MR. CAMERON: Okay. Thank you, Cindy.

What I'd like to do is perhaps hear from Roy and George and Terry -- Terry raised this -- just to get their thoughts on the table here to sort of

open up the discussion.

Roy.

MR. BROWN: Where do you want me to start? Do you want me to start with inconsistencies or --

MR. CAMERON: Whatever you -- if you want to give us your view, I mean, in summary of all of the major issues that you see here in terms of implications, maybe that would be a useful framework to start with, but I want to make sure I go to not George; Roger, Roger, and then to Terry, and then we'll see where we should go with the discussion.

MR. BROWN: Okay. Let me start then with some inconsistencies in putting together comments on this. A lot of the career member companies went back and put together lists of where they were having troubles with inconsistencies from one state to another, and we got a wide variety of comments and concerns, and I'll share a couple with you leaving state names out.

(Laughter.)

MR. BROWN: One licensing entity requires SI units only on licenses, which is, of course, in consistent from some other licensees.

Another state -- I mentioned this before -- classifies Carbon-11, Nitrogen-13 and F-18

as byproduct materials and also calls anything produced in an accelerator an activation product. So that particular state had their own definition of byproduct material, and also they redefined activation products from what we conventionally think of activation products.

Also, I mentioned before one state in particular has a ten millirem per year unrestricted release criteria and also licensing termination criteria when decommissioning versus the NRC's standard of 25 millirem.

Other examples. This isn't quite as applicable here, but one state requires cyclotron operators to have 1,000 hours of training and ten successful production runs. Another state requires only 80 hours of training with 280 hours of didactic training. Another state requires 40 hours of training. So just the training is different state by state. The requirements are different state by state, and it makes it very hard for licensees to comply.

As I also mentioned this morning, one particular state -- or I mentioned to Lee during the break -- one particular state requires the radiation safety officers to have a B.S. in health physics. So you have a situation where if the company has multiple

pharmacies and you want to transfer an RSO from one pharmacy to another, if he's qualified in one state he may not necessarily be qualified in a second state, which is very, very inconsistent.

So we've got a series of inconsistencies here that makes it very, very difficult to comply with.

Also, I have one horror story that I like to share with people and I also shared with Lee during the break. This goes back to a radiopharmaceutical manufacturer that had a new NARM radiopharmaceutical product that came out, and with a conventional byproduct material radiopharmaceutical you would simply go to the NRC, send the information in, and you would have an amendment to your distribution license, and you'd be good to distribute it in all 50 states.

However, with a byproduct or -- I'm sorry -- with a NARM radiopharmaceutical you don't have that luxury. So this particular manufacturer went to their state where they were located, which was an NRC state. They asked that state to review and approve this new NARM radiopharmaceutical. The state said, "No, I'm sorry. We don't do that. We can't help you."

So the company started going state by state and tried to find out what they needed to do to

distribute in all states. Some of the states were very cooperative and said, "Send us a copy of the labeling or the package insert. You can distribute your product into our state."

In most states that wasn't a problem. One particular state who will also remain nameless said, "Well, I'm sorry. You have to have the state that this product was being manufactured in review and approve the radiopharmaceutical after FDA approval."

And the company said, "Well, I'm sorry. Our state doesn't do that, and then the second state said, "Well, you need a state touching your state to review it and approve it."

(Laughter.)

MR. BROWN: So the company went to all five of the states that touched that particular state, and none of the states agreed to do that. So a third state or one of those states touching the original state said, "Well, if you get another state to review and approve it, then we'll review and approve it."

So a fourth state actually reviewed and approved it. It went back to one of the states touching the state where it was being manufactured. They reviewed it and approved it, and then it was finally allowed back into the first state that

wouldn't allow it in, and that whole process took six months.

So you're in a situation where many of the states, 40-plus of the states had this new radiopharmaceutical within weeks after FDA approval, but then some of the longer states that took as long as six months to get that new radiopharmaceutical into those states.

So you had a situation where physicians were taking their patients across state lines to get the diagnostic studies done, and it's just a bad public policy.

MR. CAMERON: Okay.

MR. BROWN: That's just a couple of examples. I don't want to go on and on.

MR. CAMERON: All right, and the implication is that the state inconsistencies can interfere with broad and open access.

MR. BROWN: With patient care is what it boils down to.

MR. CAMERON: Okay, and also I guess one of the questions that the NRC would like to hear is that in dealing with this norm and establishing this norm rule, what are the ways that those dysfunctionalities can be dealt with, and are there

problems of dealing with those dysfunctionalities?

I'm going to ask Roger and Terry to talk and then we're going to go to an open discussion. And I don't want to forget about the federal aspect here with George and Bonnie, but I'm just sort of trying to set the context now, and maybe George and Bonnie after we hear from Roger and Terry, maybe you would just say a few words about the federal framework so that people can factor that in.

But let's go to Roger and then we'll go to Terry. Again, we're trying to set the context here. Go ahead, Roger.

MR. MORONEY: Thank you.

Roger Moroney with PET Pharmaceuticals.

Unfortunately I gave all of my good ones to Roy, but let me give a few more inconsistencies one of which is becoming more and more of an issue with me in the states, is decommissioning funding than setting appropriate funding thresholds.

We've encountered quite a bit of variation from state to state with their expectations on funding, even down to the point of they want the bond drawn on a bank in that state, and it's a lot of overhead on our end trying to sort these details out.

Many of those regs, I think, were written

by accountants or lawyers and are difficult to interpret things, mere health physicists.

One of the other things talking with Sally was the impact that's going to happen on some of the free standing diagnostic claims. There's a lot of just plain PET diagnostic claims out there that have in the case of a non-NRC state or in the case of an NRC state have no license or no registration whatsoever and perhaps little, if any, oversight.

And then within that subset you have global path and the issues associated with, as the agreement states know well, regulating those folks.

(Laughter.)

MR. MORONEY: As far as inconsistencies, one of the biggest ones that's impacted us is a requirement to have a health physicist on site 50 percent of the time because we have a cyclotronic facility. That is a huge impact on our staffing, and it has caused quite a bit of issues with us in that particular state.

MR. CAMERON: Okay. Thanks, Roger, and you also talked before about some of the inconsistencies might come from the way the states implement these.

But keep in mind the assumption that we're

hearing is that these types of inconsistencies result in, they interfere with access, and others you may want to test that assumption. You may want to talk about, well, there's countervailing considerations.

We heard from Mary earlier this morning about the states being independent minded and with that goes there might be a need for difference because of the culture in that state. If I can use that with New Jersey, I will.

But okay. Terence, you talked about unintended consequences this morning. That's the phrase you used. Can you help us do a little more context?

DR. BEVEN: Hopefully. What I'm going to say is redundant, and that's good because I think it indicates that perhaps we have incipient consensus around this table about some of the issues we're discussing.

I would like to put out several recommendations for the consideration of the staff during this process. The first is to regulate with the accessibility rate the pharmaceuticals as a primary concern. The regulation should be written with accessibility of isotopes in mind, particularly those that are short lived and contain low levels of

radioactivity.

Incidentally, that was part of our motivation for presenting a laundry list of materials at last week's ACMUI meeting because of the dose and the impactacality (phonetic) as far as used in terrorist attacks.

We do want to reduce the possibility that delays resulting from regulation could be harmful to patients who require diagnostic and therapeutic procedures using radionuclides.

The second is to model the regulations after a successful agreement state programs, such as California, which could be used as a model to create efficient and successful regulation.

Third, include a mechanism to resolve problems post implementation.

Have a group of physicians and scientists, possibly ACMUI, to identify and, most importantly, immediately resolve any problems that materialize upon implementation.

And the last is to work closely with FDA and the medical and scientific community. The FDA has expended substantial effort over the past decade with extensive involvement by the PET community developing its recently published proposed CGMP rule and draft

guidance for PET.

Additionally, FDA has worked extensively with the regulated community and with respect to guidance on exploratory INDs and the role or ability of NRC.

The NRC should coordinate closely with the Food and Drug Administration and use FDA's scientific and regulatory expertise to develop and implement these new regulations. And I hope that NRC will continue to work with the scientific and medical community during this process as well.

MR. CAMERON: Okay. Thank you very much, Terry.

Again, and we're going to go to George and ask Bonnie if she wants to say anything on this issue. She may not, but again, you're hearing about some inconsistencies. You have to consider the assumption that this is something we need to address, and then how does the NRC address it, particularly since this rulemaking is, as I understand it, is one subset of -- I mean, there's a broader range of materials that inconsistencies apply to.

But, George, can you just -- we remember Gloria Romanelli's question. Can you just talk a little bit about the FDA framework? Terry gave you a

little bit of a lead-in, and then we'll just check in with Bonnie and we'll open it up for discussion.

DR. MILLS: All right. Thank you.

Where we're in the regulated atmosphere and area, I think, is where the key discussion should be. Number one is that when we speak of FDA approved products or drugs, that's a very limited definition in my world because we approve a drug. We license a biologic, and we regulate our INDs, our investigational materials.

So where we would immediately start working on it is this concept of definitions that we'll need to work on very carefully between the two.

The next is where we look at it in terms of your wording, radioactive drug, and I see that. First off is there are a whole lot more things. We think of source material, which we haven't put a drug together with, or that that source material has been put together as a biologic.

And so we see a multitude of definitions to work there, and so when we see that, we see if you use the word approved, you're going to get too limited and we're going to interface at the medical radiopharmaceutical use, and that's my concern and focus for us, is we don't over regulate or double

regulate or inadvertently step across in the investigational uses under IND the investigational uses under RDRC.

And as we evolve the CGMP reg and its guidance that were structured there so that we have regulations for the medical use, that we're going to be coming in observing, inspecting, and regulating in that area for you at the same time so that we have a good interface. And that's my focus for FDA's interface with you, is to be able to have that what I see as radiation safety elements coming from NRC and medical use coming from FDA and a very smooth interface.

MR. CAMERON: Okay. Thank you, George.

And we also have Rich Fejka here. Rich, do you want to add anything?

MR. FEJKA: Just that my responsibilities at the FDA deal with radioactive drug research committees, and quite a bit of PET activity is conducted under the RDRC. What's allowed to be done is well defined, but again, if you take George's look at this and see these drugs as FDA regulated, then maybe that umbrella doesn't necessarily have to be looked at as just RDRC or something that's dealt with in the division, but rather it's FDA regulated drugs.

MR. CAMERON: Okay. Thank you, Rich.

Bonnie, do you want to add anything from EPA's perspective?

MS. GITLIN: Go for it.

MR. CAMERON: I think Bonnie is probably the last --

(Laughter.)

MS. GITLIN: I'm passing on this one.

MR. CAMERON: Okay. Go ahead, Ed.

MR. BAILEY: No, and the only question was how is that different from the current byproduct material.

DR. MILLS: Well, and that's where I think our definitions have to have structure to it, because I see your material as source material when I think of in terms of my radiopharmaceuticals. You may take some of that source material and make it a diagnostic or even potentially a therapeutic. So we see that material.

But then what we get into -- and I'm getting into the definitions and so I'm going to get away from this microphone real quick -- is that we take that source material and we start compounding it to a drug, compounding it to a biologic, and so we have a whole spectrum of definitions that we want to

be sure that we have good structure with when we do rulemaking so that we don't inadvertently have categories suddenly getting into a confused area between the NRC and the FDA in terms of regulatory structure.

MR. KILLAR: Jim, if I may, one thing we have to be very careful of, and I alluded a little bit to what Lynne said earlier. When you refer to source material in the NRC world, that's Part 40 material. It has nothing to do with Part 35 material.

So we have to make sure we keep straight on that as well.

DR. MILLS: And just for cross-talk, that's my concern about getting our definitions right. I deal in another world with CMS the same way, and we have two different languages. Here I expect we are going to have to have our definitions on both sides, but know that we're consistent when we speak the terms to each other.

MR. CAMERON: And remember the acronym part. What was the last thing, the acronym you used stands for?

DR. MILLS: The Center for Medicare, okay, Medicaid Services. And so I deal with another whole regulatory group where we have completely set

different definitions for drugs and approvals and what's of value and what's going to be reimbursed versus what we're going to approve.

So, no, I have to deal with different languages across multiple agencies.

MR. CAMERON: Okay, and we're going to get into a discussion of definitions, and when we get there, George, make sure that you chime in with that. I guess I just had one question for Roy.

You're worried about the dysfunctionalities that might result from different state regulations. Is the FDA issue that George is bringing up, is that also a concern?

MR. BROWN: No, not really. FDA doesn't see byproduct material or norm radiopharmaceuticals any differently. They'd see it as drugs, and drugs are drugs. So there's no inconsistency, and we're very happy with that.

MR. CAMERON: Okay. Great, great. Thank you.

Well, let's open it up for discussion. Let's go to James and then to Lynne.

DR. CASE: When the NRC goes looking at the state regulations and saying, "Okay. I have a successful norm regulation that I want," I would say

with regard to Cardiac PET, you need to be aware of what the definition of success is, and I just jotted down what I would consider a successful regulation.

Provides for public safety and provides reasonable access to practicing in the community, clinicians.

How do we test whether or not that's working? Well, there are no events that harm public safety, and a lot of people are using the drugs. And if we look at Cardiac PET, there are currently only about 50 sites in the entire country doing Cardiac PET.

And so I would say nobody has a successful program that can be tested against, you know, open access. So when you're out there shopping, I'm not sure we've actually got there because, you know, in discussion I was having with Roy, well, would BRACO, who produces the only profusion agent widely used in Cardiac PET be excited or worried about this process, and it's a little of both.

Yeah, they'd be excited if it was a uniform process around the country, but the margins and the size of the market are so tiny and the potential is so great that in terms of providing clinical care, that we have an opportunity to write a

very good rule or a rule which ultimately puts it into Cardiac PET, keeping in mind that this is not the same thing. When you're producing in one reactor for the entire country byproduct material, it's a lot different than F-18 cyclotron producing just for a city.

So there you get the environment. We have over 100 cyclotrons in the United States which are producing material for doing PET work, and so it is a very different environment.

So when you're looking for those state regulations and say what's the definition of success I want to try to achieve, I would say you're not really there yet because the cardiology community which is largely out-patient based for nuclear cardiology hasn't been on the hook yet, and so I don't think any of the states out there have created that compatible environment yet.

MR. CAMERON: And I guess the question is where do we look for or what do we use for that regulation that's not going to impede perhaps and encourage.

DR. CASE: It needs to be a very measured risk model. I mean, remember, yeah, there's a public safety risk of radiation exposure, either accidental

or malicious, but you've got to keep in mind the number one killer of Americans isn't radiation risk. It's heart disease, and so you've got to remember that's what's sitting on the other end of this scale you're trying to keep in mind.

MR. CAMERON: Okay. Thank you, James.

Scott, let me ask you. Do you want to hear from the rest of the people before you talk or did you want to say something very specific right now.

MR. MOORE: Well, we can hear from the rest, and I'd like to go back to a suggestion that Barbara made earlier, too. Barbara made a comment earlier. She had suggested a framework for the rule specifically to define "discrete," change the definition of "byproduct material," add accelerator and, I think, radium to the Part 20 tables that come from the suggested state regs, nothing that there aren't that many suggested state regs. that cover accelerator produced.

We talk about suggested state regs, but there aren't that many specific ones to accelerator produced.

And then I would toss in something else for the medical community that's here. Regulate under Part 35, which already exists. I think when we talk

about suggested state regs, the implication, the specifics behind that are the NRC's equivalent is Part 35. so the question I guess I would have for the group is: if NRC were to regulate the accelerator produced material under the existing framework and do those other things , would that framework be an acceptable approach to the body that's here? Would that meet your needs?

MR. CAMERON: I mean, that's going to be one of the million dollar questions, and I want to check in with all of you. We can jump into that. I mean that starts off with the specific issue that we were going to start with after lunch, which is a definition.

I think Scott and Leslie, obviously the people who are going to have to write this want to go to let's see what the acceptable framework is. We're sort of in the middle of an overarching issue discussion that I think I see a lot of cards on that I think we need to finish up with before we jump into that.

So I guess I'm asking you: do you just want to cut to the chase, so to speak --

(Laughter.)

MR. CAMERON: -- or do you want to talk a

little bit more about some of these conceptual issues?

I guess we are getting close to lunch, and we do want to go to the people on the phones. I guess my take would be let's hear the people who have their cards up on this overarching issue, go to the phones, et cetera, audience, take a break, and come back and put Scott's proposal on the table in the context of the definitional issue.

Is that acceptable to everybody?

Okay. Well, good. Let's just to this way. Start with Mary, Lynne, Ralph, and Barbara and Alan, and let's hear what they have to say about the differences in state regulation issue.

Mary.

DR. MOORE: From an operational standpoint, speaking as an RSO now in a hospital, once the nuclear pharmacy, the RAM, the norm, whatever it is, arrives on my doorstep, they're basically treated the same for regulatory compliance, and basically this is me personally. Whoever has the most restrictive regulation is the one that we implement in our normal procedures.

So operationally from an RSO's point of view, with the NRC coming in and changing classification of norm to byproduct or however we end

up defining it, operationally it's not going to impact me.

As I see it, the impact is on getting these manufacturers licensed and up and running and able to distribute, and that the orders are going to be able to be filled; the physician orders can be filled quickly and as efficiently as they are now.

The actual use of it, I don't see a huge change.

MR. CAMERON: So it's pointing out that really the manufacturing is where the focus of this issue is, and, Roy, just let me ask you: hearing Mary, do you agree with that?

MR. BROWN: Yeah, I do, but I've got a little idea we can play a little game later.

MR. CAMERON: Well, that's always --

(Laughter.)

MR. BROWN: And see how we can get some of these products from where we are now, migrating into what a new state will look like, whether it's an old agreement state, still an agreement state, was an NRC state, now is a new agreement state or was an NRC state, had a halfway program and then gave up and turned it over to NRC.

So I'd like to take some of these products

like James and I were talking earlier at the break about something like rubidium-82 generator. What's done now? What's likely to be done with that in the future?

I think that would b every important.

MR. CAMERON: Where would that be the most illuminating for the group in terms of our discussion of definition or going to Scott's trying to see if there's an agreement on a general framework? Where would be the best place to do that?

Later under other issues or --

PARTICIPANT: Yes.

MR. BROWN: It's relevant now, but it may take some time. So if you want to push out till later, that's okay.

MR. CAMERON: Can we do it under other issues, Mary?

DR. MOORE: Sure. My comment was when you're running a program and you've got uses in radiation oncology, nuclear medicine, research, nuclear cardiology, and across the board, be it at a federal facility like I am or at a private facility, each RSO has to make a decision, and it's also written into their program.

If it's going to work operationally in my

experience, you standardize it. That's why I said you go with the most restrictive regulation, and then you know you've complied -- you're in compliance with everybody who has oversight.

MR. CAMERON: Okay.

DR. MOORE: The key here is standardization, and I think that's a theme that's been running the uniformity and standardization -- maybe "standardization" is the wrong phrase -- uniformity of approach is what works.

MR. CAMERON: Okay. Thanks, Mary.

And it may be useful after we get done with all of the discussions on specifics perhaps to go to use Roy's game to see what jumps out at us to revisit some of these issues. I think it will fit good later on, and it might be entertaining.

(Laughter.)

MR. CAMERON: Lynne. Let's go around this way and end up with Alan.

MS. FAIROBENT: Yes. My point isn't so much on state inconsistencies, but on the fact that let's not lose sight that also an important aspect of what I think the Energy Policy Act is attempting to do is not only from the national security issue of what is out there and available from the potential sources

from a terrorist perspective, but also we need to recognize that the radiation safety aspect of these materials is handled inconsistently at this time.

In bringing it in under the Energy Policy Act, we're putting everything back on a risk-based concern, and many of the PET isotopes, F-18 in particular, is a very highly energetic isotope that's not typically or has not in the past been used in nuclear medicine at those energy levels. And the rad safety implications of this as it percolates throughout the country from clinical use does need to be addressed and looked at, not that what we're doing today isn't safe, but we do need to have that on a level playing field, I think.

MR. CAMERON: Okay. Thank you. Thank you, Lynne.

Ralph.

MR. LIETO: I'd like to go back to the accessibility issue that we were talking about earlier and bring up a point that Sally Schwarz has reminded me about, and that has to do with the current Part 35 regulations in terms of PET radiopharmaceuticals and as it applies to specific licensees.

It's not an issue with broad scopes, but with specific licensees, which are the vast majority

of NRC licensees, and that is that in order to be able to be authorized for a radiopharmaceutical, it has to be either NDA approved or under an IND.

And I'll probably need Sally or Dr. Mills to clarify this, but my understanding is none of the PET pharmaceuticals fall under this category. So for specific licensees, there is an issue of accessibility because they couldn't get licensed because the current Part 35 regulations would preclude that in their current framework. So it's something, I think, that needs to be considered in the promulgation of the rules as they go forth.

One of the things that I think maybe follows from this is that maybe NRC staff would like to start to think outside the box a little bit. Instead of looking at things in terms of are they a drug, are they a device, are they a biologic or whatever, and it gets into the issue that Dr. Mills talked about in terms of definition. If things could just be considered in terms of their radiation safety implications, it gets to, I think, a lot of the problems that are currently existing in where do the Part 1000 materials go in terms of training and experience and so forth.

And if we could just instead of using as

the baseline the FDA definition, is this a device, is this a drug or whatever, but look at where the radiation safety aspects of this entity or substance, and then go from there and just leave the issues of how it's labeled in terms of a drug device, biologic, et cetera, to the FDA, and just try to harmonize that aspect.

MR. CAMERON: Okay. Thanks, Ralph.

And also, Sally, I guess that one question that I would ask you about that, if the NRC undertook to do that in this rulemaking, that would have a large implication for our overall rules. Is that correct?

So you're prompting the NRC to perhaps be more ambitious, as you put it, to think outside the box when we do this. And I think Scott and Leslie, Cindy are aware of what you're saying.

Do you want to say anything to that at this point? I mean, I know you're here to listen to these issues, but do you want to say anything?

MR. MOORE: Well, I think the second part of your comment, to think outside the box and look at other approaches, is important, and it's something that we need to think about not only with respect to this current rulemaking, but with respect to all of our rules.

So we'll certainly take that under consideration, but I guess I expect that you're saying that not only with respect to the PET application, but with respect to all of our medical rules; is that correct?

MR. LIETO: Yes, because in order to address the PET issue, you're going to need to address this issue regarding the IND FDA approved labeling, if you will, or definition, and if we're going to address it for the Pet, I think you could very easily just take one small step and expand it to all of the medical use and solve, I think, a large number of problems that get into the training and experience and other things that are going to come out from this.

MR. MOORE: Okay. The first part of your comment with regard to the IND and the NDA stuff, that's information at least to me. I'm not sure if the staff knew that, and so that's very, very important and relevant to us. Those are the kinds of information we need from the medical experts here today and the ones that we rely on in the ACMUI.

And so we do need information like that. It tells us that we cannot use certain formulations in the regulations as an option.

MR. CAMERON: Okay. Thank you.

Before we go on, Roy, did you -- you looked a little concerned.

MR. BROWN: Yes. Did somebody comment about FDG produced not under an NDA?

MR. CAMERON: Can you just -- FEG?

(Laughter.)

MR. CAMERON: NDA.

MR. BROWN: Well, my point is there are some states that says that you can't have a radiopharmaceutical unless it has an NDA or IND, and there are some situations where FDG, fluorine dioxiglucose are PET produced radiopharmaceutical or produced not under an NDA. So that would be dangerous language.

MR. CAMERON: Okay. All right.

PARTICIPANT: That's not my position.

DR. MILLS: And actually it's not even mine if it's produced within a state and it's used within the state because we're only involved in interstate commerce. But what the occasion is if there is material that possibly, because I'm not looking, could be produced within a state that's not under an NDA or IND and being utilized because that's a state issue. As long as it's not in interstate commerce, I'm not empowered nor am I looking.

MR. CAMERON: Okay. Thank you.

DR. MILLS: I would be that if we did end up with a regulation that said it had to have an NDA or being done under an IND, that would be deadly for some PET operations, and inappropriate, too.

MR. CAMERON: Okay, and Leslie has got --

PARTICIPANT: That's very helpful.

MR. CAMERON: Okay, good.

Barbara and Maria, you had your tents up earlier. Do you need to say anything, Maria?

PARTICIPANT: No.

MR. CAMERON: Okay. Let's go to Alan, Dr. Packard.

DR. PACKARD: Thank you, Chip.

I'd just like to very briefly say that one thing that seems to have gotten lost here is there's an equation between Pet radiopharmaceuticals and the non-material. And as part of the community that works on this material upstream before it becomes drugs, I think it's important not to omit the fact that a lot of this stuff exists in the research community, short-lived things like C-11 and F-18 that isn't in place as drugs.

So one has to be careful not to equate this material as drugs, whatever the stage, NDA, IND

or whatever. A lot of it is used just purely in research in the laboratory like mine or in animals.

The other brief comment I'd like to make is the safety issue. I don't know about other RSOs, but our RSO makes no distinction between exposure to PET radionuclides or anything else. It is exposure, period, and if I'm working with technetium 99M, there's no distinction between my exposure to that and F-18.

So it's not a source issue. It's an exposure issue.

MR. CAMERON: Okay, and that amplifies on what Mary was saying before. Thank you, Alan.

To close this out and get us to lunch so that we can get to Scott's issue and the other specific issues, and we know we have some -- we're going to discuss these issues as we go along and later on, and Roy is going to have a game for us to play or for you to play.

(Laughter.)

MR. CAMERON: Let me see if there are any comments in the audience on this access issue. Does anybody have anything to say on this? Any questions?

Yes, Sally. Go ahead.

MS. SCHWARZ: This follows along with what

Ralph was mentioning, what George has alluded to. In the whole issue of being a specific license, currently in Part 35 it does require that you can -- I'm just elaborating. Essentially it's restating what's been said, too -- but it is a specific license. You can purchase approved drugs. You can use RDRC regulated or IND drugs.

Well, FDG, as you've already heard numerous occasions here, is not an approved drug by the FDA. There are three cases George stated that do have NDAs, but in the majority of sites in the United States, it's used under a FADAMA regulation, which essentially alludes to PET radiopharmaceuticals, and then we are able to do that by following the United States Pharmacopeia in terms of preparation of these drugs.

And there is currently regulation out for comment at FDA that will eventually move us into an approved status, but this will take time.

So I think I just want to reiterate that in terms of the PET pharmacies that are making these drugs, they aren't licensed as Part 32 suppliers certainly. So this is a problem in terms of adapting the regulation. You have to think about the fact that you need to fit PET drugs and suppliers into this

current regulation when you're revising it.

MR. CAMERON: Okay. Thank you, Sally.

Ed and James, do you have a response?

MR. BAILEY: Yeah, I know the situation she's talking about, and we have faced this before. We have had to bring in or compound in accordance with state pharmacy laws, which basically covers most of the things you're talking about, I think.

So I don't know how NRC would factor state pharmacy laws.

MR. CAMERON: Okay. Thank you.

James?

DR. CASE: Yes, one thing that Alan mentioned is that trying not to equate an ARM with PET tracers. The PET tracers that are out there right now, with the exception of strontium, are all produced in low energy, low MA type cyclotrons, and then there's this whole other family of cyclotron out there, the big cyclotrons, you know, 60, 70, 200, you know, the big machines that actually produce things like thalium, strontium, iodine, stuff like that.

I think if we're looking at a risk based model, and I know that the statute doesn't give you the authority to talk about -- well, maybe you can talk about it --

(Laughter.)

DR. CASE: Of course you can talk about it.

-- but cyclotron per se, but cyclotron really does -- the type of cyclotron you're talking about, the type of energy does create a differentiation between a lot of the questions which we're talking about. The big cyclotrons look an awful lot like a reactor and won't fit into the model that already exists.

In the smaller cyclotrons, the low energy, low MA type machines do kind of fit into some kind of different bucket that doesn't look like a reactor. And so looking at the accessibility question, you know, and trying to build a regulation, I think an understanding of those two different types of machines create two different types of models for the community.

Because the smaller machines produce the shorter-lived isotopes that you have either drive across town or run through a pipe through the building. They're not going to be falling under the FDA because they're ammonia, carbon monoxide, water, FDG, things that nobody is going to bother to go to the FDA to get an approval for.

MR. CAMERON: So let's put that in the parking lot, too, when we get to the cyclotron discussion. We'll go back to this. I suggest that there should be a different approach for the big cyclotron products and the small cyclotron products, and we'll get some discussion on that.

Anybody else in the audience?

(No response.)

MR. CAMERON: Okay. Jill, are you still with us?

OPERATOR: Yes, I am, Mr. Cameron.

MR. CAMERON: Can you see if there's anybody on the phones?

OPERATOR: Sure. If you would like to ask a question or make a comment regarding today's conference at this time, please press star-one on your touch tone phone.

Once again, please press star-one if you would like to make a comment or have a question regarding today's conference.

(No response.)

MR. CAMERON: Okay. Thank you very much.

OPERATOR: We have a few questions, Mr. Cameron.

MR. CAMERON: Oh, you do? Great.

OPERATOR: Rich Gianatti, your line is open at this time, sir.

MR. GIANATTI: Yes. Thank you very much.

A quick question that's related to the language in the NRC Policy Act with respect to byproduct materials. Have we addressed that?

I know there was a similar question early on. Have we addressed that question or are going to talk about it later on?

MS. KERR: What question are you referring to?

MR. GIANATTI: The question that was earlier brought up by someone related to the language in the Energy Policy Act with respect to byproduct materials, but byproduct materials are not considered law level waste.

MR. CAMERON: We're going to get to that when we got to the waste discussion, Rich.

MR. GIANATTI: When would that be? In the afternoon session?

MR. CAMERON: Yes. By definition I think we're there.

(Laughter.)

MR. CAMERON: But, yeah, it will be, and before we break for lunch, which will be soon, we'll

try to give you a better idea of that.

MR. GIANATTI: That will be good.

MR. CAMERON: And Rich is from Pennsylvania.

MR. GIANATTI: Because I know there are a lot of state representatives who will be interested in this discussion.

MR. CAMERON: Okay, right.

MR. GIANATTI: Thank you very much.

MR. CAMERON: All right, Rich.

Now, our next one, Jill.

OPERATOR: Our last one at this time is from Judith Johns, and, ma'am, your line is open.

DR. JOHNSRUD: Yes. Unfortunately the sound system is breaking up frequently, and it's very difficult to hear. I don't know what's wrong with the transmission. Perhaps others aren't experiencing this.

But my real question goes to how the NRC will deal with the existing variations of regulation in the agreement states and others with regard to those that are most protective, as I believe Mary has indicated, versus perhaps those that have weaker existing regulations. Will the NRC address this rulemaking in terms of the maximum control?

MR. CAMERON: Okay. For those of you who do not know, this is Dr. Judith Johnsrud, State College, Pennsylvania. Sierra Club affiliated, right, Judy?

DR. JOHNSRUD: Among other things you said.

MR. CAMERON: Okay, and we're sorry if it's breaking up, and I don't know if others have experienced that out there, but as we go along through the day, we'll see if we can get input on that issue.

I'm going to ask Scott to. Scott Moore has something to say on your question.

Scott.

DR. MOORE: Yes, I can address that. As the final rule is promulgated, it will go out with a level of compatibility, and the states then will have a transition plan into the final rule.

Right now there are waivers in place. So the existing regulations that were in place in the states are continuing in place until NRC promulgates some rule.

So when the final rule goes out, there will be some level of compatibility that will be decided as the rule is developed, and that just remains to be seen what level of compatibility it is

as the rules develop, whether it requires the states to be essentially identical or to maintain the essential elements of the rule.

And whether the states are essentially identical or maintain the essential elements of the rule depends on the compatibility, and whether the rule adopts the most stringent state standards or the just consensus standard of the states or some other standard of the states will be an issue that comes out as part of the rulemaking process.

And then the states will have some time following promulgation of the rule before the waivers go away and the states are required to adopt them.

Does that answer your question, Dr. Johnsrud?

DR. JOHNSRUD: Well, I'm not sure it does. What would be the criteria for determining the level of compatibility?

MR. MOORE: The Office of State Programs has a published process for determining compatibility and STP can provide you with that, I think.

DR. JOHNSRUD: Thank you. That can help.

MR. MOORE: It's actually on the Web, I believe.

DR. JOHNSRUD: Thanks.

MR. CAMERON: And, Judy, you also have to keep in mind that where's the basic starting point in NRC regulations. That's going to be in the rule. The basic starting point for the compatibility determinations. For example, if the approach is to use the suggested state regulations as a model, then we would be facing the approach on the risk approach that's in those suggested state regulations.

DR. JOHNSRUD: Okay. That also is helpful to know. Thank you.

MR. CAMERON: Okay. Thank you. Thank you, Judy.

And, Jill, do we have anybody else?

OPERATOR: Not at this time, Mr. Cameron.

MR. CAMERON: All right. Thank you very much.

Anybody in the TV room has a comment or question?

OPERATOR: I'm looking.

Anyone?

It doesn't look like it.

MR. CAMERON: Okay. Thank all of you there.

It's about 12:15 at this point, and, Scott, do you want to give people until 1:30 for

lunch, give them a little over an hour?

PARTICIPANT: Yeah.

MR. CAMERON: Is that okay? Okay.

We're going to start, for all of you, phones and everywhere, we're going to start at 1:30, and we have two issues to go through before we get to waste. We have the definition of discrete source. We have the accelerator produced material issue.

I'm assuming that Scott's need, question about is this potential framework okay is going to come out during those two, and then we go to waste disposal and transportation.

I'm thinking we might not get to waste disposal and transportation until possibly three o'clock. That gives us an hour and a half for those other two issues, which may be too short.

So, Rich Gianatti, if you and those other who are interested in the waste issue, I think at the earliest it would be three o'clock.

MR. GIANATTI: Okay. That would be good.

MR. CAMERON: Does that, Scott, make sense?

MR. MOORE: Yes.

MR. CAMERON: MR. GIANATTI: Yes, that will be good.

MR. CAMERON: Okay. Well, thank all of you, and we'll tune back in at 1:30.

(Whereupon, at 12:19 p.m., the meeting was recessed for lunch, to reconvene at 1:30 p.m., the same day.)

MR. CAMERON: In terms of administrative issues, the transcript for this meeting is going to be available publicly within five to seven days. I don't know what. We have different turnaround times.

But we're going to get the transcript. And I think the staff will probably take a look at it. And then it will be available. Before the end of the day, we'll tell you whether that's going to be available on a Web site and/or through our Adams system . Okay? The Web site is always easier, right?

(Laughter.)

MR. CAMERON: And there are some tie-ins there with early availability of what our thinking is. And we'll go to that when we get to the end of the day.

Leslie had some -- and you're having trouble with this, obviously. Did you have a couple of other administrative announcements you wanted to make?

MS. KERR: Yes. The memo that we talked

about this morning is now available. I pass it around the table. For those in the audience, they're in the back tables where the handouts are.

MR. S. MOORE: The memo mentions an enclosure 1 and enclosure 2. Enclosure 2 is not included with the memo. It got into some contract information that we have not released. So only enclosure 1 is included with it.

If you have enclosure 1, which is the schedule, you've got the full information that is being released by the Commission at this time.

MS. KERR: And the other thing is we are interested in your feedback for this meeting. I also pass that around the table. But the feedback forms for the audience are at the back of the room. You can either leave them here today, like on the podium where you signed in, or you can complete them later and send them in.

MR. CAMERON: Okay. Thank you. Thank you, Leslie.

We have a little contest. We are going to have a game this afternoon. There is also a contest for the best name for the game. We have radiopharmanopoly.

(Laughter.)

MR. CAMERON: More appropriate may be Chutes and Ladders because that seems like that is what it is.

There are still some people puzzled, not just me, by some of the acronyms. And three that we were using a lot, NDA, IND, FSG, George Mills is --

DR. MILLS: We're going to do it right now.

MR. CAMERON: FSG?

PARTICIPANT: D as in dog, FDG.

MR. CAMERON: Are you sure there's not an FSG, too? Okay. FDG.

George is going to tell us what those stand for, but if you can illuminate it even a little bit more so that people can understand what the implications are when we're talking about that. George?

DR. MILLS: Well, in fact, let me add a couple as we go. And so we'll build it up from where I would start with the entry-level area for the RDRC, the Radioactive Drugs Research Committee.

That is one area that we have under regulation. We have had it since 1975. And that is where we actually have institutional settings where they actually can be involved in the use of

radioactive materials. They have their own standing committee. And they interface with us. Rich is involved directly with it. I have oversight with it. So that's one.

Number two is the investigational new drug, IND. And what we are looking at here is these are research areas, maybe a single investigator, maybe a large group, maybe a commercial entity, but it's a research use of radioactive materials as relates to this community. Certainly we handle all of our drugs and biologics under INDs.

Now, the NDA is a new drug application. And there is also a comparable BLA, biologics license application. So we have a biologics and a drug side. These are still investigational, but they are seeking approval for licensure. And we go through that process under those areas.

So if you think in terms of the IND, investigational use, and then when they are seeking licensure or approval, they move to the NDA or BLA status, new drug application, biologic license application. Then we give them --

MR. CAMERON: To either the new drug or the biologic, can those both include --

DR. MILLS: All of them, all of them. So

it's a much more inclusive tent, if you will, for all of what we do within the FDA. But from this grouping, all of them handle labeled radioactive materials at some level at some time. I've handled agents throughout from all levels to that. And all through here, that falls through all of these areas.

MR. CAMERON: All right. And did we do FDG?

DR. MILLS: FDG, fluorine deoxyglucose.

MR. CAMERON: Okay.

(Laughter.)

MR. CAMERON: Did you get that in the back?

DR. MILLS: Fluorine-18 deoxyglucose.

MR. CAMERON: Florian 18.

DR. MILLS: Fluorine.

MR. CAMERON: I give up.

DR. MILLS: FDG. That is what we are doing our CGMP direction --

(Laughter.)

DR. MILLS: Good manufacturing practices. Okay? So we might as well get that one on the table. That's our GMP, good manufacturing practices.

MR. CAMERON: Okay.

DR. MILLS: And that's where we have that

regulation that we're in process of getting our comments onto and the guidance.

MR. CAMERON: So you have a regulation, a proposed rule out?

DR. MILLS: Proposed rule out. That's where we started eight years. We were supposed to be done six years ago, but we got it out this year. And that's where we have that regulation proposed.

We anticipate getting the comments closed by the end of the year. And hopefully we'll move to a final regulation and a final guidance to follow.

MR. CAMERON: Okay. Good manufacturing, manufacturing practice.

DR. MILLS: Right.

MR. CAMERON: All right. And Rich?

PARTICIPANT: It's RDRC, not B.

DR. MILLS: I wasn't watching his writing.

PARTICIPANT: USP?

DR. MILLS: Oh, USP, U.S. Pharmacopeia. And they live across from the Parklawn Building, where we just moved from. And from that standpoint, that's another group which has put together a compendium of standards for purposes of developing various products, one of which is going to be the same that we covered here for FDG.

We have other ones, too, but for this discussion, the FDG falls into that.

MR. CAMERON: Okay. Good.

MR. BAILEY: Did you mention the device?

DR. MILLS: The device? Okay. The generator you want to talk about?

MR. BAILEY: Well, I mean, there is also some device approval, --

DR. MILLS: Exactly, some --

MR. BAILEY: -- some devices that you approve.

DR. MILLS: Exactly. And now you're getting another acronym. We're over in the Center for Devices, CDRH. And from that aspect, yes, they do work then. That's why they fall under regulated and not approved nor licensed because they're working with physical devices, many of which will be here in discussion.

They actually have some rare ones that are radiolabeled devices. And they have ones in there. But that is more focused discussion than that, and it doesn't relate to what happens here.

MR. CAMERON: Okay. And when we are using these acronyms and it's going to be hard for people to remember this discussion perhaps. So just keep that

in mind as we're walking along, that some of us don't know what that is.

But thank you for that walk-through. And I think that illustrates just the range of things that the Food and Drug Administration, FDA -- everybody knows FDA.

Okay. We're going to go to definition of discrete. We have Joe DeCicco, who is going to tee that up for us. I want you to as we talk about discrete, as we talk about the accelerator products keep in mind Scott's question, which he divined from listening to Barbara Hamrick and others about what needed to be done to set up this regulatory framework, define discrete.

This is the points that Scott was making that I think Barbara made. Define discrete. Change the definition of byproduct material. Add accelerator produced in radium to part 20 tables. Regulate medical under part 35. Okay. Now, that's the basics. It certainly is not going to be the outside the box suggestion that Ralph Lieto gave us this morning, which the staff also heard.

We have Tom Essig here. Let me introduce Tom. Tom is the Branch Chief for the Materials Safety and Inspection Branch within Office of Nuclear

Material Safety and Safeguards.

And at some point, Tom, you wanted to say a few words about the discrete definition?

MR. ESSIG: Yes, I did.

MR. CAMERON: Okay. Let's --

MR. ESSIG: I'll follow Joe if that's okay.

MR. CAMERON: Good. Let's go to Joe, and then we'll hear from Tom. Joe?

MR. DeCicco: Thank you.

Welcome. I am part of the task force that is led by Doug Broaddus, and I have been asked to focus on providing a definition of discrete source for the rulemaking group.

Most of what I am going to tee off with is on a two-sided, one-page handout in the back. But before I start, I wanted to read the definition of the legislative definition of where they use the term "discrete" in defining byproduct material.

The new terms that use discrete in byproduct material is any discrete source of radium-226 that is produced, extracted, or converted after extraction before, on, or after the date of enactment of this paragraph for use for a commercial, medical, and research activity or any discrete source

of naturally occurring radioactive material other than source material that the Commission in consultation with the administrator of the EPA or the Secretary of Energy or Homeland Security and the head of any other appropriate federal agency determines would pose a threat similar to the threat posed by discrete source of radium-226 to the public health and safety and the common defense and security.

I wanted to just point out that discrete is used only for radium and naturally occurring radioactive materials and to point out that in order for the material to be byproduct material, it needs to be discrete but also has other qualifying requirements.

Jumping to paragraph 3 for those of you who have that one-page, two-sided sheet, diffuse sources of radium and naturally occurring radioactive materials are not covered by the amendment. Now, I'm assuming I jump to the conclusion that discrete is diametrically opposed to diffuse. But that hasn't necessarily been established.

It does not extend the Commission's authority to NORM in its place of origin and does not include materials such as residues from drinking water and waste water treatment processes, scales from pipes

resulting in petroleum products for production, fly ash, sewage sludge, phosphate fertilizers, or other similar material.

There have also been suggestions made in developing a definition of discrete source to apply quantities and concentrations to the term to eliminate the sources that are not intended to be under NRC's jurisdiction.

However, currently there are no such levels in the NRC regulations below which the agency no longer assigns jurisdiction on byproduct material. In other words, there is no lower level where we just say it's no longer considered radioactive. The exempt quantities and concentrations that are in part 30 pertain to persons exempt from the requirements to have a license to receive, possess, use, transfer below these exempt quantities.

Paragraph 5 basically says why we're focused on discrete source. The Energy Policy Act indicated in the act that the NRC regulations show through the definition of discrete source for the purposes of the paragraphs 3 and 4, which is radium and other naturally occurring radioactive material.

Again, a couple of references that use the term "discrete" or "discrete source." You know,

everybody always goes back to Webster and those definitions are there. There were a couple of previous publications that I cite here. And two of them are NUREGs, one back in 1988.

And, again, these definitions, in all the references that I could find, people had used the term "discrete source," "discrete waste," and really have not defined what "discrete source" really means.

In the NUREG 1311, for instance, EPA emphasizes that there are two different types of NORM wastes. They do not define what a discrete source is, even though they use the term in the definition.

For instance, it says first there are discrete sources that are of higher concentration, higher radioactive concentration, such as radium needles used in medical practices and radium-contaminated drinking water cleanup resins that have radioactivity characteristics similar to those of byproduct low-level waste. But, remember, this is 1988.

Second, there are lower activities, lower activity diffuse sources. Another NUREG, more recent one, in 1993, they characterized for the purpose of the report what a discrete source was and they characterize it as a source, those which have the

relatively small dimension of a compact solid and in which the radioactivity is highly or moderately concentrated.

And then the last reference that I quote here is from the suggested state regs. They don't define discrete source, but they use the term "TENORM," which is technically enhanced naturally occurring radioactive material, whose radioactive concentrations are increased by or as a result of past or present human practices; in other words, something taken out of nature because of some activity that has concentrated naturally occurring material.

We have floated around a couple of definitions. And I have two of them here. And I put these two down not because we're going in that direction but because they kind of show two ends of the spectrum. One end of the spectrum is a two-sentence, all-inclusive more complicated than the second definition that I toss up.

Discrete source for the purpose of defining byproduct material means a source whose radioactive concentration is increased by human practice or activities. And a discrete source will have physical boundaries for preventing dispersal, such as solids or powders, liquids, and gases in a

sealed container or material suspended in a matrix. Again, that's because some of us felt that it would be nice to have boundaries set.

And then the second one is just one sentence, a lot shorter and a little more general, "Discrete source for the purposes of defining byproduct material means a source of radiation separate and distinct from the sources of radiation present in nature." And that's kind of a toss-in in saying, "Okay. This is what we're thinking. This is a little bit of the use of the word 'discrete' source. And we've got to come up with a definition that needs to go into our regulations."

MR. CAMERON: Okay. Thanks, Joe, for including the two straw men definitions that you talked about.

Let's go to Tom.

MR. ESSIG: Okay.

MR. CAMERON: And then we'll open it up for discussion.

MR. ESSIG: Yes. I just wanted to make two quick points to add on to Joe's. One is I'd like to bring us to the origin of why it is that the NRC was interested in regulating discrete sources of radium-226. This was driven by the -- many of you may

have heard of IAEA's code of conduct for the safety and security of radioactive sources.

Included in the list of sources that more attention should be paid is radium-226. The IAEA makes no distinction between radium-226 and other alpha-emitting radionuclides that the NRC had previously regulated.

In considering that, we thought it would be important to recognize that we needed to level the playing field, so to speak, between here we possibly have radium in various places without the same protections that were being promulgated for other alpha-emitting radionuclides, such as curium-244, plutonium-239, 238, et cetera. And so that was one of the drivers.

So if you look at the table that's in the code of conduct, you'll find that radium-226 has, as are the other radioactive materials in that table -- there are three categories defined, all of which describe what IAEA calls a dangerous source, meaning that if used in a malevolent manner, either incorporated in a radiological dispersal device or put in a public place just to expose members of the public who would frequent that public place, such as under a subway seat or something, something of that sort, that

these sources would need to have additional controls placed on them.

And that was sort of our interest in bringing radium-226 under the same protections as were afforded the other alpha-emitters, recognizing, of course, that radium has been in use for decades and is not in nearly as common use as it was 20, 30, or 40 years ago, but there are still a large number of radium sources around.

That was one point I wanted to make just to give you a little background perspective. And then the second point I wanted to make, Chip, maybe to help further tee up the issue is I was thinking it might be instructive to make a couple of columns on a sheet saying what a discrete source is and what it is not.

I was thinking to help us frame this definition in a rule -- I'm sure everybody understands the challenge that Scott Moore has in front of him in coming up with a good definition in a rule. And thank God we didn't have Congress define it for us because we don't know what we would have gotten then, but we would have had to live with it, whatever it was. So in this way, we've got the opportunity to define it in a rule.

And I was thinking that what it is

certainly, everyone, I believe, could agree that if I have an encapsulated source, capsulated radioactive material, that we would consider as discrete. That's something that meets these other attributes that Joe was citing. It's in a small volume and so on.

Maybe another possible attribute is that, although not encapsulated, maybe it's a pressed pellet. Maybe it was a powder at one time and it's been under some high pressure and ends up being in pellet form.

The thought here is that this is something that an individual who is going to use this source in a malevolent manner is going to pick it up and stick it somewhere, incorporate it in a radiological dispersal device, put it under a subway seat or elsewhere in a public place, and expose members of the public to the radiation or the dispersal of material from this.

Now, what it is in the is not column, we might say if it's purely a liquid without any boundaries, if it's a gas without any boundaries, if it's a powder, I know that what Joe walked through there, one of the definitions talked about a physical boundary that surrounds this material. But clearly if it doesn't have that physical boundary, then I would

think it's not a discrete source.

And so I'm just hoping that this would help maybe help stimulate some thought from people in the room to help us frame this definition better. That was my purpose here, Chip, in doing that.

MR. CAMERON: That's good. Thank you, Tom. We'll use this. And we can use it. There can be differing opinions. In other words, we can brainstorm that, so to speak, and then come back and winnow it out.

I guess just for the group's benefit, I just had a couple of questions for you and Joe before we get started. I take it that the two definitions that Joe gave us, that the elements of those definitions could be put into the is or is not. You have already done that with the boundaries thing.

So that this chart, this methodology that we're going to use, Joe's definitions could be, elements of Joe's definitions could be, placed in one or the other.

Okay. The second thing is dangerous source radium-226. Part of this discussion is what other sources besides radium-226 should be considered, right? That's a smaller part of the overall discussion?

MR. ESSIG: The reason that was in there, Chip, is because early in the formative stages of the legislation, we met with EPA. And I don't remember if Bonnie was in the room at the time or not. She was. Okay.

And EPA asked us, "Well, gee, you want to regulate radium-226. Well, what did you have in mind?"

And we pointed out, "Well, discrete sources of radium only," you know, refined, extracted, concentrated, and so on."

And then we were asked, "Well, are there other radioactive materials in that same group, the alpha-emitters, the actinides that you think ought to be regulated in a similar matter?"

And, try as we might, we couldn't think of another alpha-emitter that was similar to radium-226. And so the legislation, then, has a placeholder that if someday we think of one, it prescribes us working with the Department of Homeland Security, Department of Energy, and EPA to agree on whether or not that particular radionuclide should be added.

And so as of this time, we don't have anything, but I think that was a placeholder for the future.

MR. CAMERON: So one last question before we exit this discussion and to go the accelerator would be, does anybody have any things that they think do fit the category at this time? Ed?

MR. BAILEY: Tom's column there, two columns, it seems to me that a discrete source almost generically includes something that has been manufactured or fabricated, which would be a way to perhaps help define it. But that then brings up the issue are you not going to regulate the manufacturing or fabrication of it. But I think it has to be manufactured.

MR. CAMERON: Okay. And I don't want to tie everybody into this chart right now. You may have some larger issues, more conceptual issues, at this time. Let's get comments that aren't directly focused on filling out the chart.

I know Barbara and Maria had their cards up. Do you guys have something more conceptual at this point?

MS. HAMRICK: Yes, I do. Just in looking at the definitions that Joe put forward and this discussion, I think the thing that we have to be careful of here, I mean, to me when I read these, either one of these includes containerized waste; for

example, pipe sludge.

Once it's put in a waste container, now it's got a physical boundary and it looks like licensable material now. And that also includes the water residue that goes into a matrix, a solid matrix. You would end up with the same issue.

The other thing I think we need to think about in all of this discussion is once something falls into licensable space -- let's say, for example, you know, we did end up with a definition that included containerized waste. Could somebody open that waste container and make it diffuse now so that it's no longer regulated? I mean, I think we just need to think about that while we're doing this. Regulatable. I don't know if that is a word.

DR. KELLY: I guess I want to just clarify. So if something is defined as not discrete, it's not regulated? So just by choosing what you put in each column, you determine what you're going to regulate and not regulate?

MR. CAMERON: Yes. Could we get an answer to that?

MR. S. MOORE: I can answer that. By legislation, the legislation only gives us jurisdiction over discrete sources of radium and

discrete sources of NORM with risks equivalent to radium that we consulted with other agencies on. So if it isn't a discrete source of radium or discrete source of NORM that we don't have jurisdiction over --

DR. KELLY: The NRC doesn't, but the states --

MR. S. MOORE: That's correct.

DR. KELLY: -- still do.

MR. S. MOORE: That's correct.

MS. HAMRICK: I mean, I thought the whole purpose of this was to have safety as a goal. So it would seem to me that if you defined discrete to suit, you know, a specific purpose, that takes it out of regulation. That is kind of defeating the purpose of why we're here in the first place, which was to ensure better safety.

And, I mean, if you take liquid as a non-discrete, I mean, a lot of the medical uses of radioactive isotopes are done in a liquid medium, you know.

MR. S. MOORE: I would point out that the discrete definition only applies to radium and naturally occurring materials. The portion applying to accelerator-produced materials does not have the clause about discrete. So all of accelerator-produced

materials are under our jurisdiction.

MR. BROADDUS: Scott, can I make a clarification on that as well? This is Doug Broaddus, by the way. The fact that a source is discrete at one point and then is intentionally made non-discrete after the fact I do not believe would prevent us from continuing to regulate that because after it came discrete initially, I don't think that would necessarily prevent us from continuing to have regulation, even if it is intentionally made non-discrete at that point.

MR. CAMERON: Okay. And that's the type of information that perhaps is treated in the supplementary information. I don't know.

But, Maria, hearing that and hearing Scott's comment about there's no such limitation on the accelerator definition, does that alleviate your concern?

DR. KELLY: Yes.

MR. CAMERON: Okay. Good. Larger issues besides going to the table that may be instructive for us at this time? Mary, did you have a large -- go ahead.

DR. M. MOORE: Well, it's more for clarification. And I was going along the same road

Maria was and Barbara. Focusing only on radium and having spent and acquired a lot of dose to myself for doing leak testing of radium needles, what is the -- yes, I know I am old.

(Laughter.)

DR. M. MOORE: What's the position -- it is. It's a transition. And maybe this question has been answered. How do you handle that from a regulatory aspect? It is a discrete source. I am focusing now more on radium needles, which are defined and you can hold it in your hand. So discrete is not a real hard debate.

But it is now leaking. So now we have radon being emitted. We have another isotope being emitted. It's in a different volatile form. Plus, you may also have some radium coming out as well.

MR. CAMERON: In thinking about the --

DR. M. MOORE: Who regulates that?

MR. CAMERON: -- definitions and everything, what is your reaction, Ed?

(Laughter.)

MR. CAMERON: You were being what? You were being Ed. All right.

MR. BAILEY: I think following up on what he said, once it's leaking, leakage could be

regulated.

DR. M. MOORE: Well, somebody's going to regulate it. But here I am. I now have a leaking radium needle that nobody wants to accept as rad waste. Am I on the phone to the NRC? Am I on the phone to the state? And could you two talk to each other so those of us in the field who are handling this don't have to go through five agencies?

And I don't mean to be flip on this. I really don't because I think it is a serious issue. But I am giving you a scenario from front relying or whatever it is to this interfacing. FDA is looking for seamless interface with NRC. We're looking for a seamless interface between the NRC and the states.

And this is a prime example of where someone is going to run smack into who do we call. The nuclear pharmacies are going to run into even bigger issues.

MR. S. MOORE: Actually, I can answer that. If you have a leaking radium needle, if it's an agreement state, you're going to call the agreement state. If it's not an agreement state, you're going to call NRC because we'll have jurisdiction at that point.

That's not really in my opinion going to

be the issue. I think what really will be the issue will be if you have leaking radium needles, getting cleanup after the fact. I think that the regulatory agencies will require, you know, the leaking radium needle to be cleaned up and dealt with promptly.

And I think both of the regulatory agencies, the NRC and the state, will deal with the immediate safety and health problem effectively and efficiently. I think the bigger issue then will be cleanup of the contamination and how to deal with that.

MR. CAMERON: Scott, let me just ask you before Ed goes. Is the radium -- the radium needle would be depending on the definition, but it could fit the definition of discrete source.

MR. S. MOORE: I think it will. I think everybody --

MR. CAMERON: And, as Doug pointed out, there would still be jurisdiction, even after the boundary was violated in some ways. Is that what you --

MR. BROADDUS: Let me make sure everybody understands my point from stating that. We don't have yet a definition for discrete. We could encompass within that definition something that indicated that

once it metes a certain condition, it then stays under that condition --

MR. CAMERON: Stays. Okay.

MR. BROADDUS: -- from that point on. It stays under that regulation at that point. We don't have to -- you know, we could write it in such a way that it wouldn't exclude those situations where it was broken open after the fact.

MR. CAMERON: Okay. Good. Thank you for that clarification.

MR. BROADDUS: And what we would like to hear is your input on where you think we should go with that.

MR. CAMERON: Okay.

MR. BAILEY: I sort of heard a different question from Mary. And that was "I've got it. Where can I dispose of it?"

DR. M. MOORE: Well, that was the continuation because loss of integrity of a discrete source is one aspect, but now we started a scenario, which is what Scott was talking about. And absolutely positively I don't care if it's NRC or state, the immediate response of the regulators in my experience has always been "What do you need?" and "Keep everybody safe and contain it and deal with it."

Sincerely my gratitude is extended to all of them having been in those situations. But we have started a scenario with the cleanup, compliance. EPA comes in here. NRC does. The state does; the rad waste, who is going to take it. There's now a whole line of issues that need to be addressed. Who is overseeing that?

MR. CAMERON: And this is an issue. It sounds like this is waste disposal. Is that right?

DR. M. MOORE: It's getting there.

MR. CAMERON: Okay. Well, can we put that in -- I'll put that in the parking lot.

DR. M. MOORE: It is cleanup, then waste disposal.

MR. CAMERON: Okay. Ruth?

MS. McBURNEY: Of course, from the Health Physics Society standpoint, we would like to see the uniformity and standards section of the regulation go beyond just whatever is defined as a discrete source of NORM. But, having said that, in order to define discrete and in conjunction with what is in the legislation, we have got to also define what is a commercial activity.

I think it was mentioned earlier that waste disposal may be a commercial activity. And so

if you have got a containerized waste, even though it might not be from what was originally a discrete source, it could be a diffuse source of TENORM that was not used for its radiological properties or drinking water filters and so forth, but those may be able to be included as a commercial activity.

I would like I guess to see the discrete definition encompass the existing framework, there being some sort of concentration exempted, the level, some level, that would be generally licensed and some level that would be specifically licensed and looked at from a public health and safety standpoint, not only the security, even though that was the original intent having this with the code of conducts and so forth.

MR. CAMERON: Does that go to the point in Joe's one definition about the concentration is increased? Is that the point you're making?

MS. McBURNEY: Yes, it is.

MR. CAMERON: So that would that be something that you put on this side?

MS. McBURNEY: The concentration would be -- yes, it would be a concentrated material.

MR. CAMERON: So concentrated material?

MS. McBURNEY: But there would also be

some sort of exempt limit, just like there is for other isotopes.

MR. CAMERON: Okay. I'm going to put "exempt limit" over here.

MS. McBURNEY: When the I guess I'll call them TENORM rules were being developed, one of the ideas that were going about is those rules were set up for materials that were not used for their radiological properties; whereas, in ARM regulations along with the byproduct regulations were geared toward material that you possessed and use for the radiological properties. And it's an intentional use; whereas, things like fly ash and phosphogypsum and so forth are just sort of byproducts of other processes.

MR. CAMERON: Where does the point you raised about commercial --

MS. McBURNEY: Yes.

MR. CAMERON: We heard before about commercial research. And I forget what the other category is.

MS. McBURNEY: Medical.

MR. CAMERON: Does that have implications for this table or is that another subject?

MS. McBURNEY: It goes into the definition of a discrete -- I mean -

MR. CAMERON: Okay. Let's --

MS. McBURNEY: -- it's a consideration.

MR. CAMERON: Let's hear from Joe on that. Joe?

MR. DeCicco: In that respect, I think the activity has -- I'm sorry. Joe DeCicco.

The activity has to do with defining byproduct material. Discrete just happens to be part of the definition of the byproduct material. So they are two distinct things.

MR. CAMERON: Scott, go ahead. Go ahead, Scott.

MR. S. MOORE: I'm not too sure that it goes too much to the definition of discrete, but it's a key issue that we need to come back to at this roundtable. It was addressed to me during the break. And I'm not sure we have actually come out and discussed that completely as a group, whether the definition of commercial includes waste, and what the impact of that is on accelerator-produced material, in particular. Accelerator-produced material doesn't include the term "discrete," but we need to come back to that.

MR. CAMERON: Is that more appropriate for the next topic, accelerator?

MR. S. MOORE: Yes.

MR. CAMERON: Okay. Good. Let's hear from Felix and Bonnie and then let's go to the chart and see if we can get some if there is any agreement. Felix?

MR. KILLAR: Thank you, Chip. I figured you were just ignoring me.

(Laughter.)

MR. CAMERON: No. Never, Felix, never.

MR. KILLAR: In fact, what I was going to say has already been said. In fact, Bruce said a lot of it. From the industry's perspective, when you look at the use versus discrete, you're talking about a gray area.

When you're over here, there is no question as to discrete. When you are over here, there is no question as to use. But you've got this area in between. And so somewhere you have got to cross that line. And so the only way you can find that line is if you do a picocuries per gram or something along that line.

From the industry's perspective, we're looking at it from a health perspective. I know that radium 222 came out mainly from a security perspective, rather than a health perspective,

although it's gained a lot of notoriety from health as well.

But from our perspective, we're looking at it from a health perspective. We use thorium in welding rods. We have situation plants, easy for you to say, --

(Laughter.)

MR. KILLAR: -- that increases the phosphorus-40 concentrations. We have facilities that reprocess pipe sludge and will have you from well-drilling outfits and things along that line. And they end up with that.

And they would like to have a number that says yes, we are fine here. We're not worried about the health effects of our workers inhaling this material versus we've got to make sure that we have proper protection for our workers from this material because we have had members that have been sued over this specific issue.

And we need to have a federal regulation which says this is the number and at these levels, it is acceptable and the health hazards are appropriate and regulate.

MR. CAMERON: Okay. And I'm going to see if there are other comments on that and where that

fits into this whole business as Felix did talk about the gray area. And his suggestion, I take it, to deal with the gray area is to have some specific picocuries per gram definition. Is that right?

Okay. Let's go to Bonnie and then see if James still wants to say something. Bonnie?

MS. GITLIN: I think -- this is Bonnie Gitlin from EPA -- looking at the background piece that you put together, I think all of the elements are there, but they are in the background, not in the definition.

And my concern is that as the definition moves forward into the regulation, it will not be clear enough to avoid the kinds of unintended consequences that a lot of people have talked about.

I'm a regulator. So I hate being tied down by too specific a definition. But I think in this case, we should err on the side of being more specific, as opposed to less, because we can then eliminate a level of anxiety and confusion for large segments of industry and other affected parties by just highlighting them in the definition and saying, "No. You're not what we're talking about. And here is what we are talking about."

So to the extent that you can be as clear

as possible in the definition itself, you will save yourself a lot of heartache in terms of legislative history, you know, all of that other stuff.

I think we also have to be careful to as much as possible tie it back to the defense-related focus of why this section of the act was put into play in the first place to try to draw it back to those types of materials that might be able to be used in an improvised vice or RDD or some other threat to national security. I mean, I think that will also help us clarify the definition and avoid some of those unintended consequences.

And this is sort of not totally on the topic of the definition, but it relates to it in some ways. I think, as others said earlier today, we need to also be very thoughtful when we look at model state regulations or suggested state regulations to make sure that we don't just wholesale pick up one and plug it in without looking at what it might mean in this particular context because I think there are some areas where EPA has had issues with some of the suggested state regulations and others have as well that we can avoid in this context if we're moving those forward in this context.

Also, we have talked during the break

about the consultation process. And I'm looking forward to it. You know, I understand it will be a rather rapid rush to try to get it done in the context that you are.

But, like I pointed out, I'm in a very accelerated rulemaking myself. So I'm very sympathetic and looking forward to working with you as we try to refine this and make sure that you guys don't get something you don't want and we don't get something that we don't want either.

MR. CAMERON: Okay. Thanks, Bonnie.

What I would like to do is ask you, keeping in mind what Bonnie said about being more specific, rather than less specific, and keep the focus on the defense-related aspect, how would you build this, is or is not?

And the last point that Bonnie raised about the caution of just importing the suggested state regulation, I guess that's something for the NRC to think about in terms of your regulatory language. If you want to build on the suggested state regulation, how do you leave yourself room to consider more specific suggestions?

Bonnie, go ahead in terms of the --

MS. GITLIN: Well, I go right back to your

background piece and the language that you have in the background information under discrete sources. Where you highlight exactly what it is and what it is not, I encourage you to incorporate that type of language in your definition.

MR. CAMERON: Does everybody know what Bonnie is referring to?

MS. GITLIN: It's the two-sided one pager from the back of the room.

MR. CAMERON: Okay.

MR. GITLIN: And it talks very clearly about, you know, material that poses a threat similar. It goes on to talk about does not include material such as residues from drinking water and waste water treatment processes, scale from pipes. It is very specific about those aspects of industrial processes or commercial activities that you really are not intending to include in this regulation.

And so to the extent that those can be incorporated in the specific definition, I think it will go a long way towards resolving a lot of concern and confusion.

MR. CAMERON: I don't want to tie anybody down to agreement, but does that basic -- are people on board with that basic notion about if we use the

background piece, what it is and what it is not, that we're pretty much going to be there with a good definition?

This might be a focus for all of you as you submit written comments, too, to specifically address that. But let me go to James and then Ed and Felix and Ralph and then come back for one final check on this. And then I think we need to go to the phones. James?

DR. CASE: I don't know whether this is the right place in this, but I think it kind of came into my mind with what Felix was saying. With regard to is this the right point in the regulation to establish a de minimis concentration for --

(Laughter.)

DR. CASE: The reason why I ask this is a lot of simulators are being put together right now with radioactive components with the yttrium, for example. And you don't want to have to have a license for your yttrium in your simulator and a license for the this and that and this and that.

I guess my question to you is, how are we going to handle these I guess you might call inadvertent -- I don't know if that is the right word -- activization of things which their purpose isn't to

be activated but just as a part of it.

MR. CAMERON: I know that the term "de minimis" and that --

DR. CASE: Did I say a dirty word?

MR. CAMERON: -- three-letter, four-letter acronym always strikes fear in the hearts of everybody. This is the same idea, I think, Ruth --

MS. McBURNEY: To set an example.

MR. CAMERON: -- brought up with exempt limits.

Does anybody want to comment on what James said? Ed?

MR. BAILEY: Yes. If I understood what he said, he's talking about the incorporation of the material into a product, either an exempt quantity or exempt concentration, which is already covered under regulation, where you must have a license to do that. And then the person who receives it is exempt from regulation.

I believe that NRC -- the agreement state people agree with me. I'm not sure --

PARTICIPANT: That's an NRC license.

MR. BAILEY: Right, generally speaking. Yes. And it will be now.

MR. S. MOORE: One model is we would

regulate the introduction of accelerator-produced nuclides into products in the same manner that we would regulate the introduction of current byproduct materials pre the legislation in the manner that we do.

MS. McBURNEY: What about radium? Would you --

MR. S. MOORE: Discrete sources, discrete sources of radium.

MS. McBURNEY: Right, introduction of discrete sources of radium. I don't know that we have any exempt --

MR. CAMERON: I'm going to go to Felix, Ed, and Ralph, and then go to the audience and the phones. But I do want to check in with Tom and Joe after you hear this. You know, given the limits of how much we can go into this in this meeting space, are you getting the type of feedback that you were looking for? Is there anything else that you want to know?

Let's go to Felix and then Ed, and we'll go to Ralph. Felix?

MR. KILLAR: I actually have a real problem with what Bonnie has suggested as far as eliminating the things that are things such as fly

ash, source sludge, pipe scales, and things like that because that's the things our members are getting arguments over with the various people and stuff.

And so by eliminating them, all we have done now is continue those arguments to go on. It needs to be clarified at what level now easily, a low regulatory concern, that they --

(Laughter.)

MR. KILLAR: -- are acceptable for use. And so we need to get a concentration limit to cover that.

MR. CAMERON: So you're worried that what it is not is still going to be ambiguous in terms of industry needs.

MR. KILLAR: Right.

MR. CAMERON: Ed? Do you want to say something about it?

MR. S. MOORE: I want to respond to that, actually.

MR. CAMERON: Okay. Go ahead, Scott.

MR. S. MOORE: At this time the legislation gives us authority over discrete sources of radium and discrete sources of NORM that pose a threat that is equivalent or similar to the threat posed by a discrete source of radium-226.

At this point NRC is not thinking that there are any sources of NORM that are out there that are similar to the threat posed by discrete sources of radium-226.

So that is one area where we are thinking we have a position. It's one of the few areas where we do have a going-in position into this rulemaking. And that is that we don't see any threats similar to the threat posed by radium-226, discrete sources of radium-226, in the NORM area.

So I wouldn't envision us putting concentrations into the regulations because we can't think of any others that are out there similar to the threat posed by radium-226. If the NEI or any other stakeholders see that there are threats similar to that posed by radium-226, I would encourage you to tell us and tell us very quickly what they are because we haven't seen them.

MR. CAMERON: Scott, are you saying, then, that this need to define this boundary is only important if someone comes up with something similar to radium-226? I'm trying to tie your comment to Felix.

MR. S. MOORE: There are two issues. One is what is the definition of discrete. The second is

that definition only applies to sources of radium and sources of NORM that are equivalent to the threat posed by radium-226.

If there are no sources that are out there that are equivalent to the threat posed by radium-226, then it's an immaterial question. If there are no threats that are out there equivalent to the radium threat posed by radium-226, then it is a moot point.

MR. CAMERON: Okay. Let's go to Ed and Ralph. And a final question is this equivalent source idea. And if someone wants to weigh in on that, we can hear that. But then we are going to go to the audience. Ed?

MR. BAILEY: Yes. I would suggest that you include dials in there, radium dials. And when you do, you're going to pick up a few licensees out there who have in one case in California over a million dials and would have posed a very nice dispersal thing to use those dials.

MR. CAMERON: Does the dials issue go to --

MR. BAILEY: Discrete.

MR. CAMERON: -- the definition of discrete? And if you weren't going to list specific types of products here and you wanted to capture dials

with a more generic term, what would you -- you know, we have encapsulated, manufactured, and fabricated.

MR. BAILEY: Yes. The same thing you use for sealed source and device. Sealed source definition under the sealed source and device registry if I'm not mistaken takes into account dials.

MR. BROADDUS: I think that that would be like bound --

MR. CAMERON: Doug Broaddus.

MR. BROADDUS: Doug Broaddus.

-- bound into in a matrix. And, likewise, when you do that, though, you have to be real careful that you don't include a lot of your granddaddy's wristwatches and pocket watches.

Okay. Now, somebody talked about the level of compatibility and so forth. Halfway tongue in cheek, I would suggest that we have a high degree of compatibility with the suggested state regs when you go to look at it.

I would caution you on wanting a concentration limit, particularly if you go with radium, because the radium will blow you out of the water at a very low concentration and, in fact, concentrations much lower than what are commonly allowed to be used for cleanup. So I'm not sure that

you would really want to go there.

The last thing that I want to mention is that one of the things that has bothered me about the statement of hazard equivalent to a discrete source of radium, I don't know how big that discrete source of radium is. And if I've got a tilt of a microcurie radium source, half the world equals that. But, on the other hand, if it's a 10-milligram, 5-milligram, 100-milligram needle, there's a heck of a lot of different hazard there.

So at some point, I think you've got to put what level radium source you're going to equate things to.

MR. CAMERON: Scott?

MR. S. MOORE: And I think on that I think we would like comments or suggestions. What threat should that be based on? I mean, the legislation itself said would pose a threat similar to threat posed by discrete source of radium-226.

What should the basis for that threat be? Should it be based, as Bonnie suggested, on a security threat when you go back to the basis for the regulations? Should it be based on a safety threat? Should we take both into account? That's the kind of thing we need to know in the --

MR. CAMERON: You need that type of information. That's the missing piece.

MR. S. MOORE: Right.

MR. CAMERON: Okay. Let's hear from Ralph, and let me check in with Tom. We really need to go to the audience, I think.

MR. LIETO: Well, actually, what I was going to say kind of follows up on what Scott just mentioned. It seems like you are talking about a two-tiered level because what is a threat to health might be considered something at some fraction of the dose limit, which is not a defense issue. Yet, you also want -- it says by the act that you have to establish a discrete source based on common defense in security.

And I see two very large differences here. You know, what is a threat to health and safety is not necessarily a threat from a common defense or security standpoint.

So it almost appears that you're going to have to establish two levels for discrete sources based on what you are going to define for discrete. And also if you take the lowest one, it's basically ruling out any level above which is really a security issue.

MR. CAMERON: Do people generally agree with Ralph that you are going to need two different levels? Barbara?

MS. HAMRICK: That already exists. I mean, we do that with byproduct material. We have increased controls for certain licensees who have sources above a certain threshold that flowed out of security concerns originally. And, yet, sources below those levels are still regulated, still specifically licensed or generally licensed or exempt.

And I think you'll see the same multi-tiered approach in regulating radium. There are going to be some exempt levels, some generally licensed types, I would imagine, general licenses for some devices, potentially. No? Ed is shaking his head no. Don't consider that specific license.

And then there will some licensees that are going to be subject to higher controls due to the amount of radium that they might have.

MR. CAMERON: Okay. Tom, did you get what you needed, do you think?

MR. ESSIG: Yes. I just wanted to comment that in response somewhat to Ed's question -- and Barbara kind of raised the point, too. And that is that the threshold values that are in the code of

conduct for radium, for example, for category 3 is one curie. So we're talking about a fairly large source here.

And in terms of the health effects question that Ralph raised, the code of conduct was formulated. And we bought into this as a methodology of what was called severe deterministic health effects, meaning that it would kill or severely injure an individual within a certain specified time frame when exposed to that source in the manner prescribed in the document.

Now, what it didn't take on very well is the smaller sources, dispersal of them, and the so-called psychological factor, where you could certainly take a very small source, even exempt source, and wrap an explosive around it, disperse it, and some terrorist organization could say, "I disperse radioactive material" and put the fear of that into members of the public. That was really off the table as far as the code of conduct was concerned because I didn't want to get into that.

MR. CAMERON: Is that back on? Do you have to have that back on the table, the psychological impact, now or is that still on?

MR. ESSIG: No. We recognize it's there.

MR. CAMERON: Right.

MR. ESSIG: But we're not wanting to go there because it's boundless.

MR. CAMERON: Okay.

MR. ESSIG: You know, it's an in the eye of the beholder kind of thing. What constitutes fear?

MR. CAMERON: Okay. So everybody emphatically said yes.

MR. ESSIG: Yes.

MR. CAMERON: It's off the table. Okay. Thank you.

Audience, anybody in the audience? Yes, sir? Go ahead. And please introduce yourself.

MR. LUX: Hello. I'm Jeff Lux with Kerr McGee. And I guess I would like to say that without the type of quantity concentration, volumetric limits, I hope that everybody realizes that there is a lot of processing equipment, tanks, impoundments, bag houses -- it goes on and on and on -- that contain residues from processing many different types of ores, minerals, sands, phosphates that could be classified as discrete sources, oil field equipment, -- it contains scales or sludges - as well as the shop, the storage facilities that utilize our work on that equipment could become discrete sources.

So the universe of discrete sources could expand very rapidly without some type of limitations there. And it would be a real challenge for NRC to exempt so many materials by type without reference to such limits.

Felix mentioned the fly ash. Well, we're talking radium-226. There are just so many products and materials that are used volumes can be enormous. And if an impoundment contained technically enhanced material, then we have just expanded the universe resources phenomenally.

MR. CAMERON: And, Jeff, just let me ask you a question. The one definition that Joe read was that the concentration was increased. That sort of a broad definition would not eliminate the problem that you are suggesting. Is that correct?

MR. LUX: That is correct. Almost any time you process any type of mineral, sand, any type of ore to extract some component, what happens is all the components you're not expecting are concentrated. So you wind up with more radium than you receive.

MR. CAMERON: Okay. Thank you. Thank you very much.

Let's go over here. Yes?

MR. KIRK: Scott Kirk, ORAU.

I would like to elaborate on a couple of things. You know, the IAEA code of conduct was really to implement import/export requirements, even more so on source tracking. And that limits those sources to categories 1, 2, and 3.

But I think it ought to at least be identified that there are other agencies out there that are currently right now picking up sources using different sets of thresholds. And I think if we use the IAEA code of conduct as a benchmark, we might be missing the mark at a later date because there are other sources that are being picked up across the country that are orphaned that are much lesser activities. But I guess when it comes to the first principles, I think we ought to be looking at byproduct materials and protecting society against the stochastic effects.

So I think, again, it goes to those same three issues. You should have an exempt source. You should be having levels that protect public health and safety from a stochastic risk. And you should be able to have some flexibility that you can protect national security interests for whether you're using a two rem protective action guise for the cleanup, like the off-site source recovery and GTI does, and not

necessarily tie ourselves to the IAEA code of conduct.

MR. CAMERON: Great. Thank you. Thank you very much, Scott.

Oh, all right. I'll be back. Okay. This is Mr. Little from Department of Commerce, I believe, but please introduce yourself.

MR. LIETO: I'm Robert Little. I'm with the Department of Commerce, Bureau of Industry and Security. It is my pleasure to be here today.

As you may or may not know, radium-226 was our responsibility at the Department of Commerce. We look forward to working with Joe and others at NRC in defining this source because it is very important.

We want to make sure that there are no gaps that exist and that the transfer of this source as you go through your proposed rulemaking, final rulemaking, process. And we hope that you consider other proposed rulemakings that are on faster track than this one when you're talking about defining the definition of the source, meaning that it should be consistent.

What is defined here should be also consistent in other regulatory making groups here. I know there are a number of task forces that NRC has. And one of them is the tracking task forces.

So Commerce is urging that whatever is agreed to -- and we look forward to working with you, Joe, on that -- is that whatever is agreed to as the definition of the source be carried out, all the rulemakings, so that there is consistency.

And obviously we will be looking forward to working with NRC in a harmonized way so that when their rules come into effect, Commerce also has rules to let their folks know that it is now in the NRC's jurisdiction.

Thank you.

MR. CAMERON: That's great. Thank you, Mr. Little. And thank you for being here.

And, Joe, I take it you know Mr. Little and the contact information. That's great.

Yes, sir?

MR. DOREMUS: Steve Doremus with the U.S. Navy Radiological Affairs Support Office. A little follow-up to Ed's pointing out with radium dials and gauges.

The majority of those gauges today exist in DOD and municipal landfills. So it's something you should consider. The disarray there, sometimes we find them fully intact and sometimes you just have a rusty soil with probably a highly uniform

concentration of radium. So for your definition, you might want to consider at one time it was manufactured and is no longer in that array.

We also see it in slag material that we use to do the melting of our aircraft also. So a lot of our facilities, we expanded our boundaries. And so there are a lot of radium dials and gauges also in that material. You might want to consider will that have to be licensed or not and how we'll deal with it.

You've got to remember the presumptive remedy for these landfills is we're going to leave them in place. So it's not really a rad waste issue.

We also right now are dealing with the BRAC facilities under CERCLA. So what kind of dual regulation would you have there also? So thank you.

MR. CAMERON: Thank you. Important issues.

Yes?

MR. SETLOW: I'm Loren Setlow. I'm with the Environmental Protection Agency's Radiation Protection Division. I am also the Chairman of the Interagency Steering Committee on Radiation Standards, NORM Subcommittee.

And I certainly would invite you to meet with us, perhaps after Thanksgiving, at some point so

that we can discuss various aspects of your proposal in terms of the definition of discrete as well as the rulemaking proposals, because I believe you will get an awful lot of very valuable input from the eight agencies that are members of our subcommittee.

MR. CAMERON: Great. Thank you. Thank you, Loren, for telling us about that. I'm sure the staff will take you up on that.

Yes? Tom, go ahead.

MR. ESSIG: Chip, I just wanted to make a reply to the comment that Scott Kirk made a few minutes ago, namely that when I introduced he comment on tech IAEA's code of conduct, what I should have clarified is that the code of conduct is a minimum program for all IAEA member states considering the safety and security of sources. And so it prescribes legislation and he regulatory process that they should have in place.

What I didn't mean to relay was that we are now all of a sudden setting aside any concerns for cancer induction as an endpoint. We still are concerned about those stochastic health effects. And that part of our regulatory program is not being changed.

I didn't mean to convey that we were all

of a sudden looking at the severe deterministic health effects as a new paradigm and that we weren't concerned about what we had been concerned about in the past. That remains pretty much the same.

MR. CAMERON: Okay. Thank you, Tom.

Yes, sir?

MR. SIMMONS: Thank you, Chip.

I'm Charlie Simmons. I'm with the law firm Thompson and Simmons. And we represent clients in industrial minerals, uranium mining and processing, and water treatment.

A couple of quick comments I just wanted to make after observing everybody's discussion is, really, this is an opportunity for NRC to really define the limits of its IAEA jurisdiction over certain classes of materials. And it may be a luxury or it may not be.

One other observation worth sharing is I note on the roster of the tenants we don't have anybody from the Occupational Safety and Health Administration here. We do? Oh, all right.

I'm so glad you're there because that's an agency that has announced as of May of this year its intention to revise the 1910.1096 radiation protection standards, which if certain classes of naturally

occurring materials, like the radiums and whatever ultimately is defined as discrete sources of radium-226 and NORM will then become within NRC's jurisdiction and outside of OSHA's following that promulgation.

And, consequently, if there are no other naturally occurring radioactive materials that are of similar threat, it might be OSHA really only has ionizing radiation machines to regulate after that. I don't know. It has implications, shall I say?

MR. CAMERON: Okay.

MR. SIMMONS: All right?

MR. CAMERON: You didn't look lethal when you said that.

MR. SIMMONS: In terms of defining the boundaries of what constitutes the types of material of interest here, we have heard about activity per unit mass, which is a typical way of defining something, a picocurie per gram, a becquerel per gram.

There was also a component here of total activity, total activity being used by agencies such as DOT in defining a limitation on a consignment. I think there is another component here, too, when listening to the threat-based definition. It may also be activity per unit volume of something, which might

be of concern. The physical parameters, not just activity concentration but other physical parameters, should be considered here.

We have heard the term "sealed source" as perhaps being descriptive of the types of materials that would be of interest. There is a corollary in DOT's rules, and that is radionuclides in special form, which also bears scrutiny because that is something which is essentially confined and contained.

Finally, a comment on IAEA's principles and how the statutory language describes determining something is a threat. This could be a threat. If it's interpreted as a threat to the common defense and security, then I believe it would be under the Atomic Energy Act, NRC's, the Commission's, exclusive jurisdiction. Over anything, there is the threat to the common defense and security. And neither states' agreement or non-agreement would have anything to say about it.

On the other hand, if it's a health-based concern, then it is something that can be transferred to the states under the Atomic Energy Act.

Finally, just to note, some of the consequences around the world that are almost silly in some respects and some would think otherwise. And

that is I am informed the government of Singapore has ordered that all radium-226-containing lightning rods be removed, collected, and disposed of because they pose a radiological threat to the persons or people living in that member state. Perhaps so, but it's worth considering the *in situ* remediation versus the actual collection and removal insofar as those things are concerned.

MR. CAMERON: Thanks, Charlie. That was very helpful.

We are going to go to the phones. I would just note on your common defense and security issue that it seems if the Congress contemplated that the NRC would regulate this for purposes of security and then they could turn that over to the states, that I'm not sure if there's a legal issue there or not, but thanks for bringing that up. We won't let Bailey say anything.

MR. BROADDUS: Would you like me to address that? Would you like me to address that or, Scott, would you prefer?

MR. S. MOORE: You can go ahead. And then I'll --

MR. BROADDUS: From the standpoint of common defense and security versus self and safety, --

this is Doug Broaddus, by the way -- a couple of things to consider. First of all, the legislation specifically does talk about establishing agreements with states and for our continuation of the regulatory oversight of the material by existing states that have agreements in place, which if the --

MR. CAMERON: Keep going. Keep going. That's fine.

MR. BROADDUS: You know, if the intent was for it to be solely under common defense and security, it seems out of place that they would have included that in there. However, from the standpoint of common defense and security and health and safety and comparison between the two, if you address the common defense and security issue through health and safety, if it's addressed by the health and safety regulations, that is another way to look at that you have already addressed the common defense and security issue as well.

And we have used that approach in the issuance of some of our increased controls up to this point as well to point the additional control measures to enhance the security of certain materials already under health and safety.

MR. CAMERON: Okay. Thanks.

And, Scott, final comment? We'll go to the phones and the TV room and then jump right into the accelerator. Go ahead.

MR. S. MOORE: I guess two things. I wanted to follow up on Doug's comment. One area of this is we can look at the threat in the area of security of materials. That doesn't necessarily mean it's a common defense and security area.

For instance, we have regulations under 20.1801 and 1802. And those are safety-based regulations. So those are under the agreement states' purview.

Getting back to Mr. Setlow's comments, the act itself does require us on these discrete sources of naturally occurring material that pose threats similar to radium-226 to consult with the administrator or I presume their designee of the EPA, the Secretary of Energy and Secretary of Homeland Security, and also the head of any other appropriate federal agency.

And we will be doing that, as you noted, although it will need to be earlier than after Thanksgiving due to our expedited schedule. And so we're looking at probably the week before Thanksgiving or maybe even sooner. So we will -- so right. Yes.

That is the time frame we're looking.

MR. CAMERON: Okay. Let's go to the phones. Jill, do we have anybody who wants to talk?

JILL: If you would like to ask a question or place a comment regarding today's conference, just press *1 at this time.

MR. CAMERON: So do we have anybody, Jill?

JILL: We have Robert Scuronick. Sir, your line is open at this time.

MR. SCURONICK: Hi. This is Bob Scuronick from the Michigan Department of Environmental Quality.

I would like to offer a potential definition for discrete source. A discrete source of radium-226 is any item fabricated for use in commerce, medicine, or research where radium-226 is deliberately used because of its radioactivity.

MR. CAMERON: Okay. Thank you. Thank you for that. That's a very concise definition. I don't know what people around the table think of that, but I think everybody heard it. And I'm not sure. They're nodding, perhaps not approvingly, but I think that there is some food for thought there.

We'll just go to Tom Essig for one comment on that.

MR. ESSIG: I just wanted to reflect that

it does capture I think the point that Ruth was raising earlier about being used for its radioactive properties.

MR. CAMERON: Okay.

MR. ESSIG: That's an important thing to include.

MR. CAMERON: Thank you.

Operator, do we have another person?

JILL: Yes, we do. We have one other from Scott Siemen.

Sir, your line is open at this time.

MR. SIEMEN: Hi. This is Scott Siemen, Siemen Nuclear Corporation, a moisture density gauge manufacturer.

Regarding the definition portion, a threat similar to radium-226, our experience is that regulators view this threat differently. Some just see it as a radiation emitter. Others have other concerns. They're worried about pressure build-up within capsules, which is actually something that's missed by calculation and measurement, it's been found to be less than an atmosphere.

And the old history of leakage of radium does not include industrial capsulization. Sources manufactured and distributed by us by Amersham, you

know, to our knowledge, we're not aware of any radium industrial source that has leaked. We find regulators are interested in imposing greater leak test frequencies and things. And so I don't know if any further definition needs to be made of what the threat is of radium. You know, it's similar in toxicity, radiotoxicity, to erasium. So it's just a problem that we fight from time to time.

MR. CAMERON: Okay. Thank you, Scott.

MR. SIEMEN: Thank you.

MR. CAMERON: Jill, is that it for the phones?

JILL: That's all we have, Mr. Cameron.

MR. CAMERON: Okay. We'll be back to you later on in the day, and I'm going to ask if anybody over in the TV conference room has anything to add for us.

PARTICIPANT: We do have one comment.

MR. CAMERON: Great.

MR. JOHN JANKOVICH: This is Peter Johnjancovich. I am on the NRC staff. I work for Tom Essig in his branch as the team leader for sealed source.

I would like to point out that there are two definitions, well-accepted in medical and

commercial sources. Those are for sealed sources from gaining byproduct material.

However, my point is that if we use those definitions and start dressing them up with all the considerations that we have heard so far, we may achieve a good definition for this source.

Let me point out what those two definitions are. One is in the NRC regulations in part 30. Let me raise it shortly. There the source is defined as material, byproduct material, in case in a capsule. So it means it is maintained and in order to prevent leakage and/or escape. So that gives us already some reaction how we could go with the definition.

The other accepted definition, both nationally and internationally, is the applicable standard. There are two standards, American National Standard, ANSI standard, N43.6. And there is another item to the definition for sources in the international standard, ISO standard 2919.

That definition is a little longer but similar to the NRC. And it says that the material is in a capsule in abundant cover. And the containment is strong enough to present both the outside, the dispersion of the material.

So I suggest this definition should be considered that we go to next. Thank you.

MR. CAMERON: Okay. Thank you. Those are analogies that should be explored.

Anybody else?

(No response.)

MR. CAMERON: Okay. Thank you.

I know we are behind, but I don't think it's fatal yet.

(Laughter.)

MR. CAMERON: We do have accelerator. And Dick Blanton is here. And I'm suggesting let's move through accelerators.

I know that there is some interest in waste and transportation. We have Derek Widmayer with us and Rob Lewis on those issues. Well, we will see where we are when we are done with accelerators because I think you probably want to take a break. So when we're done with accelerators, let's take a break. And maybe this will go fairly quickly. Who knows?

(Laugther.)

MR. CAMERON: Dick, a lot of pressure on you.

Mary, a clarification?

DR. M. MOORE: No. Just I was wondering

could we have the break now before we start the accelerators? Five minutes? Ten minutes?

MR. CAMERON: Fifteen? No. Well, I'll tell you what. We have been at it for an hour and a half. And we probably are going to go over. Okay? So why don't we take a break. Scott, is that okay with you?

MR. S. MOORE: Sure.

MR. CAMERON: Take a break now? How long do you want to release people for? Give them 15? Ten? Okay. Ten minutes. Thanks, Mary.

(Whereupon, the foregoing matter went off the record at 3:01 p.m. and went back on the record at 3:15 p.m.)

MR. CAMERON: On the record. George Mills and Rich left. They had another engagement. So I think that this accelerator issue is probably our last big substantive discussion. We are going to talk about waste though and transportation. I'm not sure. I don't think that's going to be too big a deal.

There were a lot of other issues that we got the sense of the group on in terms of putting information out earlier, longer comment period. So I'm trying to look on anything after this discussion as just gravy just because I want to try to be

optimistic. But at any rate, Dick Blanton, accelerator, tee it up for us please.

MR. BLANTON: Okay. We have an accelerator. We operate it. We produce some material. It's radioactive so it's accelerator produced radioactive material, but it's a byproduct material. The Energy Policy Act gives NRC authority over certain accelerator produced material but not all of it nor over the accelerator that produces it.

The Act gives the NRC authority by amending the definition of byproduct material to include the accelerator produced radioactive material. But it also specifies three things that kind of define what accelerator produced material we're going to regulate.

First, it has to be produced in a particle accelerator and we presume that means any kind of a particle accelerator, linear accelerator, cyclotron, whatever. It also can be produced before, on or after the effective date of the regulation. This effectively means there is no grandfathered material that's exempt from that regulation. Then we get to the third criteria. It's produced, extracted or converted after extraction for use in a commercial, medical or research activity. These things are not

defined within the Act.

So we look at the production of accelerator produced material. In general, we can see that there's probably going to be two types of materials produced. The intended material, the product that we're trying to produce resulting from the irradiation of the target material, this generally we understand does not happen instantaneously. It takes a period of time. There will also be the production of some incidental material and this could be due to the irradiation of target contaminants if any or the irradiation of the accelerator internals, things like magnets, beam stops, beam guides, whatever.

So we come up with two issues to be resolved. When does the accelerator produced material become byproduct material if it is being produced for a commercial, medical or research use? Should we start the regulatory clock when the first atom of the product material is created within the accelerator? Should we wait until the irradiated target is removed from the accelerator? Or should we wait further until the product material is separated from any incidentally produced material?

If you look back at the history of

discussions that led up to the Act, people talked about all of these things. So it's not clear exactly where we should start in. What we want is discussion. What do you think we should do? Where should we start the clock?

The second thing is what about the incidentally produced byproduct material itself? On one hand it's being argued that this is produced during the production of material that's intended to be used as byproduct material in a commercial, medical or research use but it itself is not intended for use in another commercial, medical or research activity. So should it be regulated or should we not regulate it? We'd like to have your thoughts and comments on those issues.

MR. CAMERON: Are you done?

MR. BLANTON: Yes. You said be quick.

MR. CAMERON: Okay. Is my mike on? All right. We already have some cards up. Thank you, Dick, for that presentation. You saw how Dick formulated the two primary issues there. Let's start it this way with Roger and go around that way. Ruth and Maria and Roy. Roger.

MR. MORONEY: Thank you, Dick, on the discussion there. For us, I mentioned earlier we

operate 42 PET-radio pharmacies in the U.S. and each one of the facilities has a cyclotron.

A couple of concerns from our operational experience, and perhaps my cohort/comrade over at Eastern would have the same experience over there. The exposure to the cyclotron staff, probably the largest portion, is to the cyclotron engineer who is doing the maintenance on the equipment and we'll typically see exposures reaching a significant fraction of the primary limit. So if we're concerned about safety issues with staff, employees and radiation workers, then I think perhaps we should consider something in that area there.

Another area which we have some recent experience having decommissioned a PET facility is the largest cost of the decommissioning was the cyclotron itself by far. There was really nothing to speak of in the rest of the facility as far as removal cost and it was significant.

Then the last thing, I guess I'm at a loss as to where the commercial is really defined in regards to separating the material that's regulated with material that's not regulated. We are by definition in the commercial process in the commercial activity and it would almost seem like reading the

rulemaking or the legislation is that the entire cyclotron would be covered because we're using it for a commercial process and I know how you're defining it today but what's going to happen tomorrow is what I'm concerned with.

MR. CAMERON: When you say what's going to happen tomorrow, what is specifically that concern?

MR. MORONEY: Could there be a different interpretation tomorrow versus what we just heard today? Is the cyclotron covered? Is the target body covered? Is the activation products in the tank and the deeds, the shielding?

MR. CAMERON: Is that what we're here to do?

PARTICIPANT: Yes.

MR. CAMERON: That's what we're going to be doing.

MR. MORONEY: I find it hard to be able to separate those as a physicist.

MR. MOORE: That's a key point. We don't have a definition today and we want to hear everybody`s input on that. Certainly a very narrow definition would be only the target should be under our jurisdiction. A very broad definition would be the target, any backing and all activation products

would be under our jurisdiction.

The legislation does not give us authority over the cyclotron itself but it does give us authority over accelerator produced material for research, medical and commercial use. So the question is what is that and how should we write the regulation for that and we want to hear from you on that.

MR. MORONEY: Let me clarify. I think a lot times when it's exploited is between machine sources of radiation and radioactivity. I assume that's what it is. When I was talking about regulation of the cyclotron itself, I wasn't talking about that you would get into the business of machine generating radiation machines at all. It's strictly the radioactivity produced within it and a system used where the primary purpose of the system is the radiation itself would simply, would obviously not fall within this range. But a cyclotron, a particle accelerator where the radiation produced is incidental to producing some radioactivity for distribution commercially would seem to fall within this range.

MR. CAMERON: Okay. Thanks.

MR. MORONEY: And I'm putting these out because again going back early on, we're looking for uniformity, consistency and it's often once you put a

cyclotron into a nuclear pharmacy that's when you start running into these gray areas because there's not in many states, many states there are, a defined program or defined guidelines and they try to shoehorn as best as they have into machine registers.

MR. CAMERON: And remember Scott gave us, I don't know if they're two ends to the spectrums but he gave us two possibilities for how we should define this. Keep in mind. I think, James, you brought up the big and small issue before which is something that is relevant to this discussion too. So remember that comment and James may remind us of that later. Ruth.

MS. McBURNEY: From the standpoint of trying to develop uniform standards for accelerator produced material in those non agreement states, I think it would be really the right thing to do on two levels because you're not going to then have two different agencies regulating similar material in the same facility.

Also where you're going to run into it mostly is during the licensing process because you're going to need to review the manufacturing facility for the radioactive material, not only that that's being produced and to review the shielding and the hot cells and so forth dealing with that radioactive material

but you also have to take into consideration the material that's going to build up in the shielding for when you're doing doses to the public and to the workers and so forth. So really you're going to have to take those materials into consideration during the licensing process. Also during decommissioning when you're decommissioning the manufacturing of accelerator produced radioactive material, not only does any residual radioactive material in the target appear there but you also have the activation products and so forth.

In agreement states, I don't know how other ones do it but we first register the machine for its machine properties and then when production starts or before production starts we review it as a license and license that manufacturing activity. So I really think it's the right thing to do to cover the whole activity in that manufacturing process.

MR. CAMERON: So, Ruth, you're suggesting that the NRC should be as broad as possible.

MS. McBURNEY: Broader. Yes.

MR. CAMERON: All right. Maria.

DR. KELLY: That's just what I was going to ask Roger. So in other words, you're saying that the byproduct material whether it's intended or

incidental creates a safety risk and so it should be covered that way. So there shouldn't be any distinguishing between them unless you set a limit or something.

MR. CAMERON: Okay. Did you get the clarification? All right. Barbara.

MS. HAMRICK: I just wanted to expand a little bit on what Ruth said not only will those products be there at the time of license termination but it's my understanding that in your license termination process under your NEPA obligations you would have to look at some things that you wouldn't necessarily license for example, radium at uranium processing facilities under your NEPA authority. You would have to look at that anyway and it seems to me that this would probably end up in the same box in a license termination scenario.

The other thing I wanted to say was about what Roger said about the exposure and currently the regulations if you're looking at exposure limits, they have to look at exposure from all sources of radiation whether or not it's a licensed source. So that exposure would still be accounted for and regulated for the occupational worker but not necessarily for the public.

MR. CAMERON: Thanks, Barbara. Let's go to Mary.

DR. MOORE: One of my major concerns with this change is the compartmentalization and duplication and confusion. So let me ask a clarifying point with byproduct material. It comes from reactors and NRC licenses reactors. I am not clear in understanding. Will the states register and license the cyclotrons and where and at what time does the NRC now become involved? It's unclear to me.

MR. MOORE: The analogy to reactors, NRC has authority over the whole reactor, not just the material coming from the reactor. Under the Energy Policy Act, we got authority only over the material coming from cyclotron. We didn't get authority over the cyclotron itself. So we don't have jurisdiction as a regulatory agency over the cyclotron. We only have authority over the radioactive material produced by the cyclotron.

DR. MOORE: And at that point and as our discussion has been, I also support a broad definition because I think that helps simplify life for everybody and will also enhance smoother operations and therefore enhance safety. Is the NRC's authority now over the lifetime, and I can't think of a better word,

of that radioactive material? In other words, do you cover from birth to disposal of decay? All right. Decay.

MR. MOORE: That would depend on how we define it in the regulations and that's what we're asking for input on. We haven't yet defined the regulations and that's why we're holding the meeting today.

DR. MOORE: Understood.

MR. MOORE: But we were to define it broadly, if we were to consider that it is commercial from birth to the endpoint, then I would presume that we could make an argument that we would have authority over decommissioning of the cyclotron because it would involve activated products if we concluded that it was commercial at that point.

We have authority over accelerator produced material for medical, research and commercial uses. So if we concluded as an agency that it was accelerator produced and if the activated products were accelerator produced and they were commercial because of their waste potential, then we would have jurisdiction over it and we could regulate it.

DR. MOORE: I can one conflict happening among the states if this broad definition and this

scope is not implemented is that the states will be involved at the birth, the licensing and citing and review of shielding and all that. Operationally, NRC comes in and then when they want to decommission it, all of a sudden it comes back to the states unless this broad definition. Is my understanding analogy correct?

MR. MOORE: Yes.

DR. MOORE: In non agreement states, right.

MR. CAMERON: Okay. So we're hearing that people seem to be supporting for various reasons a broader definition at this point. James?

DR. CASE: Whether enough people around this table are interested in broadening the definition, I don't think Congress gave you the authority to do that. Cyclotron is not what's on the table here. It is the material coming out of the cyclotron and that doesn't mean we can stretch it out to processes or the cyclotron or however you try and continue to reach. Congress says what's on the table is byproduct material and I think we need to stay focused on the byproduct material and try and not get too much mission creep onto the cyclotron itself.

MR. MOORE: We have not yet had a

discussion of why the concept of commercial use may apply to waste and Ruth brought that up earlier. So maybe Ruth might want to discuss further the concept of waste being commercial.

MS. McBURNEY: I think there has been some case law. Scott Kirk who's the Health Physics Society's legislation/regulation chair of that committee said there has been case law that would define waste as a commercial activity. So from that standpoint, whether or not NRC took into account that once this material becomes a waste for disposal that it would be covered under the definition.

MR. BAILEY: Yeah. Can I just interject one quick thing in that regard? I think if you look at the low-level waste compact in the legislation, the reason you couldn't ban waste coming to your site was because it was a violation of the interstate commerce clause of the Constitution and so I would presume that somebody has determined that it's in commerce. Somebody's getting paid and as Roger pointed out, that machine is in the process of commerce and it's generating whatever it's generating. It's already there.

MS. McBURNEY: Or at least the activity in it. The machine itself.

MR. CAMERON: But besides this issue when we were talking about broad or narrow, we were talking about broad or narrow in the sense of the two possibilities that Scott gave us earlier. But he very clearly said the machine is excluded.

MR. MOORE: Right. It has to be broad or narrow with respect to the radioactive material in the machine. Getting back to Dr. Case's point, we have no jurisdiction over the machine. It can only be with respect to radioactive material in the machine. We have no authority over operation of the machine.

MR. CAMERON: So that at least should be clear.

DR. CASE: Let me just be clear what you're referring to. So if as the negative ion being swirling around there, runs into the side of the cyclotron, activates an atom within the cyclotron, then the cyclotron comes under that atom now as under the jurisdiction of the NRC.

MR. MOORE: It could be and that's what we're discussing. An activated --

DR. CASE: And that's my question. Did Congress give the NRC the statutory authority to do that or have you just crept over into regulating the cyclotron?

MR. CAMERON: Let me -- Can someone give us a clear response to that because I think it's very important and, Dick, I don't know if you wanted to or Roger. But I would like someone to address that specific question so that we can end the confusion.

MR. BAILEY: I would like to read what is here leaving out a few words. It says it's radioactive material produced for use for, an example, a research activity or a commercial activity or a medical activity. It is radioactive material produced in the process of doing that. It doesn't have to be extracted. It doesn't have to be converted. It just has to be produced.

MR. CAMERON: So in other words, it's in the process so that the --

DR. CASE: You added the word "process." Congress didn't. Congress put "for" in there. If Congress wanted process, they would have put process in there. That's my point.

MR. MOORE: My understanding is that Congress didn't produce any committee report along with the legislation. So all we have to go on is the words in the Act at this point.

DR. CASE: Which is "for" not "process." That's my point.

MR. CAMERON: Which can be a big difference between process and for.

DR. CASE: I think that will need to be clarified.

MR. CAMERON: Okay. Good important issue that needs to be addressed. Let's go to Roy, Ed and then we'll go back around to Ralph and Mary. Roy.

MR. BROWN: Yes Dick. First of all, let me say I think you guys really nailed the crux of the issue here on when and what needs to be regulated. I think going back to when it's created. I think for ease of operating and for ease of licensee CORAR (PH) would be in favor of taking of control of it as soon as it becomes radioactive. Not only is the product you're selling becoming radioactive but the target backing, the big machines, the medium plain, the whole five feet around the whole building would be the concrete would be activated, the steel rebar in the wall would be activated, the cesium-137, cesium-134, cobalt-60, all that is part of the commercial operation and I think CORAR would be in the side of that's all part of the commercial operation and should be regulated.

You also have in terms of one to regulate some of the processes like making I-123. You

circulate Xenon gas in and out of the cyclotron on a continuous loop and I think CORAR would be on the side of every time one of those Xenon particles become activated to I-123, then it becomes regulated. It's not a case where you put it in the machine and take it out of the machine. But the gas is continuously circulating.

Also in terms of Incident 2 production, I think all this is Incident 2 production because it's part of the commercial process and CORAR would be on the side that this should all be regulated.

MR. CAMERON: So, Roy, you're saying broader too. I just want to make sure that we understand this as much as we can using Dr. Case's example of the side of the machine becoming radioactive. How would you parse that out?

MR. BROWN: My feeling would be that's part of the commercial process. So that material is in commerce. That's radioactive. So therefore it's covered.

MR. CAMERON: Okay. Dr. Case, did you want to say anything to that?

DR. CASE: Again, that may be something worth thinking about here but definitely just straight reading of what the statute says, that's not what

Congress had in mind. I mean Congress says as been made, radioactive by use of a particle accelerator and is produced, no mention of processes. I really think you're on a slippery slope of over stretching the authority.

MR. CAMERON: So if you dealt with, using your example, that material as a waste it really wouldn't have been produced. They wouldn't have met the produced-for definition.

DR. CASE: The reason why this is an important issue and getting to the big and small accelerator type argument is if you're talking about regulating a small radiopharmacy and their small cyclotron and now they have to go through the same thing that Three Mile Island would have to do in decommissioning, these are the issues that I think we have to be aware of in creating our rule. Is it risk based? Is it what Congress intended? I think right now our concern as clinicians in terms of access is being able to work within what CMS gives us in terms of a reimbursement in a way of raising healthcare costs.

MR. CAMERON: CMS?

DR. CASE: Center for Medicare Services. So what I think is very important for us is if we try

and chase down every last atom that may have been activated in this cyclotron that Congress didn't give us the ability to discuss anyway, I think we're asking other agencies of the government to pay more money for getting radioisotopes necessary for taking care of Medicare patients.

MR. CAMERON: Can we have specific responses to that and let's go to Barbara, Ralph and Ruth.

MS. HAMRICK: I just want to say that those activities though are already regulated by most states. So in an agreement state, that decommissioning criteria is still going to apply. It's already in place. So the fact that they might take on this activity would promote consistency but it wouldn't really change the fact that that's a regulated activity right now.

MR. CAMERON: Okay. And Ralph.

MR. LIETO: I just wanted to give an example of a more nightmarish situation that could exist is that you have a state agency that has one state agency regulating NARM, another one regulates the radiation machines and is an NRC state. So if we followed the criteria or the very narrow scope of what we're saying here, you could potentially have a

cyclotron having to meet three regulatory agencies to operate one machine. So if you don't think that's going to drive up the cost, I think that that's a very real situation.

I think also that with this controversy maybe we need to have some type of general counsel input on this aspect at least for the nonagreement states as to where this is going to begin. I personally would want a more general approach that you have one agency regulating the radioactive materials regardless of where it's produced. As Barbara and the agreement states have pointed out, they've established exempt levels and maybe there are some of these situations that are going to occur in these smaller cyclotrons that would minimize the impact that Dr. Case is referring to. But I would be concerned that we would have over regulation for a single machine that could occur in nonagreement state facilities.

MR. CAMERON: Ruth, we're still on this specific issue.

MS. McBURNEY: Right. Whether or not NRC does regulate all the material, they are going to have to take it into account on the design basis and the licensing of those facilities whether it's a big one or a little one. And the size of the cyclotron or

accelerator, they're going to have to look at is it protective. Once it starts producing radioactive material, is it protective of the workers and the public? So whether or not they regulate it, they're going to have to take it into account and then at the decommissioning whether that's then regulated by one agency or two. It's just the right thing to do if it's within the legal framework and the regulations wouldn't have to deal with the size of the operation. That could be handled through the licensing guidance.

MR. CAMERON: Okay. Let's go to Roger and Ed.

MR. MORONEY: Are you talking on the same topic?

MR. CAMERON: Same thing.

MR. MORONEY: Okay.

MR. CAMERON: You got a little different -- Then we'll check in with Mary. You're on this same topic.

DR. MOORE: Generally.

MR. CAMERON: Okay. Let's go Roger, Mary and then Ed. Roger.

MR. MORONEY: Okay. Roger Moroney again. Two comments that Dr. Case made that of the separation between the small cyclotron and the larger cyclotron.

Prior to coming to the PET, I worked in a facility with these larger machines and at the risk of inviting more regulation, I can tell you the smaller ones are not quite as innocuous as you might think they are and I made the statements earlier not to invite more regulation. It's to invite consistent and a level playing field across the United States for those of us that work across the United States. That's our goal in coming here is that level playing field from state to state and a consistent interpretation of the regulations.

MR. CAMERON: Okay. Mary.

DR. MOORE: In following this definition of the role of the activated components of this cyclotron during the production of any ram, the target has to be changed. That target now becomes as activated. It's radioactive. It's an accelerator produced radioactivity and it has to now be handled as waste. Under whose purview is that, the state or is that the NRC?

MR. MOORE: That's what we're discussing.

DR. MOORE: I'm bringing -- Right, I understand we're discussing it. But this is one of the issues. The cost goes up. Confusion goes up. With a broad definition of the accelerator produced

radioactivity is used for the NRC, would the NRC then be the regulatory group?

MR. MOORE: Well, again to answer your question, it really comes down to a question of is the target backing produced, extracted or converted after extraction for commercial, medical or research activity? That's really what it comes down to.

DR. MOORE: Well it was used for commercial activity to produce the product.

MR. MOORE: And if you answer the question that way, then it would be an NRC regulated activity.

DR. MOORE: Is there room in nonagreement states for 17 of us, are there I think, to individually negotiate that with the NRC?

MR. MOORE: I think that will have to come out in the transition plan and you can answer that.

MR. BROADDUS: The definition that we're talking about right now whether it's broad or narrow would not be something that could be negotiated after the rule's put in place. However, the transition plan that the task force will be developing will as part of that be addressing whether or not or proposing to the Commission some options for whether or not the NRC could establish limited agreements with states for the oversight of the newly defined material.

DR. MOORE: So the answer is in nonagreement states the point of intervention of or beginning of intervention -- I guess it's when does the state come back into it can be negotiated individually with each nonagreement state. So you may or may not have --

MR. MOORE: No, not the point that the state comes back into it. Whether or not NRC has jurisdiction or not, that will be the same regardless of which state you're in. Whether or not the nonagreement state wishes to have an agreement with NRC on a limited basis for NARM material is something we're looking at specifically under the transition plan.

DR. MOORE: Okay. And another thing. Are you looking at Ruth was referring to the fact that you all are going to have to look at personal exposure shielding and site design. Why? You're not licensing it. You're not citing it.

MR. MOORE: If we took a broad definition of the materials that are activated and produced, then we would be responsible for the safety of people working around those materials. So under Ruth's construction and I haven't necessarily accepted that, but under Ruth's construction, then we would be

responsible for regulating safety under that. So we would have to look at anybody that worked under that. So you would have to look at site safety under that. You'd have to look at all issues under that.

DR. MOORE: Right. And I do know that. But what I'm trying to get to as we're delineating this is as a potential licensee submit the request to the state to register, then license my cyclotron. I might also now going to be submitting information to you before the products I'm producing.

In other words, how do you all get pulled into this and communicate? Are the states going to be sending this information to you or do I have to write another check and write a bunch of -- Yeah, I have to write another check. I should have known that. And send more forms. We're duplicating a registration and a citing and a shielding and a safety review process. I know Congress did not give you the authority over the cyclotron but operationally and worrying about expenses particularly for the same small nuclear cardiology sites as well as the large facilities and operations that have sites in all the states, we've just driven up the cost and duplication.

MR. CAMERON: One idea here is to, and I think the NRC needs to take in account that you're

hearing around the table and it might be useful to make sure that your comments go to this, is to think about interest. What are your concerns in terms of broad or narrow? We heard it may be more costly, too many agencies, too much bureaucracy, conflicts. We heard a lot of that and I guess I just wanted to have Dr. Case articulate what his concern is. He talked about his view of the legislative history and I know that he's not just doing that from an academic interest in legislative history. But can you just articulate your concern, Dr. Case, about this broad definition that we're talking about?

DR. CASE: Well, I think it is an academic. The other thing I do as a person who lives in the State of Missouri which is an NRC state, I also pay Missouri taxes and I can tell you that if you want them to create a regulatory structure to become an agreement state under this, they may tell you to get lost if you haven't followed what the statutory language is supposed to do. The state could go ahead and sue the NRC and say, "Look. You didn't follow what Congress told you to do." So even though it may sound like a great idea, if Congress didn't tell you to do it, you have to go back to Congress and get Congress to tell you something a little different than

what they told you. This is really the limit of what the language is in here that we can do.

Now from a practical standpoint, aside from just saying I don't think you could get away with it if you start wandering too far from what Congress told you to do, I think as a practical matter, we have to be very cautious about what is good regulation. Is good regulation providing access to materials or is good regulation providing strict control of radioactive materials?

If you look at the history, the amount of dose, carcinogenesis due to environmental exposure to radiation, the incidence of heart disease in our country, these issues have to be weighed and balanced as a risk based model. And if we're talking about cardiac PET which is really in its infancy right now and saying we're going to put a 10 MEV, 11 MEV machine on the same playing field as a 67 MEV machine which is producing strontium or a nuclear reactor and we're going to put them all in the same bucket, it just doesn't make sense.

And that's why when I sit here and I hear people creeping beyond where Congress has told us to go, I know that not only nuclear cardiologist may have a problem with that. State legislatures will have a

problem with that and people who have to pay for the cost of enforcing this regulation might have a problem with it. And it could stifle. But the purpose of this is ultimately is not to restrict access to these materials but to create a safe way of creating access to these materials.

MR. CAMERON: Okay. Thank you. Let's hear from Gary before we go to Ed and Lynne.

DR. DILLEHAY: Gary Dillehay. I've found the whole day to be quite informative because I had no idea of the scope of issues that come up when you start talking about this. But we've heard all kinds of things today about safety and that sort of thing. I'm glad that we finally got around a little bit to regulatory issues related to cost because as an enduser in what I think is a good state, Illinois, an agreement state, I don't think that anything I've heard today is going to cause me to do a lot more or have to do a lot more than what I already do.

On the other hand, if you increase the paperwork and the regulatory burden and the cost, it is possible that you'll get to a point where access to these sorts of things is not cost effective for the institution offering these studies. I don't know what the endpoint is for that but that all has to be

figured in to what you do.

I have to tell you that when we go before the CMS and the people who pay for what we do, they're not very sympathetic with the fact that do you know that because I practice nuclear medicine I have to do a lot more paperwork than the internist or the pediatrician. They don't understand that and they think that we're in some ways padding what our time is. But somebody has to do it whether it's me or my tech or my administrative person or radiation safety officer or health physicist, you name it. It has to be done and just to be cognizant of that when you're thinking about these regulations is what I wanted to make sure was heard today.

MR. CAMERON: That's good and then sometimes when we do when we go out with a proposed rule, we ask people to address specific questions or to keep things in mind when they comment. Perhaps this might be one of those times where we really specify what do you think the effect on access might be, for example or whatever those questions are going to be to really focus people on that. Let's go to Ed and I think we should try to go to the various audiences also at this point.

MR. BAILEY: I said I wanted to change

streams a little bit and I want to focus on accelerators used for research. Unless you take into account all of the activated material created in an accelerator, you're going to create a real puzzle factory and I did work for a company that built accelerators.

Sometimes you're experimenting with a beam. That's research because you're trying to improve the bending magnets. You're trying to do something. You're trying to create a better target. You're trying to do all kinds of things. So that the part of the beam tube that gets activated while you're doing that research, I don't know how you would separate that from what occurred during normal production. Or if you had an accident or you lose a magnet or whatever, is that not in research?

If we take that then and the discussion about the medical isotope is wonderful except now you're going to create I can have the same accelerator, I'm doing research with it and part of it's covered. But if it's being used straight for production it's not covered and I don't know. You all must be a lot smarter than I am if you think you can figure out which one caused which and where you're going to do on each accelerator, which products you're

going to regulate and which you're not.

MR. CAMERON: Okay. Great. Thank you, Ed. Pointing out another difficulty that needs to be taken into account here. Anybody in the audience? All right. All of you who did speak from the audience if we could just make sure that you sign in on the sheets so that Lindsey can get a correct spelling of your name.

MR. COSCA: Jim Cosca, Eastern Isotopes. We have 12 PET facilities, about 17 machines. We're PETnet's little brother. Nice to see Roger here today. One of the things that I haven't heard all day is at what limits do we start regulating. There's exempt quantity tables that are in there, Table B, Part 30 that I don't know how they were established back in 1972 or what the logic was.

Whereas the DOT tables for Type A packaging, Type A quantities are established on what the emergency responder gets in 30 minutes to get his five rems for the year. Where that was a Q value system. What was that actual risk to that emergency responder?

When we're looking at what the intent of Congress was it was to protect us from a terrorist action of handling these materials. It also looks

like you have to do a Q value analysis on every single isotope and say if this isotope in the hands of a terrorist, is there a potential for it to be used in a dirty bomb? Then you have to establish exemption points far above Table B. Table B right now doesn't include any accelerator produced and the data is so old it's amazing. That's just one comment.

MR. CAMERON: Okay. Barbara, do you want to say something on that?

MS. HAMRICK: Yes, I just want to respond to that.

MR. CAMERON: Go ahead.

MS. HAMRICK: Actually, I think in the legislation it does also talk about protection of health and safety not just security and so that aspect is going to be covered. In the suggested state regulations, there are those limits that you're talking about, the concentrations, the exempt limits for the accelerator produced nuclides. So what we were talking about earlier this morning, they were able to just pull those concentrations and those numbers out. Then they would have those available for use.

MR. COSCA: Asking any health physicist at the table, what built that Table B?

MR. BAILEY: I can tell you exactly how that table was built. The quantity of material, there were two calculations done for the exemption quantity. One was direct exposure. The other was assuming that the amount of material that came airborne in a certain sized room and there was an inhalation and it was related back to dose.

The unfortunate part and that procedure is spelled out in the NARM guides published by the conference because we did it purposely for the accelerator produced materials. The problem with those quantities and it's probably something people don't want to hear is that those quantities were never adjusted when we went from 500 to 100 or when we went from 15 to 12 to 5 rem a year. So if you look at those quantities, you'd better use the old methodology or you won't have any exempt quantities that you can measure.

MR. COSCA: So the Table B is generous.

MR. BAILEY: Yes.

MR. COSCA: The Table B is generous right now not looking at the DOT Type A-1, A-2 value tables, the Q value tables that they have there.

MR. BAILEY: The exempt quantity tables are -

MR. COSCA: Are overly generous.

MR. BAILEY: Are overly generous in the amount of material.

MR. COSCA: Okay. So we won't ask you to reevaluate those.

MR. CAMERON: That's said on the record. That's not a request to reevaluate.

MR. BAILEY: But I would note that the parameters under which they were calculated were really quite conservative because it would be difficult for you to wrap yourself around and smear around the source to get the external and so forth.

MR. COSCA: Well, I just oversimplify it. If the A-2 value for F-18 is 10 curies and that's an emergency responder getting five rems in a half hour and I say the general public is 100 millirems, I would take 150 of A-2 value and that's my exempt level. To me that's an oversimplification.

But the A-1, A-2 table is built using the Q value, all routes of inhalation all five. Some health physicists had a lot of time on his hands when he built those A-1, A-2 tables. There's a lot of number crunching that went in there and I don't think 10 CFR recognizes that.

MR. CAMERON: Is there a second comment?

MR. COSCA: A second comment, yes. The accelerators, the cyclotrons, are registered by the x-ray departments in most states. Those are relatively easy forms and the fees aren't that bad. They're not asking questions on bolt efficiency studies and things like that. The State of Illinois, Gary and his crew, they really know their stuff where they ask the right questions. They want to see our bolt efficiencies. They want to see our decommissioning plans. They want money out of our pockets up front.

As the little guy on the block versus our friend across the table who has Siemens to back him up for decommissioning, I don't, I need to come up with $300,000 and now $500,000 because I have two machines, $500,000 cash flow in a CD bond. That was stifle the PET industry throughout the country. Other alternatives for bonding of course is corporate guarantees. You're lucky you have Siemen in your back pocket but I don't.

So there's a thing here and for some reason the State of Illinois would not let us, we couldn't talk our way out of it. They just said you're going to post the bond. We don't care what you say. And we could bring in the consultants. We could bring the scientists. We could bring in samples. We

could bring in everything. No. They made up their mind. We have to post the bond.

Now if the NRC comes up with a new reg 1556 Volume 157 Cyclotron Operation guideline and now we have suggestion from NRC that bonds and surety devices are required or strongly suggested for all cyclotron operations, you're going to put PET facilities out of business.

MR. CAMERON: Okay. I think we get that point and let me test that hypothesis. Already having to post the bond for State of Illinois under whatever scheme we come with, not whatever but is it practical to expect that there would be an additional bond posting for companies such as this gentleman?

MR. MOORE: I don't think there would be. I don't think that we would expect that there would be additional financial assurance on top of per facility in agreement states.

MR. COSCA: No, he's got me already.

MR. MOORE: But, Chip, it goes back to the question of what is licensed or what is under our jurisdiction. If we only have jurisdiction over just the activated product at a cyclotron, then it's unlikely that we would require financial assurance because you have very little material.

MR. COSCA: And we're thinking about the broad definition as was discussed.

MR. MOORE: If you take a broad definition, you have a lot of activated material, concrete, rebar, all that kind of stuff. You get into decommissioning and decontamination issues and then we probably would end up requiring financial assurance and that would be by facility I think.

MR. CAMERON: The bond that you're talking about in Illinois is to take care of the same type of thing that --

MR. COSCA: Thirty years in the future. When I go bankrupt, they have the money.

MR. CAMERON: So it's a question of there would be, your concern is that there would be more states that might be requiring this of you wherever you operate.

MR. COSCA: All 50 states would. If the NRC came out with level playing field consistent regulations and you had determined you had an hour on that target, that's enough to hit decommissioning levels and you came up with that conclusion, then we're going to be posting bonds everywhere. You will put PET facilities out of business because these people don't have the cash flow or the means to post

the bonds. They may have gotten away with it so far in some states that weren't aware of the requirement or enforced the requirement consistently. But you will put PET facilities out of business if you come across the whole country and say we want a bond from everybody.

MR. CAMERON: Okay.

MR. MOORE: I'm not sure how our financial assurance regulations compare to Illinois's. But I do know under our financial assurance requirements we do offer various options.

MR. COSCA: Avenues to do the bonding, yes.

MR. CAMERON: Okay. Let's go back out here to this gentleman. I know that Roger just wants to tell you that Siemens is not going to be as big a help as you think.

MR. MORONEY: We built that facility up before she even bought it. So we've been down that road.

MR. CAMERON: All right. So this point is the one that Gary raised in terms of an interest.

PARTICIPANT: I'm just supporting Dr. Case that too much regulation will stifle the industry.

MR. CAMERON: Too much regulation will

stifle the industry. Okay. Thank you, sir. Yes, sir.

MR. FENNER: Roger Fenner with the State of Tennessee. So far all the beams we've talked about have been going in circles and every once and a while they start going in a straight line. I would like to ask about a couple of those. In Tennessee, we have a free electron laser facility that produces no product at the end of its cycle. All it does is produce a laser that is then used for research. So would the NRC be interested in that particular beam because it is not there for any purpose of commercialization unless you buy the purpose of waste? It produces lots of activation, tons of activation. But it produces no product for research, no product for anything else except the laser. Now that's one aspect of it.

The other aspect is if a graduate student comes along and starts playing with chicane and and stuff like Ed was talking about later and starts seeing the stuff being activated, can be reduced in terms of the amount of activation and does research on that for his graduate thesis, then does the NRC come in and get interested in the thing?

The third prospect is if the laser that is used goes upstairs to a medical suite and is used in

medicine and is used as a commercial use, the laser itself, does that part then become interested of the NRC in terms of what's being used with it? So the beams are used in different ways and it's not everything going in circles. They can be used in straight lines and they can be used sometimes and they don't produce something that is a product that is activated. So it's something that you need to keep in mind when you think of your information.

MR. CAMERON: Thank you very much. Does that go to the definition of what is research?

MR. MOORE: Yes.

MR. CAMERON: All right. Thank you. Let's go over here to Christopher and then we'll go to the phones.

MR. GALLAGHER: Yes. Christopher Gallagher with the American Society of Nuclear Cardiology. I just had a question. I know I had heard that the Society for Nuclear Medicine mentioned California as a possible template because I know I think part of this is to look at state models that might be adopted. I'm not familiar with what California does in terms of how it would affect cardiac PET for example and I know that Sally Schwarz. I guess Missouri is a nonagreement state. For

example, if you're in Missouri and the NRC comes up with California as a template, how would that affect Missouri?

MR. CAMERON: And California was one example given but maybe, Ed, that would be instructive if you could just quickly give us a read on that.

MR. BAILEY: Okay. What I would basically tell you is that we have no specific regulations that deal with how you operate a PET facility. We do in the licensing process look at the handling systems and the processing facilities that are associated with them and we look at things like air emissions and so on.

I have not heard of anybody in California who even though they're paying California fees which may not be quite as high as NRC's that has not put in a facility because of cost. More often, it's how long it takes to get something approved and that is a slow process. So I would not encourage anyone to emulate our speed in getting things processed.

We have made an effort in recent years working with the nuclear medicine community to try to, and we have a nuclear medicine council that comes in and one of their jobs is to tell us of new things that are coming about and we have our whole medical

licensing staff there and inspection and so forth and we basically ask them the questions before these new processes come online or we try to so that we've already asked all the questions that we were going to ask 50 different doctors or 50 different hospitals.

I think if you talk to some of the people, the medical community from California, they have found that very helpful to do that. That's the only part that I would really suggest that you emulate.

MR. CAMERON: Okay. Thank you, Ed. Let's go to make sure that we hear from the people on the phones and in the TV room. Jill, do we have anybody who wants to make a comment on this last conversation? Jill.

PARTICIPANT: She may have ended at 4:00 p.m.

MR. CAMERON: Okay. That's Jill for us. TV? Anybody in the room over there?

PARTICIPANT: Anyone have a comment? I don't think we have any comments.

MR. CAMERON: Thanks. And we figured that out. Thank you. Okay. Let's have three quick comments to finish this out. Sally, go ahead.

MS. SCHWARZ: Just have a question about decommissioning costs in California.

MR. BAILEY: They're among the most reasonable in the United States.

MR. CAMERON: Okay, Ed. Thank you, Ed. Could I have Derek and Rob? Rob's there. Derek is going to come up. I just want to three. Can you just make this quick, Roy, James and Lynne? Okay, Roy.

MR. BROWN: Yeah, real quick. I just wanted to respond to Chris's question because this gets into the game I suggested to play this morning but we're not going to have time for unfortunately. The way I understand it I'd like to get the State of California's opinion on this and then NRC's opinion. Take something specific that Chris mentioned like the rubidium-82 generator. It's an accelerator produced product. In California, it's licensed along with everything else that the State of California does. It doesn't handle a rubidium-82 generator any differently than technetium generator. So it would be seamless and in specific in the State of California.

In the case like Missouri, that's another great example where right now you can probably bring it into the State of Missouri fairly easily with nothing more than a registration on your State of Missouri form. So under the new scenario, I would think Missouri would be one of those that may likely

choose not to become an agreement state. The jurisdiction would fall back to NRC. So NRC may have to regulate NARM and old byproduct material in the State of Missouri. Is NRC prepared to do that and is that your assumption too?

MR. MOORE: Yes, and I think it's important for people who didn't understand that before is that if the states that are not agreement states now and we take over jurisdiction there and they don't want to become agreement states for this limited purpose, then the state is basically out of the business and the NRC is going to do it.

MR. CAMERON: James.

DR. CASE: Yeah, I think a real important question is how would the rules affect? I don't know much about California's approach an agreement state relative to Missouri which takes NRC's. Maybe you could inform us. I'm glad to hear that you're offer some of the most reasonable decommissioning rates of any -- My question is that it still doesn't seem as if and maybe you could give me a little bit of an idea that if the bureaucracy takes an enormous amount of time in California, they may have a well written or well reasoned regulation but as a practical matter becomes difficult to implement in a state like

California, in Missouri where potholes are a big deal, it seems like we're going to be considerably slower than we are. Maybe you could let us know or give us a little insight as to how your regulation would look if it were on a national scale.

MR. BAILEY: Okay. Now in Missouri, are there PET production facilities?

MS. SCHWARZ: Yes.

MR. BAILEY: Okay. One?

MS. SCHWARZ: There are several.

MR. BAILEY: Okay. The real problem I think in handling any pro view type facility is the first one is the most difficult one of all generally speaking and the more experience the people have both as an applicant and as a reviewer, the quicker it goes. I would think a state with a single PET facility probably if they're not an agreement already, they're not going to sign one of these agreements. I can't see any reason for them to. So it would come back then to NRC.

I don't know. Right now, things are continuing along under the waivers. As the rules come out, the states are going to have to look at it and decide is this industry, do they have enough interest in regulating it to put out the extra effort. Several

people have mentioned that the state's going to require to register. The NRC is going to license and then the state is going to be involved in the clean-up. To me that is the epitome of asking for delays is having two or possibly three different agencies looking at the permitting and decommissioning of the facility. So from my standpoint, I think I'd rather have one agency doing it regardless of whether it's NRC or the state agency.

MR. CAMERON: Okay. Thank you, Ed. Quickly Lynne and then Tom Essig and then we will go to Derek.

MS. FAIROBENT: Yes, I just have a slightly different question for both Roger and Chris based on something Chris said which is are you finding then that you're putting more PET cyclotrons into states that do not require financial assurance for decommissioning and is that therefore then skewing the access to patients for where PET is at currently?

MR. MORONEY: For me, Roger, no. It's driven strictly by the market, how many scanners in the area, is Eastern in there already. If I could sneak in here real quickly on the comment about licensing, sorry. We did recently license six months ago a rubidium generator in California and I was

amazed it was turned around in like four weeks and back out. They had a licensing guideline.

MR. CAMERON: Okay. Tom Essig.

MR. ESSIG: I just wanted to offer a comment on when we're talking about broad versus narrow perspective and what the Energy Policy Act was intended to capture. I can only offer from an earlier version of the statute when it was still a bill and had been introduced by various members of Congress that the word "discrete" was associated with both the radium-226 and the accelerator produced material. And somewhere along the way, the word "discrete" was removed from the accelerator produced material.

So I don't know if the thinking was that earlier on we would focus on the product more and being that, it's kind of a discrete source, something that could be removed and used for malevolent purposes versus if you take the word discrete away, then you possibly open it to a broader approach. It doesn't answer any questions.

MR. CAMERON: If there's a prior version of the bill where discrete was used with accelerators, how much would that affect the discussion that we're having right now?

MR. ESSIG: I was thinking it would focus

on the narrower approach.

MR. CAMERON: So it would focus it on the narrower approach. Okay. We have Derek Widmayer of the NMSS staff with us who's just going to quickly address waste disposal. We have Rob Lewis here. What I'd like to do is have Derek go and Rob go if we could and then open it up for questions or discussion. It might make it a little bit more efficient. Do you want Rob to come up? Come on up, Rob. Go ahead, Derek.

MR. WIDMAYER: Okay. I don't believe that there are copies of these handouts. Is that correct?

PARTICIPANT: That's right.

MR. WIDMAYER: Okay and there are only two slides of any significance. Last but not least, of course waste disposal. I'm used to being last on the agenda. My name is Derek Widmayer, Project Manager. I'm in the Decommissioning Directorate of the Division of Waste Management/Environmental Protection. That's also in NMSS. And I mistakenly put my phone number and my email address. I noticed that nobody else from the NRC had done that today. So quickly write it down before I change this slide.

I have two things that I want to cover, broad background on waste disposal topics and then a

discussion of the issues. The background is basically just discussing the provisions of the Energy Policy Act and that was what there were some questions earlier about that we tabled and now unfortunately those people are no longer on the phone.

There are provisions in the Energy Policy Act that specifically address waste disposal and the background material that was handed out provides additional explanation to these bullets. But essentially one of the provisions makes sure that the new definition of byproduct material, the things that are added in, are not to be considered low-level radioactive waste for the purposes of the Low-Level Radioactive Waste Policy Amendments Act and the intention of that is not to muddy the waters with respect to the definition of low-level waste but to just have no impact on the compacting process that that law establishes. That's the reason for the provision.

The second provision in the Act that affects waste disposal is it says that regardless of the fact that you're not calling it low-level radioactive waste it ought to be disposed of in an NRC-licensed facility which presumably means under Part 61.

Then the third provision that's very important is notwithstanding that second provision. It's that these new materials in byproduct material definition can be disposed of in facilities permitted under Federal and state hazardous and solid waste regulations which has the effect of hopefully not impacting the current solutions that are used for the disposal of these materials.

So I think that the person's issue that was on the phone before was I understand if it's not low-level waste where is it supposed to go and that initial provision that I talked about is simply to not affect the compacting process. Because of Part 61 actually does not use the definition of low-level radioactive waste, it does appear in other NRC regulations. But it doesn't actually appear in Part 61. So hopefully when we make all the necessary amendments to the rules it will not be too confusing anymore hopefully.

There were several waste disposal issues that had arisen in the working group already. The first one we've already touched on several times and I don't think it bears repeating. Depending on how the NRC decides to define accelerator produced radioactive material and where our regulatory

authority begins, I think we'll have an effect on waste disposal particularly in the areas that we were talking about before where the beam and/or cyclotron creates a lot of materials that are activated that to one person's definition has nothing to do with the actual materials that are being made radioactive for benevolent purposes. And another issue I'll speak about later will also talk about that.

Specifically the addition of radium-226 to the definition of byproduct material may in fact have a specific ramification on waste disposal. Back in 1986, the CRCPD asked NRC under this regulatory framework that you invented for low-level waste, what would you guys do with radium and NRC actually did answer that in a technical memorandum. NRC said they would add radium-226 to the tables that are in the Part 61 waste classification system specifically defining it the same way as they defined transuranic waste.

One thing I might point out with that is Part 61 of course was created and the rules are place based on an ancient radioactive methodology. So whether or not those numbers that were proposed back in 1986 make sense to add now I think is an issue. The other thing I have on this bullet is depending on

how NRC defines discrete sources and how that definition turns out is the possibility that there would be other sources that might need to have some sort of specific regulation. I don't know of anything off the top of my head but of course, uranium and thorium and some of the longer-lived radionuclides come to mind as far as whether anything needs to be addressed if there's a broad-brushed definition of discrete source.

Now I touched on this briefly. The table in Part 61 is where there would seemingly be an impact if we add radium. Now radium-226 is already addressed in waste acceptance criteria at the State of Washington's U.S. Ecology facility. That's another option that could be used is to incorporate their bases for disposal requirements and include that somehow in Part 61. It may or may not impact the table. As far as we've gotten so far, that radium-226 issue is really the only one that jumps out as far as an impact on regulations.

Now with respect to the provision in the law that allows that waste to be disposed of in a solid or hazardous waste disposal facility, we're still thinking about this of course but it's been suggested that perhaps a provision in Part 20 that

allows that to occur would be the way to go. There are already provisions in Part 20.2002 specifically that we could use but that generally requires individual applications and treatment of individual situations. So there might be a reason to do a blanket change to the regulation to allow these two specific types of byproduct material to go into these other facilities.

One reaction I've gotten to that already is that's none of your business. So you don't need to have that provision in your regulations. We'll have to see how that goes.

As we were having all the discussions today, I wrote down a couple other things that probably belong on this chart now, one of which I had already thought of that was the impact that our redefinition of byproduct material might have on CERCLA and CERCLA clean-up not that NRC necessarily would be able to do anything about it. But we do already have a memorandum of understanding with EPA as to how clean-ups that are done under NRC authority are handled and when we consult with EPA, there potentially is an impact on what materials NRC suddenly has jurisdiction over during a clean-up.

And specifically speaking of clean-up, we

talked already about the decommissioning funding. The primary reason for the decommissioning funding requirements in NRC regulations is because of the waste and you have to calculate how much waste you're think you're going to generate in the lifetime of your facility and make sure you have adequate funding to not only clean up your facility but to get rid of the stuff you have to get rid of.

So if we were to have a broad definition of the regulation for accelerator produced materials in bullet no. 1 it does suggest that NRC might be in the business of coming up with whatever decommissioning funding requirements would be necessary for an accelerator. That question might go to jurisdiction and that's literally out of my ballpark. But that question obviously is something that we need feedback on.

Your comment about large accelerators versus small accelerators, NRC does have a graded approach as far as decommissioning funding assurances and it would seem like it may just walk lock, stock and barrel with the way that that's already defined. Large accelerator would end up needing to do a whole decommissioning plan and come up with how much waste they're going to get. Others, smaller accelerators,

just have to have a certain amount regardless of the waste that they're going to generate and those numbers are not particularly high. That's my TF on waste disposal.

MR. CAMERON: Very good, Derek. That's very useful and let's get Rob on and then we'll go back for questions and, Derek, we might impose upon you since Rich Gianitti was not on the phone. Perhaps it might be useful to call Rich Gianitti of Pennsylvania to just tell him about what you were saying. This is Rob Lewis, Spent Fuel Project Office, NRC.

MR. LEWIS: Thanks. I am very interested to know if anybody sees any pitfalls at all in the transportation area for this legislation because our initial view of this is that there's essentially no impact on transportation resulting from expanding NRC's regulatory authority into NARM.

The reason is that the DOT transportation regulations on which our regulations are derived, if you will, don't have anything to do with the Atomic Energy Act authority and in fact, the Tables A-1, A-2 and the Transportation's Exempt table already have the nuclides listed in the DOT rule and in the NRC rule just because we wanted the table to be identical even

though we didn't have the authority. We don't want people to have to look at two different tables that are several pages long. So we put them in our rule anyway last year. I mean they've always been in there but we updated it last year.

And I think I'll leave it at that. I think there's no impact. There's maybe some minimal impact that's really only if in the rare case, there was a Type B quantity. Part 71 would be directly applicable to you now versus applicable by reference to the DOT requirement that you use a Type B package and let's something for theoreticians but in practice, it's the same requirement anyway.

MR. CAMERON: Okay. Great. Thank you, Rob. Let's go to James.

DR. CASE: Okay. I don't know. Just to say this, you put up there regulate medical under Part 35. That stuff you put up there, I hope you're not making the assumption that those things are stipulated.

MR. LEWIS: No.

DR. CASE: I just want to make sure we get to that because opening up the kettle of worms of Part 35 it took many years to resolve and doesn't cover really what was the mandate here. I don't want that

sort of thing to be stipulated.

Now getting to the question of transportation-related things, we spoke very early on about where does NRC's authority get picked up and where does it get dropped off in the whole process. Is it out of the cyclotron and into the syringe and somehow when it's being transported it's under somebody else. Could someone try to walk me through that model? If what I want to do is extract some material from the cyclotron and now I put it into a car and I drive it across town and now it's in somebody else's facility and they're going to compound it with some new F-18 flow agent, some kind of shake and bake, like tetraphosmin and now inject it, where do you see NRC's authority coming into play, out of play, maybe back into play again in that whole delivery scheme?

PARTICIPANT: It's the same way.

DR. CASE: But then do you have overlapping authorities is my question.

PARTICIPANT: (Off microphone.)

MR. CAMERON: Let's get Rob back.

MR. LEWIS: It's has always been subject to DOT. It would continue to be subject to DOT and agreement statement regulations. There's an exemption

for physicians transporting their own material that applies for the NRC requirements that may be applicable in that case. But I guess the DOT requirements as long as it's in furtherance of a commercial enterprise the HAZMAT regulations for DOT would apply to it.

DR. CASE: But it would also now have NRC as well in a nonagreement statement like Missouri. Is that right?

MR. MOORE: There's only one point in that process where NRC itself doesn't have jurisdiction over part of the process and that's the transportation end of it itself and the Department of Transportation actually regulates the transport of the material and Rob could explain this better. But the transport itself comes under DOT regs. So the transport from one point, from point A to point B, is regulated under the DOT regs but the material itself comes under NRC's jurisdiction in the hypothetical case that you laid out. Rob.

MR. LEWIS: That's right. That's the way I understand it.

MR. CAMERON: Let's go to Barbara.

MS. HAMRICK: I'm just going to clarify on that point and this varies from state to state because

our California Highway Patrol has authority to enforce the Department of Transportation regulations. So that framework already exists.

MR. CAMERON: That's a delegation.

MR. MOORE: And actually we do too. We have an MOU with the Department of Transportation to cite against DOT regulations. So we can enforce against DOT regulations but the authority is with DOT.

MR. CAMERON: Lee, do you want to talk to this point before we move?

MR. COX: Sure. North Carolina has the same thing. We incorporate their regs and our regs by reference and we have reinforced the DOT.

MR. CAMERON: Okay. Ralph and then Lynne.

MR. LIETO: Well, I was just going to say to answer Rob's inquiry I don't see any effect in terms of transportation on medical users. The one point that I wanted to just make to Derek is that in reading the Energy Act there is a lot of confusion out there with that reference that it's not low-level radioactive waste. It's very confusing to those trying to read it and not understand the nuances of what this is, the intent of that reference is. Because just taking it at face value, it's like this doesn't make any sense.

So I think as NRC goes along, I think you really need to explain that reference and that the Act actually, it appears to me in the addition bullets that you had, actually provides for some additional mechanisms to dispose of NARM that would be available to users. Again, I think that's a positive aspect that needs to be better communicated to the community.

MR. CAMERON: And Barbara, quickly.

MS. HAMRICK: Yes, I was part of a group that we also drafted proposed legislation on this issue with the HPS and Scott might be able to speak to this better. But the specific intent of that is just as he stated that people were already disposing of radium not under the LLRW scheme. So for example, California could take its radium to Washington and dispose. Whereas under the compact system we could not. In fact, in some states, permittee or licensee can dispose in RCRA facilities already radium materials and so the intent of the HPS in asking to keep that in was to not eliminate any avenues that already existed for disposal.

MR. CAMERON: Okay.

MR. BAILEY: And OAS.

MS. HAMRICK: And OAS, that's correct.

MR. CAMERON: All right. Lynne.

MS. FAIROBENT: Derek, I just have a slight different question and it's been so long since I've focused on levels of activity in waste definitions.

MR. WIDMAYER: That's an advantage to you.

MS. FAIROBENT: We'll trade afterwards. Do you foresee any discrete radium sources that may fall into the category of greater-than-Class-C and that would not in fact fall under Part 61?

MR. WIDMAYER: I believe that there are such a thing, yes.

MS. FAIROBENT: That's what I thought.

MR. CAMERON: Okay. I want to try to get us to wrap up with some process issues here and I listed some of them that were raised earlier but I think it's very important. James brought this up. This were some points that Scott had picked up based on what Barbara had said earlier in terms of what we need to do in terms of this regulatory regime.

It's not what NRC is proposing right now. It's more of a strawman for discussion and I'm not even sure what this particular point was. I would ask Scott if he wanted to revisit this and get any reactions from people around the table. Define discrete. Change definition of byproduct material.

Add accelerator produced and radium to Part 20 tables and regulate medical under Part 35. Do you want to say anything about this?

MR. MOORE: Sure. In terms of formulating the rule, this would be the least invasive approach to coming up with a rulemaking and as far as the last bullet, regulate medical under Part 35, we could go into Part 35 as necessary but in a limited number of places pick up in Part 35 PET and any other uses of accelerator produced but make no other changes to Part 35.

We have an existing regulatory structure for medical under Part 35. It seems to be working to the extent that's possible with the community and I think we would propose one option which is to include PET and other accelerator produced material in that structure to the extent possible.

MS. HAMRICK: And in 33 states now that's the way that material is regulated already.

MR. CAMERON: Okay. James.

DR. CASE: Yeah, but Part 35 took six, seven years to actually get through the rulemaking process and Congress gave you 18 months to get through this particular process. I think though you may want to use a surgeon's approach to adjusting that. But

what Roy was saying seemed to be a much more broad discussion of training and regulations and I think it's opening up that whole kettle of fish that potentially if you open up 35 which I think is beyond the scope of your statutory authority again, really it's more appropriate to stay in 20 than to start going over into 35. I think that's probably how I would say.

If you want to try and get through it, it's not going to be physically sitting down and scrawling out a regulation that's going to make this a slow process. What's going to make this a slow process is if you have a rule which the ink is still wet in 35 but now you're going to go back to the states and say, "Hey, guess what? We've just fiddled around with it again" and all of the societies are going to be worrying about that as well and all the societies and their training regulations. I think then you're going to open up a Pandora's box which definitely you're not going to do in 18 months.

MR. MOORE: Can I be specific about what I meant under regulate medical under Part 35?

MR. CAMERON: Yes.

MR. MOORE: I didn't mean add new parts to Part 35. I meant under the existing parts in Part 35,

100, 200, essentially regulate the accelerator produced under 100, 200 and any other existing parts, not add new portions to Part 35.

MR. CAMERON: Okay. And I just want to make sure that we hear from Gloria Romanelli but keep in mind that we did hear two proposals that would have been far-reaching today. One was Roy's let's try to eliminate these, I'm calling them, dysfunctionalities. And we also heard a suggestion from Ralph to be creative, think out of the box. We heard another perspective on that from James which is to be very surgical to use his term. This is Gloria Romanelli. Gloria, please tell us what your concerns are here.

MS. ROMANELLI: Gloria Romanelli with the ACR. The only comment I wanted to make has to do with process. My concern is it's 45 minutes past the posted time on the notice. The people who were on the conference call have been cut off. ACR's representative is no longer at the table. SNM's representative is no longer at the table. HPS representative's is no longer at the table. What I would like to do is have NRC post these questions and give the societies an opportunity to provide a written response if this is being seen as the medical community's input into this process. I understand

there will be other processes during the rulemaking but I feel like a lot of people aren't going to have an opportunity to bring their views to the table because we are past the posted cut-off time of this meeting.

MR. CAMERON: And that's true and I think that this was one opportunity. But there is a written comment period that runs with this where people will have an opportunity to look at the transcript.

MR. MOORE: I guess I can address the opportunities for input. This was one opportunity and we built it in actually under a very tight schedule to receive input. There's also an opportunity when the proposed rule goes out and we built in an opportunity if the Commission agrees when the rule is with the Commission to post it on the web. It remains to be seen whether the Commission agrees with that.

You make a good point that we're past the point when the meeting was set to end. I think we can probably accommodate written comments until the end of next week. So if anybody in the room would like to provide written comments we can receive them until the end of next week and we could accommodate those in our rule development process. But beyond the end of next week, I can't tell you that we could accommodate them

within the time schedule.

MS. HAMRICK: Who should those be sent to?

MR. MOORE: Those should be sent to Leslie.

MR. DELLIGATTI: This is Mark Delligatti. Those should be sent to Leslie Kerr.

MR. CAMERON: All right.

MR. MOORE: It's in the Federal Register that announced the meeting.

MR. CAMERON: We have a few more cards around the table. Lynne, you had yours.

MS. FAIROBENT: Yes. Scott, just on your strawman for consideration and if you follow Gloria's suggestion perhaps of posting some questions on the Medical users tool kit by the end of this week, then people can respond. I would not overlook the fact that regardless of what may be done in Part 35 there are considerations that we have to look at in Part 30 and Part 32 as well.

MR. MOORE: That's a good point and one thing we've been thinking of is there are couple things we didn't touch on in this meeting. One is security issues and another is industrial issues. Certainly, there are issues like cobalt-57. There are industrial devices out there and the rule will have to

pick up those issues as well.

MS. FAIROBENT: Yes, and my concern is in Part 32 where you regulate the suppliers for the pharmaceuticals.

MR. MOORE: That's correct.

MS. FAIROBENT: I just don't want to lose sight that from a user's standpoint Part 35 is where the regulations will primarily, I think, be adjusted to include a broader definition of byproduct. But I don't want to lose sight that there are other parts in the Part 30 chain that also need to be looked at and modified consistent with whatever the decisions are down the pike.

MR. MOORE: Great point.

MR. CAMERON: Okay. And Ralph and Felix.

MR. LIETO: A couple of points and questions. I wanted to assure Dr. Case that the ACMUI has no intention of looking at training experience in the future. So that rest assured, that we don't want to make changes there although it will stay in Part 35.

One of the points though is that I think there are going to have to be made, a lot of specific changes will have to be made in Part 35 to incorporate some of the NARM aspects for the nonagreement states.

One thing just shooting from the hip here has to do with cobalt-57 sources which are relatively large radioactive sources if you will and there are multiple numbers of those used for QC purposes in nuclear medicine. So there may be a need of some aspect of Part 35 needing to be adjusted to make that more flexible for nonagreement states.

One question I had also to the conscientious subject about when would the transcript be available for this. Do you have a time frame for that? I'm just wondering with this short -- I'm just thinking that people might want to take a look at that to see where they might need to make comments on it and that was just a thought.

MR. MOORE: The transcript itself I think we can get it up on the web probably next week. I think we get it back within three to five days and then we can get it up on the web within a couple days after that.

MR. CAMERON: I'm looking at Lindsey and our contract, our delivery on this is three days. Okay. Good. So we can get that up on the web so that if people wanted to look at that and make additional comments for the period of time for anything but especially the period of time when their

representative had to leave they could do that.

MR. MOORE: And then next week we would need comments by in writing.

MR. CAMERON: All right. Good. Mark, I'm sorry.

MR. DELLIGATTI: Mark Delligatti. I appreciate your interest in seeing the transcript but please if there's anything you think you may have even talked about fully today send it to us in writing if you have any concern because the clock is ticking and Congress doesn't allow us to stop the clock. So please if you have anything that you want to get to us, if you thought of specific parts of the regs for instance that you think we need to look at to change, get that information to us because whether it's in the transcript or we get it from you separately, we can only use it if we get it by the end of next week.

MR. CAMERON: All right. Felix.

MR. KILLAR: Actually, Lynne picked up a couple points I thought I wanted to mention. You need to look at Parts 30 and 32 as well. But I also think you need to look at Part 40 as well because it's the base for source material. So you need to go beyond the 30 parts but you need to look at 40 as well and no one has mentioned Part 40.

MR. CAMERON: Thanks, Felix. Scott.

MR. KIRK: Thank you. Scott Kirk. Ruth McBurney left but she asked for me to make a statement for the Health Physics Society and as Barbara has mentioned, the Health Physics Society and the Organizations of Agreement States did draft some model legislation on this issue as well that we had submitted to Congress. One of the key things that we didn't mention which Barbara noted was is that we thought that waste disposal options, what we looked at was opening the doors and one of the key things that's missing here is what we had proposed is an equivalency statement for 11(e)2 to allow these new materials, 11(e)3 and 4 materials so that it would open up the use of uranium mill tailing sites for disposal of radium. That's also consistent with the suggested state regulations under Part N. So we think there's a very good nexus here to take another look at disposals of some of these radium maybe at the mill tailing sites.

One of the things that was missing in the presentation was there's another option for disposal and that was at any site as you had mentioned, Derek, that NRC had licensed but it also says for any facility that's safe. So we think that further opens

up the door. But because there wasn't that equivalency statement that we had proposed, the issue that's still on the table is that DOE hasn't yet agreed to take title to those sites at the end of the life of those facilities.

So what we would really encourage is for NRC to begin some deliberations with DOE and maybe begin some development of a memorandum of understanding to develop some generic waste acceptance criteria specifically for the radium but maybe other radionuclides that would go hand-in-hand with the suggested Part N regulations because we think if that MOU is signed and agreed to by DOE and NRC then it will also address that issue. That's my comment.

MR. MOORE: Scott. As I understand it though and you and I talked during one of the breaks, you don't envision that any regulatory change is needed for that. Right? You envision that as an implementation issue that only an agreement between NRC and DOE would be needed.

MR. KIRK: Correct. And there's currently some deliberations right now. I think the National Mining Association and the Fuel Cycles Facility Forum, they submitted a white paper to move this forward as well and there's also an NRC policy that talks about

disposals of non-11(e)2 materials. So there's already a box to carry this on but again we just wanted to make the point that we think now is the time for NRC to actually begin maybe development of an MOU with DOE to move this further along and again that would be an implementation issue.

MR. CAMERON: Great. And thanks for backing up on Health Physics. Anybody else? Okay. This is the EPA.

MR. SETLOW: I'll try and keep this brief. I hadn't expected to be talking about this. Loren Setlow with Radiation Protection Division of EPA. In regards to the last set of comments, the use of radium mill tailing impoundments, EPA had established the standards for materials to be disposed in these facilities and they were subsequently adopted by NRC and then certainly DOE for their acceptance ultimately as the final repositor and licensee for these facilities.

One of the problems about using these facilities for additional disposal of radium is that because of the high amounts of radon it may result in if there is too much of this material the premature closure of a number of the facilities because they may wind up exceeding the radon standards that have

already been promulgated of 40 CFR 192 and then subsequently in the NRC standards.

So this is a very important issue and in addition to that, the Generic Environment Impact Statement which was developed by the NRC for the uranium mill tailing impoundments and their regulation did not include in their premise the acceptance of materials such as these. So we had provided letters to NRC previously in response to National Mining Association proposals to expand the use of these facilities for decommissioning materials and other low-level waste and so on. To say that if in fact this was the ultimate intention of NRC to expand these uses, then we believe that this would also require an additional evaluation under NEPA because of a change in the original intent for use of these facilities that had undergone a larger public review and a larger impact statement. So we've been on record on that previously.

MR. CAMERON: Okay. And I just need to ask Scott and Derek whether there's something that needs to be clarified here. In Scott's comments, it seemed like he was referring to a broader set of disposal options than those that you presented, Derek, that are in the Act and I don't know if that's true or

not. But do we need to go back? Do you need to clarify anything about what is actually permitted under the Act?

MR. MOORE: As I understand it, what Scott has suggested is that the Act gives some broader disposal options as Scott reads the Act and those could be put in place as Scott sees it through an agreement between NRC and DOE. But it doesn't require regulatory change. So I've encouraged Scott to talk to the Division of Waste Management Environmental Protection.

MR. CAMERON: Okay. That's great.

MR. MOORE: But as far as what we need to do in the rule space and development of the rule, it doesn't require us to make any regulatory changes and I don't know what DOE's position on it is and frankly, I'm not sure what NRC's position is on that within the Act itself either.

MR. CAMERON: Okay. Final comment on this from Ed and I just want to review some of your process suggestions. Ed.

MR. BAILEY: The statement about adding other material, if I'm not mistaken the impoundments are designed and evaluated with a certain source term. So whether that source term comes in as dirt from a

rare earth processing facility or uranium mill, as long as the source term is not exceeded, there shouldn't be a problem.

Now some of the other things, and I would suggest that if you looked at the oil and gas industry thing, all the studies I have seen indicate in fact that the radium is bound up tighter in those than it is in any of the mill tailings and so is the radon. So there shouldn't be a real problem. That's just a comment on why I don't think you have to go back through the whole process. But maybe you do.

MR. CAMERON: Okay. There were a number of process points made today. One was the transition issue but I think Mary raised that right off the bat. And as part of that transition, I know that Sally and others were concerned about what are the implications for nonagreement states.

We heard that people would like to have earlier access to draft rule language somehow. Leslie pointed out that while the Commission is reviewing this it is going to be on the web so that people can get prepared for it for commenting if the Commission agrees to it.

We heard that the comment period should be 60 to 90 days. We're presently contemplating a 45-day

comment period.

And Roy Brown and others brought up the collaborative process in terms of identifying and working with differences in state regulations. Scott, I know that you have some concerns about how much we can do along those lines because of Scheduler and perhaps Federal Advisory Committee Act concerns. But again, all comments on this. I know we are over time. Do we want to stop now or do you want to see if there's any final comments on any of these process issues?

MR. MOORE: I think that's up to the attendees. I have some specific information about how to get information into us, but I think that's up to you.

MR. CAMERON: Well, let's hear from Maria and then why don't we turn it over to you.

DR. KELLY: I just was taken by the number of people who said that a lot of these definitions are used in a number of different agencies and I would just want to say that I think that should be part of the transition is having all the agencies using the same language and definitions so you're not held to regulations that are interpreted differently by different regs.

MR. CAMERON: Okay. Thanks, Maria. Anybody else? I think we're ready to wrap up. Go ahead, Mary.

DR. MOORE: Just as an overview comment, with the objective in mind. and I understand you are requesting guidance and concerns, I keep coming back to the kiss principle that the simpler it is the cleaner it is, the greater the probability of quality, enhanced safety, lower cost and improved efficiency so there are no delays keeps coming to the forefront.

I think and I may be speaking heresy here but I think the limitations that the Act has put on this operation is one of the things that is the biggest roadblock to having streamlined easy to enhance compliance. But you have to play the cards you were dealt and I understand that and in trying to work within that tight frame as long as the overview of everybody and I'm sure it is by all the heads that are bobbing that everybody is trying to get to the same goal. I applaud you for that and I just ask you to continue your efforts in that regard. Thanks.

MR. CAMERON: And, Scott, do you want to close us out. I just would thank everybody for their comments and for following the groundrules. I'll turn it over to Scott for any final comments.

MR. MOORE: Sure. I'd ask first that if you do have any written comments you submit them in writing by the end of next week and that you also call Leslie and inform her that you've submitted written comments and that you also email the written comments to her at this address so that we have them immediately. There is Leslie's telephone number and her email address.

I'd like to remind everybody about the meeting feedback forms if you could submit them if you wish as well.

I guess the final comments that I'd add are the task before us in the rulemaking group is a monumental one. We essentially have about seven to eight weeks to write a proposed rule. With your input at the end of next week, we'll have six and a half to seven weeks to write the proposed rule and get it out to the agreement states by January 3rd.

We're actually getting it out to the agreement states after the Christmas holidays so that they won't be getting it during the Christmas holiday season and then they have to turn it around very fast as well. They're only getting the set limit of 30 days which makes it very tight for them.

So it's a very daunting task for us and

them. Our staffs are going to have to work very hard to do it. But we're working to the legislative mandate which is not negotiable. Congress gave us that date and we've worked a schedule that will work to it and we will meet it. We're trying to build opportunities within that schedule for dialogue with the key stakeholders such as we've had today.

I think what we've heard today has been very helpful to us. It's given us a lot of input. We have to figure out how to incorporate that into the proposed rule itself and we'll look at what you all submit to us over the next week and a half to feed it into the rule. We have a working group working on the rule. We have a steering group that will advise us as well. And we'll get input from the states and other, the ACMUI, along the way. So we really appreciate the input we've received. Thanks.

MR. CAMERON: And we thank our ACRS/ACNW help over there. He did a great job and thank you to Lindsey also. Did someone leave their glasses? I thought maybe Dr. Dillehay had left his glasses. Anyway, thanks for coming all this way and talking. Off the record.

(Whereupon, at 5:09 p.m., the above-entitled matter was concluded.)