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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

1 PARTICIPANTS: (CONT.)

2 GARY L. DILLEHAY

3 LYNNE A. FAIROBENT

4 RICH FEJKA

5 BONNIE GITLIN

6 BARBARA HAMRICK

7 MARIA D. KELLY

8 LESLIE KERR

9 FELIX KILLAR

10 RALPH P. LIETO

11 RUTH MCBURNEY

12 GEORGE MILLS

13 MARY E. MOORE

14 SCOTT MOORE

15 ROGER MORONEY

16 ALAN B. PACKARD

17

18

19 ALSO PRESENT:

20 DOUG BROADDUS

21 CHARLES MILLER

22 THOMAS CARDWELL

23 MARK DELLIGATTI

24 SALLY SCHWARZ

25 CINDY FLANNERY

1 JENNY TOBIN

2

3 ALSO PRESENT: (CONT.)

4 RICH GIANATTI

5 JUDITH JOHNSRUD

6 JOE DeCicco

7 THOMAS ESSIG

8 RICHARD BLANTON

9 LYDIA CHANG

10 DEREK WIDMAYER

11 ROB LEWIS

12 SCOTT LEWIS

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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

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

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

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

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

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

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

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

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

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

1 you very much.

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

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

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

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

9 MR. CAMERON: Thank you, Ed. Felix.

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

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

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

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

5 MR. CAMERON: Thanks, Roy.

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

11 MR. CAMERON: Thank you, James.

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

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

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

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

5 MR. CAMERON: Thank you, Mary.

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

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

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

21 MR. CAMERON: Thank you, Bonnie.

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

1
2 DR. KELLY: I'm Maria Kelly. I'm a
3 Radiation Oncologist at the University of Virginia,
4 and I'm Government Relations Chair for American
5 Society of Therapeutic Radiology in Oncology. And
6 like the other physicians here, I'm representing the
7 interest of patients and diagnosis and treatment, and
8 how these rules will affect them.

9 MR. CAMERON: Thanks, Maria.

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

14 MR. CAMERON: Thanks, Rich.

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

25 MR. CAMERON: Thank you, George.

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

11 MR. CAMERON: Roger.

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

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

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

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

7
8 MR. MOORE: I'm Scott Moore. I'm the Chief
9 of the Rulemaking Guidance Branch in the Division of
10 Industrial Medical Nuclear Safety, and my branch has
11 the responsibility to write the rule.

12 MR. CAMERON: Okay. Great. And Charlie.

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

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

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

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

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

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

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

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

16 MS. KERR: Yes, there are.

17 MR. CAMERON: All right.

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

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

22
23 MR. CARDWELL: Thomas Cardwell with the
24 Texas Department of State Health Services.

25 MR. CAMERON: Okay. Thanks.

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

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

6 SPEAKER: Correct.

7 MR. CAMERON: Okay.

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

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

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

17 MR. CAMERON: Okay. Lydia.

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

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

22 MS. CHANG: Lydia Chang.

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

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

1 actually here representing ACMUI and the Nuclear
2 Pharmacy Section.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9 The amended byproduct material definition
10 is applicable to materials produced, extracted, or
11 converted after extraction before, on, or after August
12 8th, 2005. Now that's a long-winded way of saying
13 pretty much any time it was produced, then it comes
14 under NRC jurisdiction. The materials have to be used
15 according to the legislation in commercial, medical,
16 or research activities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 The expertise provided by the state

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 Basically, right now we are proposing a
15 45-day comment period. However, we intend to have
16 posted the proposed rule text on the NRC website
17 concurrently with it going to the Commission as of
18 March 10th, 2006, which would give a full 75 days, so
19 that it will be in the public domain.

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

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

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

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

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

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

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

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

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

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

14 MR. CAMERON: Okay. Good question.

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

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

25 MR. CAMERON: Okay. Lots of coordination

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

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

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

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

20 MR. BROWN: That's fine.

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

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

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

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

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

18 MR. CAMERON: Okay.

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

23 MR. CAMERON: Dr. Case.

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

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

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

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

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

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

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

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

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

9 One program that the CRCPD has used in the
10 past or has explored is the licensing state, and they
11 developed this about 15-20 years ago, and the original
12 intent was to offer resources to the states for NARM
13 material, but the concept didn't receive funding, and
14 17 states went through the process to become licensing
15 states. And the program kind of tinkered out, we
16 shall say.

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

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

15 I don't know to the extent that states
16 actually use these or enforce them, so they are out
17 there as guidance, but it would be very helpful for us
18 to know if they're used and if they're successful in
19 their use. And so another method that we've been
20 using to get input, we have Martha Dibblee who's on
21 the Task Force, and Lee Cox are getting on the phone
22 with the representatives from each of the states, all
23 50 of them, and asking them if they have programs for
24 regulating NARM. And they have a specific list of
25 questions, and they're constructing a big matrix for

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 MR. CAMERON: Okay.

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

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

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

10 MR. CAMERON: Okay.

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

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

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

7 MS. HAMRICK: No.

8 MR. MOORE: Okay.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 talking about.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 SPEAKER: A and B are both --

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

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

1 and talk about the implications for
2 radiopharmaceutical availability. Roger.

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

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

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

4 MR. MORONEY: Yes, very much so.

5 MR. CAMERON: Okay.

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

8 MR. CAMERON: Go ahead, Ed.

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

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

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

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

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

1 MS. TOBIN: Can I respond?

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

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

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

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

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

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

7 MR. LIETO: Non-agreement.

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

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

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

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

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

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

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

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

9
10 MS. HAMRICK: Just quickly, I think that
11 is addressed, or is supposed to be addressed through
12 the transition plan that the Task Force is going to be
13 developing. That transition plan is being developed
14 in order to move non-agreement into either agreement
15 status, or for the NRC to start regulating. That's
16 what that transition plan is for. That's not
17 developed yet.

18 MR. CAMERON: Is that correct?

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

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

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

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

25 MR. CAMERON: Okay. Thank you. And,

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

3 JILL: Yes, Mr. Cameron.

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

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

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

15 JILL: That is fine.

16 MR. CAMERON: Okay. Thank you, Jill.

17 JILL: You're welcome.

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

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

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

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

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

11 MS. KERR: Yes.

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

15 (Whereupon, the proceedings went off the
16 record at 10:52 a.m. and went back on the record at
17 11:23 a.m.)

18 MR. CAMERON: Okay. Here's Leslie.

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

25 I just want to go over a couple of things

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

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

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

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

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

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

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

19 And here we go, Cindy. Cindy Flannery.

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

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

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

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

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

22 MR. CAMERON: Okay. Thank you, Cindy.

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

1 open up the discussion.

2 Roy.

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

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

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

20 (Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 (Laughter.)

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

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

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

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

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

13 MR. CAMERON: Okay.

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

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

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

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

1 problems of dealing with those dysfunctionalities?

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

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

13 MR. MORONEY: Thank you.

14 Roger Moroney with PET Pharmaceuticals.

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

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

25 Many of those regs, I think, were written

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

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

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

13 (Laughter.)

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

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

25 But keep in mind the assumption that we're

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

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

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

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

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

1 radioactivity.

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

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

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

15 Third, include a mechanism to resolve
16 problems post implementation.

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

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

1 guidance for PET.

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

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

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

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

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

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

3 DR. MILLS: All right. Thank you.

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

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

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

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

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

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

14 MR. CAMERON: Okay. Thank you, George.

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

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

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1 MR. CAMERON: Okay. Thank you, Rich.

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

4 MS. GITLIN: Go for it.

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

7 (Laughter.)

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

9 MR. CAMERON: Okay. Go ahead, Ed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 MR. CAMERON: Okay. Thank you, James.

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

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

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

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

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

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

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

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

24 (Laughter.)

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

1 little bit more about some of these conceptual issues?

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

9 Is that acceptable to everybody?

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

14 Mary.

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

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

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

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

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

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

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

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

17 (Laughter.)

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

25 So I'd like to take some of these products

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

5 I think that would be very important.

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

11 Later under other issues or --

12 PARTICIPANT: Yes.

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

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

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

25 If it's going to work operationally in my

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

5 MR. CAMERON: Okay.

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

11 MR. CAMERON: Okay. Thanks, Mary.

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

17 (Laughter.)

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

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

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

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

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

17 Ralph.

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

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

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

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

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

25 And if we could just instead of using as

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

8 MR. CAMERON: Okay. Thanks, Ralph.

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

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

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

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

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

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

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

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

25 MR. CAMERON: Okay. Thank you.

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

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

5 MR. CAMERON: Can you just -- FEG?

6 (Laughter.)

7 MR. CAMERON: NDA.

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

15 MR. CAMERON: Okay. All right.

16 PARTICIPANT: That's not my position.

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

1 MR. CAMERON: Okay. Thank you.

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

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

7 PARTICIPANT: That's very helpful.

8 MR. CAMERON: Okay, good.

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

11 PARTICIPANT: No.

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

14 DR. PACKARD: Thank you, Chip.

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

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

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

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

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

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

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

20 (Laughter.)

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

24 Yes, Sally. Go ahead.

25 MS. SCHWARZ: This follows along with what

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

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

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

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

1 current regulation when you're revising it.

2 MR. CAMERON: Okay. Thank you, Sally.

3 Ed and James, do you have a response?

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

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

11 MR. CAMERON: Okay. Thank you.

12 James?

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

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

1 (Laughter.)

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

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

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

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

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

7 Anybody else in the audience?

8 (No response.)

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

11 OPERATOR: Yes, I am, Mr. Cameron.

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

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

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

21 (No response.)

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

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

25 MR. CAMERON: Oh, you do? Great.

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

3 MR. GIANATTI: Yes. Thank you very much.

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

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

10 MS. KERR: What question are you referring
11 to?

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

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

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

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

23 (Laughter.)

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

1 try to give you a better idea of that.

2 MR. GIANATTI: That will be good.

3 MR. CAMERON: And Rich is from
4 Pennsylvania.

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

8 MR. CAMERON: Okay, right.

9 MR. GIANATTI: Thank you very much.

10 MR. CAMERON: All right, Rich.

11 Now, our next one, Jill.

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

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

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

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

5 DR. JOHNSRUD: Among other things you
6 said.

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

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

13 Scott.

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

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

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

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

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

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

14 Does that answer your question, Dr.
15 Johnsrud?

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

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

22 DR. JOHNSRUD: Thank you. That can help.

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

25 DR. JOHNSRUD: Thanks.

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

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

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

13 And, Jill, do we have anybody else?

14 OPERATOR: Not at this time, Mr. Cameron.

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

17 Anybody in the TV room has a comment or
18 question?

19 OPERATOR: I'm looking.

20 Anyone?

21 It doesn't look like it.

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

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

1 lunch, give them a little over an hour?

2 PARTICIPANT: Yeah.

3 MR. CAMERON: Is that okay? Okay.

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

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

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

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

20 MR. GIANATTI: Okay. That would be good.

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

23 MR. MOORE: Yes.

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

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

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

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

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

16 (Laughter.)

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

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

25 MS. KERR: Yes. The memo that we talked

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

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

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

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

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

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

25 (Laughter.)

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

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

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

9 MR. CAMERON: FSG?

10 PARTICIPANT: D as in dog, FDG.

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

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

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

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

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

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

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

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

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

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

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

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

9 DR. MILLS: FDG, fluorine deoxyglucose.

10 MR. CAMERON: Okay.

11 (Laughter.)

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

14 DR. MILLS: Fluorine-18 deoxyglucose.

15 MR. CAMERON: Florian 18.

16 DR. MILLS: Fluorine.

17 MR. CAMERON: I give up.

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

20 (Laughter.)

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

24 MR. CAMERON: Okay.

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

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

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

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

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

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

14 DR. MILLS: Right.

15 MR. CAMERON: All right. And Rich?

16 PARTICIPANT: It's RDRC, not B.

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

18 PARTICIPANT: USP?

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

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

3 MR. CAMERON: Okay. Good.

4 MR. BAILEY: Did you mention the device?

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

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

9 DR. MILLS: Exactly, some --

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

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

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

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

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

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

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

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

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

1 Material Safety and Safeguards.

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

4 MR. ESSIG: Yes, I did.

5 MR. CAMERON: Okay. Let's --

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

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

10 MR. DeCicco: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

13 For instance, it says first there are
14 discrete sources that are of higher concentration,
15 higher radioactive concentration, such as radium
16 needles used in medical practices and
17 radium-contaminated drinking water cleanup resins that
18 have radioactivity characteristics similar to those of
19 byproduct low-level waste. But, remember, this is
20 1988.

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

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

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

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

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

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

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

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

17 Let's go to Tom.

18 MR. ESSIG: Okay.

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

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

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

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

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

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

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

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

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

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

25 And I was thinking that what it is

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

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

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

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

1 think it's not a discrete source.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 example, pipe sludge.

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

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

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

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

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

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

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

7 MR. S. MOORE: That's correct.

8 DR. KELLY: -- still do.

9 MR. S. MOORE: That's correct.

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

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

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

1 materials are under our jurisdiction.

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

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

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

19 DR. KELLY: Yes.

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

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

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

5 (Laughter.)

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

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

17 MR. CAMERON: In thinking about the --

18 DR. M. MOORE: Who regulates that?

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

21 (Laughter.)

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

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

1 regulated.

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

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

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

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

25 That's not really in my opinion going to

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

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

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

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

18 MR. CAMERON: And, as Doug pointed out,
19 there would still be jurisdiction, even after the
20 boundary was violated in some ways. Is that what you
21 --

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

1 once it meets a certain condition, it then stays under
2 that condition --

3 MR. CAMERON: Stays. Okay.

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

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

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

14 MR. CAMERON: Okay.

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

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

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

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

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

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

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

15 MR. CAMERON: Okay. Ruth?

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

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

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

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

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

19 MS. MCBURNEY: Yes, it is.

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

22 MS. MCBURNEY: The concentration would be
23 -- yes, it would be a concentrated material.

24 MR. CAMERON: So concentrated material?

25 MS. MCBURNEY: But there would also be

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

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

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

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

17 MS. MCBURNEY: Yes.

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

21 MS. MCBURNEY: Medical.

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

24 MS. MCBURNEY: It goes into the definition
25 of a discrete -- I mean --

1 MR. CAMERON: Okay. Let's --

2 MS. MCBURNEY: -- it's a consideration.

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

4 Joe?

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

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

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

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

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

1 MR. S. MOORE: Yes.

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

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

8 (Laughter.)

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

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

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

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

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

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

7 (Laughter.)

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

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

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

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

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

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

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

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

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

25 So to the extent that you can be as clear

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

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

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

25 Also, we have talked during the break

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

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

11 MR. CAMERON: Okay. Thanks, Bonnie.

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

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

24 Bonnie, go ahead in terms of the --

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

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

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

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

10 MR. CAMERON: Okay.

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

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

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

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

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

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

15 (Laughter.)

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

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

1 be activated but just as a part of it.

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

4 DR. CASE: Did I say a dirty word?

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

8 MS. MCBURNEY: To set an example.

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

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

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

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

22 PARTICIPANT: That's an NRC license.

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

25 MR. S. MOORE: One model is we would

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

6 MS. MCBURNEY: What about radium? Would
7 you --

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

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

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

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

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

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

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

8 (Laughter.)

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

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

15 MR. KILLAR: Right.

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

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

20 MR. CAMERON: Okay. Go ahead, Scott.

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

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

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

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

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

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

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

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

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

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

20 MR. CAMERON: Does the dials issue go to
21 --

22 MR. BAILEY: Discrete.

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

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

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

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

9 MR. CAMERON: Doug Broaddus.

10 MR. BROADDUS: Doug Broaddus.

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

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

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

1 you would really want to go there.

2 The last thing that I want to mention is
3 that one of the things that has bothered me about the
4 statement of hazard equivalent to a discrete source of
5 radium, I don't know how big that discrete source of
6 radium is. And if I've got a tilt of a microcurie
7 radium source, half the world equals that. But, on
8 the other hand, if it's a 10-milligram, 5-milligram,
9 100-milligram needle, there's a heck of a lot of
10 different hazard there.

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

14 MR. CAMERON: Scott?

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

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

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

3 MR. S. MOORE: Right.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 MR. CAMERON: Right.

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

4 MR. CAMERON: Okay.

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

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

9 MR. ESSIG: Yes.

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

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

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

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

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

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

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

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

24 Let's go over here. Yes?

25 MR. KIRK: Scott Kirk, ORAU.

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

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

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

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1 necessarily tie ourselves to the IAEA code of conduct.

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

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

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

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

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

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

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

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

11 Thank you.

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

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

16 Yes, sir?

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

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

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

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

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

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

16 MR. CAMERON: Thank you. Important
17 issues.

18 Yes?

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

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

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

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

9 Yes? Tom, go ahead.

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

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

25 I didn't mean to convey that we were all

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

5 MR. CAMERON: Okay. Thank you, Tom.

6 Yes, sir?

7 MR. SIMMONS: Thank you, Chip.

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

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

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

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

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

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

11 MR. CAMERON: Okay.

12 MR. SIMMONS: All right?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 And we have used that approach in the
21 issuance of some of our increased controls up to this
22 point as well to point the additional control measures
23 to enhance the security of certain materials already
24 under health and safety.

25 MR. CAMERON: Okay. Thanks.

1 And, Scott, final comment? We'll go to
2 the phones and the TV room and then jump right into
3 the accelerator. Go ahead.

4 MR. S. MOORE: I guess two things. I
5 wanted to follow up on Doug's comment. One area of
6 this is we can look at the threat in the area of
7 security of materials. That doesn't necessarily mean
8 it's a common defense and security area.

9 For instance, we have regulations under
10 20.1801 and 1802. And those are safety-based
11 regulations. So those are under the agreement states'
12 purview.

13 Getting back to Mr. Setlow's comments, the
14 act itself does require us on these discrete sources
15 of naturally occurring material that pose threats
16 similar to radium-226 to consult with the
17 administrator or I presume their designee of the EPA,
18 the Secretary of Energy and Secretary of Homeland
19 Security, and also the head of any other appropriate
20 federal agency.

21 And we will be doing that, as you noted,
22 although it will need to be earlier than after
23 Thanksgiving due to our expedited schedule. And so
24 we're looking at probably the week before Thanksgiving
25 or maybe even sooner. So we will -- so right. Yes.

1 That is the time frame we're looking.

2 MR. CAMERON: Okay. Let's go to the
3 phones. Jill, do we have anybody who wants to talk?

4 JILL: If you would like to ask a question
5 or place a comment regarding today's conference, just
6 press *1 at this time.

7 MR. CAMERON: So do we have anybody, Jill?

8 JILL: We have Robert Scuronick. Sir,
9 your line is open at this time.

10 MR. SCURONICK: Hi. This is Bob Scuronick
11 from the Michigan Department of Environmental Quality.

12 I would like to offer a potential
13 definition for discrete source. A discrete source of
14 radium-226 is any item fabricated for use in commerce,
15 medicine, or research where radium-226 is deliberately
16 used because of its radioactivity.

17 MR. CAMERON: Okay. Thank you. Thank you
18 for that. That's a very concise definition. I don't
19 know what people around the table think of that, but
20 I think everybody heard it. And I'm not sure.
21 They're nodding, perhaps not approvingly, but I think
22 that there is some food for thought there.

23 We'll just go to Tom Essig for one comment
24 on that.

25 MR. ESSIG: I just wanted to reflect that

1 it does capture I think the point that Ruth was
2 raising earlier about being used for its radioactive
3 properties.

4 MR. CAMERON: Okay.

5 MR. ESSIG: That's an important thing to
6 include.

7 MR. CAMERON: Thank you.

8 Operator, do we have another person?

9 JILL: Yes, we do. We have one other from
10 Scott Siemen.

11 Sir, your line is open at this time.

12 MR. SIEMEN: Hi. This is Scott Siemen,
13 Siemen Nuclear Corporation, a moisture density gauge
14 manufacturer.

15 Regarding the definition portion, a threat
16 similar to radium-226, our experience is that
17 regulators view this threat differently. Some just
18 see it as a radiation emitter. Others have other
19 concerns. They're worried about pressure build-up
20 within capsules, which is actually something that's
21 missed by calculation and measurement, it's been found
22 to be less than an atmosphere.

23 And the old history of leakage of radium
24 does not include industrial capsulization. Sources
25 manufactured and distributed by us by Amersham, you

1 know, to our knowledge, we're not aware of any radium
2 industrial source that has leaked. We find regulators
3 are interested in imposing greater leak test
4 frequencies and things. And so I don't know if any
5 further definition needs to be made of what the threat
6 is of radium. You know, it's similar in toxicity,
7 radiotoxicity, to erasium. So it's just a problem
8 that we fight from time to time.

9 MR. CAMERON: Okay. Thank you, Scott.

10 MR. SIEMEN: Thank you.

11 MR. CAMERON: Jill, is that it for the
12 phones?

13 JILL: That's all we have, Mr. Cameron.

14 MR. CAMERON: Okay. We'll be back to you
15 later on in the day, and I'm going to ask if anybody
16 over in the TV conference room has anything to add for
17 us.

18 PARTICIPANT: We do have one comment.

19 MR. CAMERON: Great.

20 MR. JOHN JANKOVICH: This is Peter
21 Johnjancovich. I am on the NRC staff. I work for Tom
22 Essig in his branch as the team leader for sealed
23 source.

24 I would like to point out that there are
25 two definitions, well-accepted in medical and

1 commercial sources. Those are for sealed sources from
2 gaining byproduct material.

3 However, my point is that if we use those
4 definitions and start dressing them up with all the
5 considerations that we have heard so far, we may
6 achieve a good definition for this source.

7 Let me point out what those two
8 definitions are. One is in the NRC regulations in
9 part 30. Let me raise it shortly. There the source
10 is defined as material, byproduct material, in case in
11 a capsule. So it means it is maintained and in order
12 to prevent leakage and/or escape. So that gives us
13 already some reaction how we could go with the
14 definition.

15 The other accepted definition, both
16 nationally and internationally, is the applicable
17 standard. There are two standards, American National
18 Standard, ANSI standard, N43.6. And there is another
19 item to the definition for sources in the
20 international standard, ISO standard 2919.

21 That definition is a little longer but
22 similar to the NRC. And it says that the material is
23 in a capsule in abundant cover. And the containment
24 is strong enough to present both the outside, the
25 dispersion of the material.

1 So I suggest this definition should be
2 considered that we go to next. Thank you.

3 MR. CAMERON: Okay. Thank you. Those are
4 analogies that should be explored.

5 Anybody else?

6 (No response.)

7 MR. CAMERON: Okay. Thank you.

8 I know we are behind, but I don't think
9 it's fatal yet.

10 (Laughter.)

11 MR. CAMERON: We do have accelerator. And
12 Dick Blanton is here. And I'm suggesting let's move
13 through accelerators.

14 I know that there is some interest in
15 waste and transportation. We have Derek Widmayer with
16 us and Rob Lewis on those issues. Well, we will see
17 where we are when we are done with accelerators
18 because I think you probably want to take a break. So
19 when we're done with accelerators, let's take a break.
20 And maybe this will go fairly quickly. Who knows?

21 (Laughter.)

22 MR. CAMERON: Dick, a lot of pressure on
23 you.

24 Mary, a clarification?

25 DR. M. MOORE: No. Just I was wondering

1 could we have the break now before we start the
2 accelerators? Five minutes? Ten minutes?

3 MR. CAMERON: Fifteen? No. Well, I'll
4 tell you what. We have been at it for an hour and a
5 half. And we probably are going to go over. Okay?
6 So why don't we take a break. Scott, is that okay
7 with you?

8 MR. S. MOORE: Sure.

9 MR. CAMERON: Take a break now? How long
10 do you want to release people for? Give them 15?
11 Ten? Okay. Ten minutes. Thanks, Mary.

12 (Whereupon, the foregoing matter went off
13 the record at 3:01 p.m. and went back on
14 the record at 3:15 p.m.)

15 MR. CAMERON: On the record. George Mills
16 and Rich left. They had another engagement. So I
17 think that this accelerator issue is probably our last
18 big substantive discussion. We are going to talk
19 about waste though and transportation. I'm not sure.
20 I don't think that's going to be too big a deal.

21 There were a lot of other issues that we
22 got the sense of the group on in terms of putting
23 information out earlier, longer comment period. So
24 I'm trying to look on anything after this discussion
25 as just gravy just because I want to try to be

1 optimistic. But at any rate, Dick Blanton,
2 accelerator, tee it up for us please.

3 MR. BLANTON: Okay. We have an
4 accelerator. We operate it. We produce some
5 material. It's radioactive so it's accelerator
6 produced radioactive material, but it's a byproduct
7 material. The Energy Policy Act gives NRC authority
8 over certain accelerator produced material but not all
9 of it nor over the accelerator that produces it.

10 The Act gives the NRC authority by
11 amending the definition of byproduct material to
12 include the accelerator produced radioactive material.
13 But it also specifies three things that kind of define
14 what accelerator produced material we're going to
15 regulate.

16 First, it has to be produced in a particle
17 accelerator and we presume that means any kind of a
18 particle accelerator, linear accelerator, cyclotron,
19 whatever. It also can be produced before, on or after
20 the effective date of the regulation. This
21 effectively means there is no grandfathered material
22 that's exempt from that regulation. Then we get to
23 the third criteria. It's produced, extracted or
24 converted after extraction for use in a commercial,
25 medical or research activity. These things are not

1 defined within the Act.

2 So we look at the production of
3 accelerator produced material. In general, we can see
4 that there's probably going to be two types of
5 materials produced. The intended material, the
6 product that we're trying to produce resulting from
7 the irradiation of the target material, this generally
8 we understand does not happen instantaneously. It
9 takes a period of time. There will also be the
10 production of some incidental material and this could
11 be due to the irradiation of target contaminants if
12 any or the irradiation of the accelerator internals,
13 things like magnets, beam stops, beam guides,
14 whatever.

15 So we come up with two issues to be
16 resolved. When does the accelerator produced material
17 become byproduct material if it is being produced for
18 a commercial, medical or research use? Should we
19 start the regulatory clock when the first atom of the
20 product material is created within the accelerator?
21 Should we wait until the irradiated target is removed
22 from the accelerator? Or should we wait further until
23 the product material is separated from any
24 incidentally produced material?

25 If you look back at the history of

1 discussions that led up to the Act, people talked
2 about all of these things. So it's not clear exactly
3 where we should start in. What we want is discussion.
4 What do you think we should do? Where should we start
5 the clock?

6 The second thing is what about the
7 incidentally produced byproduct material itself? On
8 one hand it's being argued that this is produced
9 during the production of material that's intended to
10 be used as byproduct material in a commercial, medical
11 or research use but it itself is not intended for use
12 in another commercial, medical or research activity.
13 So should it be regulated or should we not regulate
14 it? We'd like to have your thoughts and comments on
15 those issues.

16 MR. CAMERON: Are you done?

17 MR. BLANTON: Yes. You said be quick.

18 MR. CAMERON: Okay. Is my mike on? All
19 right. We already have some cards up. Thank you,
20 Dick, for that presentation. You saw how Dick
21 formulated the two primary issues there. Let's start
22 it this way with Roger and go around that way. Ruth
23 and Maria and Roy. Roger.

24 MR. MORONEY: Thank you, Dick, on the
25 discussion there. For us, I mentioned earlier we

1 operate 42 PET-radio pharmacies in the U.S. and each
2 one of the facilities has a cyclotron.

3 A couple of concerns from our operational
4 experience, and perhaps my cohort/comrade over at
5 Eastern would have the same experience over there.
6 The exposure to the cyclotron staff, probably the
7 largest portion, is to the cyclotron engineer who is
8 doing the maintenance on the equipment and we'll
9 typically see exposures reaching a significant
10 fraction of the primary limit. So if we're concerned
11 about safety issues with staff, employees and
12 radiation workers, then I think perhaps we should
13 consider something in that area there.

14 Another area which we have some recent
15 experience having decommissioned a PET facility is the
16 largest cost of the decommissioning was the cyclotron
17 itself by far. There was really nothing to speak of
18 in the rest of the facility as far as removal cost and
19 it was significant.

20 Then the last thing, I guess I'm at a loss
21 as to where the commercial is really defined in
22 regards to separating the material that's regulated
23 with material that's not regulated. We are by
24 definition in the commercial process in the commercial
25 activity and it would almost seem like reading the

1 rulemaking or the legislation is that the entire
2 cyclotron would be covered because we're using it for
3 a commercial process and I know how you're defining it
4 today but what's going to happen tomorrow is what I'm
5 concerned with.

6 MR. CAMERON: When you say what's going to
7 happen tomorrow, what is specifically that concern?

8 MR. MORONEY: Could there be a different
9 interpretation tomorrow versus what we just heard
10 today? Is the cyclotron covered? Is the target body
11 covered? Is the activation products in the tank and
12 the deeds, the shielding?

13 MR. CAMERON: Is that what we're here to
14 do?

15 PARTICIPANT: Yes.

16 MR. CAMERON: That's what we're going to
17 be doing.

18 MR. MORONEY: I find it hard to be able to
19 separate those as a physicist.

20 MR. MOORE: That's a key point. We don't
21 have a definition today and we want to hear
22 everybody's input on that. Certainly a very narrow
23 definition would be only the target should be under
24 our jurisdiction. A very broad definition would be
25 the target, any backing and all activation products

1 would be under our jurisdiction.

2 The legislation does not give us authority
3 over the cyclotron itself but it does give us
4 authority over accelerator produced material for
5 research, medical and commercial use. So the question
6 is what is that and how should we write the regulation
7 for that and we want to hear from you on that.

8 MR. MORONEY: Let me clarify. I think a
9 lot times when it's exploited is between machine
10 sources of radiation and radioactivity. I assume
11 that's what it is. When I was talking about
12 regulation of the cyclotron itself, I wasn't talking
13 about that you would get into the business of machine
14 generating radiation machines at all. It's strictly
15 the radioactivity produced within it and a system used
16 where the primary purpose of the system is the
17 radiation itself would simply, would obviously not
18 fall within this range. But a cyclotron, a particle
19 accelerator where the radiation produced is incidental
20 to producing some radioactivity for distribution
21 commercially would seem to fall within this range.

22 MR. CAMERON: Okay. Thanks.

23 MR. MORONEY: And I'm putting these out
24 because again going back early on, we're looking for
25 uniformity, consistency and it's often once you put a

1 cyclotron into a nuclear pharmacy that's when you
2 start running into these gray areas because there's
3 not in many states, many states there are, a defined
4 program or defined guidelines and they try to shoehorn
5 as best as they have into machine registers.

6 MR. CAMERON: And remember Scott gave us,
7 I don't know if they're two ends to the spectrums but
8 he gave us two possibilities for how we should define
9 this. Keep in mind. I think, James, you brought up
10 the big and small issue before which is something that
11 is relevant to this discussion too. So remember that
12 comment and James may remind us of that later. Ruth.

13 MS. MCBURNEY: From the standpoint of
14 trying to develop uniform standards for accelerator
15 produced material in those non agreement states, I
16 think it would be really the right thing to do on two
17 levels because you're not going to then have two
18 different agencies regulating similar material in the
19 same facility.

20 Also where you're going to run into it
21 mostly is during the licensing process because you're
22 going to need to review the manufacturing facility for
23 the radioactive material, not only that that's being
24 produced and to review the shielding and the hot cells
25 and so forth dealing with that radioactive material

1 but you also have to take into consideration the
2 material that's going to build up in the shielding for
3 when you're doing doses to the public and to the
4 workers and so forth. So really you're going to have
5 to take those materials into consideration during the
6 licensing process. Also during decommissioning when
7 you're decommissioning the manufacturing of
8 accelerator produced radioactive material, not only
9 does any residual radioactive material in the target
10 appear there but you also have the activation products
11 and so forth.

12 In agreement states, I don't know how
13 other ones do it but we first register the machine for
14 its machine properties and then when production starts
15 or before production starts we review it as a license
16 and license that manufacturing activity. So I really
17 think it's the right thing to do to cover the whole
18 activity in that manufacturing process.

19 MR. CAMERON: So, Ruth, you're suggesting
20 that the NRC should be as broad as possible.

21 MS. McBURNEY: Broader. Yes.

22 MR. CAMERON: All right. Maria.

23 DR. KELLY: That's just what I was going
24 to ask Roger. So in other words, you're saying that
25 the byproduct material whether it's intended or

1 incidental creates a safety risk and so it should be
2 covered that way. So there shouldn't be any
3 distinguishing between them unless you set a limit or
4 something.

5 MR. CAMERON: Okay. Did you get the
6 clarification? All right. Barbara.

7 MS. HAMRICK: I just wanted to expand a
8 little bit on what Ruth said not only will those
9 products be there at the time of license termination
10 but it's my understanding that in your license
11 termination process under your NEPA obligations you
12 would have to look at some things that you wouldn't
13 necessarily license for example, radium at uranium
14 processing facilities under your NEPA authority. You
15 would have to look at that anyway and it seems to me
16 that this would probably end up in the same box in a
17 license termination scenario.

18 The other thing I wanted to say was about
19 what Roger said about the exposure and currently the
20 regulations if you're looking at exposure limits, they
21 have to look at exposure from all sources of radiation
22 whether or not it's a licensed source. So that
23 exposure would still be accounted for and regulated
24 for the occupational worker but not necessarily for
25 the public.

1 MR. CAMERON: Thanks, Barbara. Let's go
2 to Mary.

3 DR. MOORE: One of my major concerns with
4 this change is the compartmentalization and
5 duplication and confusion. So let me ask a clarifying
6 point with byproduct material. It comes from reactors
7 and NRC licenses reactors. I am not clear in
8 understanding. Will the states register and license
9 the cyclotrons and where and at what time does the NRC
10 now become involved? It's unclear to me.

11 MR. MOORE: The analogy to reactors, NRC
12 has authority over the whole reactor, not just the
13 material coming from the reactor. Under the Energy
14 Policy Act, we got authority only over the material
15 coming from cyclotron. We didn't get authority over
16 the cyclotron itself. So we don't have jurisdiction
17 as a regulatory agency over the cyclotron. We only
18 have authority over the radioactive material produced
19 by the cyclotron.

20 DR. MOORE: And at that point and as our
21 discussion has been, I also support a broad definition
22 because I think that helps simplify life for everybody
23 and will also enhance smoother operations and
24 therefore enhance safety. Is the NRC's authority now
25 over the lifetime, and I can't think of a better word,

1 of that radioactive material? In other words, do you
2 cover from birth to disposal of decay? All right.
3 Decay.

4 MR. MOORE: That would depend on how we
5 define it in the regulations and that's what we're
6 asking for input on. We haven't yet defined the
7 regulations and that's why we're holding the meeting
8 today.

9 DR. MOORE: Understood.

10 MR. MOORE: But we were to define it
11 broadly, if we were to consider that it is commercial
12 from birth to the endpoint, then I would presume that
13 we could make an argument that we would have authority
14 over decommissioning of the cyclotron because it would
15 involve activated products if we concluded that it was
16 commercial at that point.

17 We have authority over accelerator
18 produced material for medical, research and commercial
19 uses. So if we concluded as an agency that it was
20 accelerator produced and if the activated products
21 were accelerator produced and they were commercial
22 because of their waste potential, then we would have
23 jurisdiction over it and we could regulate it.

24 DR. MOORE: I can one conflict happening
25 among the states if this broad definition and this

1 scope is not implemented is that the states will be
2 involved at the birth, the licensing and citing and
3 review of shielding and all that. Operationally, NRC
4 comes in and then when they want to decommission it,
5 all of a sudden it comes back to the states unless
6 this broad definition. Is my understanding analogy
7 correct?

8 MR. MOORE: Yes.

9 DR. MOORE: In non agreement states,
10 right.

11 MR. CAMERON: Okay. So we're hearing that
12 people seem to be supporting for various reasons a
13 broader definition at this point. James?

14 DR. CASE: Whether enough people around
15 this table are interested in broadening the
16 definition, I don't think Congress gave you the
17 authority to do that. Cyclotron is not what's on the
18 table here. It is the material coming out of the
19 cyclotron and that doesn't mean we can stretch it out
20 to processes or the cyclotron or however you try and
21 continue to reach. Congress says what's on the table
22 is byproduct material and I think we need to stay
23 focused on the byproduct material and try and not get
24 too much mission creep onto the cyclotron itself.

25 MR. MOORE: We have not yet had a

1 discussion of why the concept of commercial use may
2 apply to waste and Ruth brought that up earlier. So
3 maybe Ruth might want to discuss further the concept
4 of waste being commercial.

5 MS. MCBURNEY: I think there has been some
6 case law. Scott Kirk who's the Health Physics
7 Society's legislation/regulation chair of that
8 committee said there has been case law that would
9 define waste as a commercial activity. So from that
10 standpoint, whether or not NRC took into account that
11 once this material becomes a waste for disposal that
12 it would be covered under the definition.

13 MR. BAILEY: Yeah. Can I just interject
14 one quick thing in that regard? I think if you look
15 at the low-level waste compact in the legislation, the
16 reason you couldn't ban waste coming to your site was
17 because it was a violation of the interstate commerce
18 clause of the Constitution and so I would presume that
19 somebody has determined that it's in commerce.
20 Somebody's getting paid and as Roger pointed out, that
21 machine is in the process of commerce and it's
22 generating whatever it's generating. It's already
23 there.

24 MS. MCBURNEY: Or at least the activity in
25 it. The machine itself.

1 MR. CAMERON: But besides this issue when
2 we were talking about broad or narrow, we were talking
3 about broad or narrow in the sense of the two
4 possibilities that Scott gave us earlier. But he very
5 clearly said the machine is excluded.

6 MR. MOORE: Right. It has to be broad or
7 narrow with respect to the radioactive material in the
8 machine. Getting back to Dr. Case's point, we have no
9 jurisdiction over the machine. It can only be with
10 respect to radioactive material in the machine. We
11 have no authority over operation of the machine.

12 MR. CAMERON: So that at least should be
13 clear.

14 DR. CASE: Let me just be clear what
15 you're referring to. So if as the negative ion being
16 swirling around there, runs into the side of the
17 cyclotron, activates an atom within the cyclotron,
18 then the cyclotron comes under that atom now as under
19 the jurisdiction of the NRC.

20 MR. MOORE: It could be and that's what
21 we're discussing. An activated --

22 DR. CASE: And that's my question. Did
23 Congress give the NRC the statutory authority to do
24 that or have you just crept over into regulating the
25 cyclotron?

1 MR. CAMERON: Let me -- Can someone give
2 us a clear response to that because I think it's very
3 important and, Dick, I don't know if you wanted to or
4 Roger. But I would like someone to address that
5 specific question so that we can end the confusion.

6 MR. BAILEY: I would like to read what is
7 here leaving out a few words. It says it's
8 radioactive material produced for use for, an example,
9 a research activity or a commercial activity or a
10 medical activity. It is radioactive material produced
11 in the process of doing that. It doesn't have to be
12 extracted. It doesn't have to be converted. It just
13 has to be produced.

14 MR. CAMERON: So in other words, it's in
15 the process so that the --

16 DR. CASE: You added the word "process."
17 Congress didn't. Congress put "for" in there. If
18 Congress wanted process, they would have put process
19 in there. That's my point.

20 MR. MOORE: My understanding is that
21 Congress didn't produce any committee report along
22 with the legislation. So all we have to go on is the
23 words in the Act at this point.

24 DR. CASE: Which is "for" not "process."
25 That's my point.

1 MR. CAMERON: Which can be a big
2 difference between process and for.

3 DR. CASE: I think that will need to be
4 clarified.

5 MR. CAMERON: Okay. Good important issue
6 that needs to be addressed. Let's go to Roy, Ed and
7 then we'll go back around to Ralph and Mary. Roy.

8 MR. BROWN: Yes Dick. First of all, let
9 me say I think you guys really nailed the crux of the
10 issue here on when and what needs to be regulated. I
11 think going back to when it's created. I think for
12 ease of operating and for ease of licensee CORAR (PH)
13 would be in favor of taking of control of it as soon
14 as it becomes radioactive. Not only is the product
15 you're selling becoming radioactive but the target
16 backing, the big machines, the medium plain, the whole
17 five feet around the whole building would be the
18 concrete would be activated, the steel rebar in the
19 wall would be activated, the cesium-137, cesium-134,
20 cobalt-60, all that is part of the commercial
21 operation and I think CORAR would be in the side of
22 that's all part of the commercial operation and should
23 be regulated.

24 You also have in terms of one to regulate
25 some of the processes like making I-123. You

1 circulate Xenon gas in and out of the cyclotron on a
2 continuous loop and I think CORAR would be on the side
3 of every time one of those Xenon particles become
4 activated to I-123, then it becomes regulated. It's
5 not a case where you put it in the machine and take it
6 out of the machine. But the gas is continuously
7 circulating.

8 Also in terms of Incident 2 production, I
9 think all this is Incident 2 production because it's
10 part of the commercial process and CORAR would be on
11 the side that this should all be regulated.

12 MR. CAMERON: So, Roy, you're saying
13 broader too. I just want to make sure that we
14 understand this as much as we can using Dr. Case's
15 example of the side of the machine becoming
16 radioactive. How would you parse that out?

17 MR. BROWN: My feeling would be that's
18 part of the commercial process. So that material is
19 in commerce. That's radioactive. So therefore it's
20 covered.

21 MR. CAMERON: Okay. Dr. Case, did you
22 want to say anything to that?

23 DR. CASE: Again, that may be something
24 worth thinking about here but definitely just straight
25 reading of what the statute says, that's not what

1 Congress had in mind. I mean Congress says as been
2 made, radioactive by use of a particle accelerator and
3 is produced, no mention of processes. I really think
4 you're on a slippery slope of over stretching the
5 authority.

6 MR. CAMERON: So if you dealt with, using
7 your example, that material as a waste it really
8 wouldn't have been produced. They wouldn't have met
9 the produced-for definition.

10 DR. CASE: The reason why this is an
11 important issue and getting to the big and small
12 accelerator type argument is if you're talking about
13 regulating a small radiopharmacy and their small
14 cyclotron and now they have to go through the same
15 thing that Three Mile Island would have to do in
16 decommissioning, these are the issues that I think we
17 have to be aware of in creating our rule. Is it risk
18 based? Is it what Congress intended? I think right
19 now our concern as clinicians in terms of access is
20 being able to work within what CMS gives us in terms
21 of a reimbursement in a way of raising healthcare
22 costs.

23 MR. CAMERON: CMS?

24 DR. CASE: Center for Medicare Services.
25 So what I think is very important for us is if we try

1 and chase down every last atom that may have been
2 activated in this cyclotron that Congress didn't give
3 us the ability to discuss anyway, I think we're asking
4 other agencies of the government to pay more money for
5 getting radioisotopes necessary for taking care of
6 Medicare patients.

7 MR. CAMERON: Can we have specific
8 responses to that and let's go to Barbara, Ralph and
9 Ruth.

10 MS. HAMRICK: I just want to say that
11 those activities though are already regulated by most
12 states. So in an agreement state, that
13 decommissioning criteria is still going to apply.
14 It's already in place. So the fact that they might
15 take on this activity would promote consistency but it
16 wouldn't really change the fact that that's a
17 regulated activity right now.

18 MR. CAMERON: Okay. And Ralph.

19 MR. LIETO: I just wanted to give an
20 example of a more nightmarish situation that could
21 exist is that you have a state agency that has one
22 state agency regulating NARM, another one regulates
23 the radiation machines and is an NRC state. So if we
24 followed the criteria or the very narrow scope of what
25 we're saying here, you could potentially have a

1 cyclotron having to meet three regulatory agencies to
2 operate one machine. So if you don't think that's
3 going to drive up the cost, I think that that's a very
4 real situation.

5 I think also that with this controversy
6 maybe we need to have some type of general counsel
7 input on this aspect at least for the nonagreement
8 states as to where this is going to begin. I
9 personally would want a more general approach that you
10 have one agency regulating the radioactive materials
11 regardless of where it's produced. As Barbara and the
12 agreement states have pointed out, they've established
13 exempt levels and maybe there are some of these
14 situations that are going to occur in these smaller
15 cyclotrons that would minimize the impact that Dr.
16 Case is referring to. But I would be concerned that
17 we would have over regulation for a single machine
18 that could occur in nonagreement state facilities.

19 MR. CAMERON: Ruth, we're still on this
20 specific issue.

21 MS. McBURNEY: Right. Whether or not NRC
22 does regulate all the material, they are going to have
23 to take it into account on the design basis and the
24 licensing of those facilities whether it's a big one
25 or a little one. And the size of the cyclotron or

1 accelerator, they're going to have to look at is it
2 protective. Once it starts producing radioactive
3 material, is it protective of the workers and the
4 public? So whether or not they regulate it, they're
5 going to have to take it into account and then at the
6 decommissioning whether that's then regulated by one
7 agency or two. It's just the right thing to do if
8 it's within the legal framework and the regulations
9 wouldn't have to deal with the size of the operation.
10 That could be handled through the licensing guidance.

11 MR. CAMERON: Okay. Let's go to Roger and
12 Ed.

13 MR. MORONEY: Are you talking on the same
14 topic?

15 MR. CAMERON: Same thing.

16 MR. MORONEY: Okay.

17 MR. CAMERON: You got a little different
18 -- Then we'll check in with Mary. You're on this same
19 topic.

20 DR. MOORE: Generally.

21 MR. CAMERON: Okay. Let's go Roger, Mary
22 and then Ed. Roger.

23 MR. MORONEY: Okay. Roger Moroney again.
24 Two comments that Dr. Case made that of the separation
25 between the small cyclotron and the larger cyclotron.

1 Prior to coming to the PET, I worked in a facility
2 with these larger machines and at the risk of inviting
3 more regulation, I can tell you the smaller ones are
4 not quite as innocuous as you might think they are and
5 I made the statements earlier not to invite more
6 regulation. It's to invite consistent and a level
7 playing field across the United States for those of us
8 that work across the United States. That's our goal
9 in coming here is that level playing field from state
10 to state and a consistent interpretation of the
11 regulations.

12 MR. CAMERON: Okay. Mary.

13 DR. MOORE: In following this definition
14 of the role of the activated components of this
15 cyclotron during the production of any ram, the target
16 has to be changed. That target now becomes as
17 activated. It's radioactive. It's an accelerator
18 produced radioactivity and it has to now be handled as
19 waste. Under whose purview is that, the state or is
20 that the NRC?

21 MR. MOORE: That's what we're discussing.

22 DR. MOORE: I'm bringing -- Right, I
23 understand we're discussing it. But this is one of
24 the issues. The cost goes up. Confusion goes up.
25 With a broad definition of the accelerator produced

1 radioactivity is used for the NRC, would the NRC then
2 be the regulatory group?

3 MR. MOORE: Well, again to answer your
4 question, it really comes down to a question of is the
5 target backing produced, extracted or converted after
6 extraction for commercial, medical or research
7 activity? That's really what it comes down to.

8 DR. MOORE: Well it was used for
9 commercial activity to produce the product.

10 MR. MOORE: And if you answer the question
11 that way, then it would be an NRC regulated activity.

12 DR. MOORE: Is there room in nonagreement
13 states for 17 of us, are there I think, to
14 individually negotiate that with the NRC?

15 MR. MOORE: I think that will have to come
16 out in the transition plan and you can answer that.

17 MR. BROADDUS: The definition that we're
18 talking about right now whether it's broad or narrow
19 would not be something that could be negotiated after
20 the rule's put in place. However, the transition plan
21 that the task force will be developing will as part of
22 that be addressing whether or not or proposing to the
23 Commission some options for whether or not the NRC
24 could establish limited agreements with states for the
25 oversight of the newly defined material.

1 DR. MOORE: So the answer is in
2 nonagreement states the point of intervention of or
3 beginning of intervention -- I guess it's when does
4 the state come back into it can be negotiated
5 individually with each nonagreement state. So you may
6 or may not have --

7 MR. MOORE: No, not the point that the
8 state comes back into it. Whether or not NRC has
9 jurisdiction or not, that will be the same regardless
10 of which state you're in. Whether or not the
11 nonagreement state wishes to have an agreement with
12 NRC on a limited basis for NARM material is something
13 we're looking at specifically under the transition
14 plan.

15 DR. MOORE: Okay. And another thing. Are
16 you looking at Ruth was referring to the fact that you
17 all are going to have to look at personal exposure
18 shielding and site design. Why? You're not licensing
19 it. You're not citing it.

20 MR. MOORE: If we took a broad definition
21 of the materials that are activated and produced, then
22 we would be responsible for the safety of people
23 working around those materials. So under Ruth's
24 construction and I haven't necessarily accepted that,
25 but under Ruth's construction, then we would be

1 responsible for regulating safety under that. So we
2 would have to look at anybody that worked under that.
3 So you would have to look at site safety under that.
4 You'd have to look at all issues under that.

5 DR. MOORE: Right. And I do know that.
6 But what I'm trying to get to as we're delineating
7 this is as a potential licensee submit the request to
8 the state to register, then license my cyclotron. I
9 might also now going to be submitting information to
10 you before the products I'm producing.

11 In other words, how do you all get pulled
12 into this and communicate? Are the states going to be
13 sending this information to you or do I have to write
14 another check and write a bunch of -- Yeah, I have to
15 write another check. I should have known that. And
16 send more forms. We're duplicating a registration and
17 a citing and a shielding and a safety review process.
18 I know Congress did not give you the authority over
19 the cyclotron but operationally and worrying about
20 expenses particularly for the same small nuclear
21 cardiology sites as well as the large facilities and
22 operations that have sites in all the states, we've
23 just driven up the cost and duplication.

24 MR. CAMERON: One idea here is to, and I
25 think the NRC needs to take in account that you're

1 hearing around the table and it might be useful to
2 make sure that your comments go to this, is to think
3 about interest. What are your concerns in terms of
4 broad or narrow? We heard it may be more costly, too
5 many agencies, too much bureaucracy, conflicts. We
6 heard a lot of that and I guess I just wanted to have
7 Dr. Case articulate what his concern is. He talked
8 about his view of the legislative history and I know
9 that he's not just doing that from an academic
10 interest in legislative history. But can you just
11 articulate your concern, Dr. Case, about this broad
12 definition that we're talking about?

13 DR. CASE: Well, I think it is an
14 academic. The other thing I do as a person who lives
15 in the State of Missouri which is an NRC state, I also
16 pay Missouri taxes and I can tell you that if you want
17 them to create a regulatory structure to become an
18 agreement state under this, they may tell you to get
19 lost if you haven't followed what the statutory
20 language is supposed to do. The state could go ahead
21 and sue the NRC and say, "Look. You didn't follow
22 what Congress told you to do." So even though it may
23 sound like a great idea, if Congress didn't tell you
24 to do it, you have to go back to Congress and get
25 Congress to tell you something a little different than

1 what they told you. This is really the limit of what
2 the language is in here that we can do.

3 Now from a practical standpoint, aside
4 from just saying I don't think you could get away with
5 it if you start wandering too far from what Congress
6 told you to do, I think as a practical matter, we have
7 to be very cautious about what is good regulation. Is
8 good regulation providing access to materials or is
9 good regulation providing strict control of
10 radioactive materials?

11 If you look at the history, the amount of
12 dose, carcinogenesis due to environmental exposure to
13 radiation, the incidence of heart disease in our
14 country, these issues have to be weighed and balanced
15 as a risk based model. And if we're talking about
16 cardiac PET which is really in its infancy right now
17 and saying we're going to put a 10 MEV, 11 MEV machine
18 on the same playing field as a 67 MEV machine which is
19 producing strontium or a nuclear reactor and we're
20 going to put them all in the same bucket, it just
21 doesn't make sense.

22 And that's why when I sit here and I hear
23 people creeping beyond where Congress has told us to
24 go, I know that not only nuclear cardiologist may have
25 a problem with that. State legislatures will have a

1 problem with that and people who have to pay for the
2 cost of enforcing this regulation might have a problem
3 with it. And it could stifle. But the purpose of
4 this is ultimately is not to restrict access to these
5 materials but to create a safe way of creating access
6 to these materials.

7 MR. CAMERON: Okay. Thank you. Let's
8 hear from Gary before we go to Ed and Lynne.

9 DR. DILLEHAY: Gary Dillehay. I've found
10 the whole day to be quite informative because I had no
11 idea of the scope of issues that come up when you
12 start talking about this. But we've heard all kinds
13 of things today about safety and that sort of thing.
14 I'm glad that we finally got around a little bit to
15 regulatory issues related to cost because as an
16 enduser in what I think is a good state, Illinois, an
17 agreement state, I don't think that anything I've
18 heard today is going to cause me to do a lot more or
19 have to do a lot more than what I already do.

20 On the other hand, if you increase the
21 paperwork and the regulatory burden and the cost, it
22 is possible that you'll get to a point where access to
23 these sorts of things is not cost effective for the
24 institution offering these studies. I don't know what
25 the endpoint is for that but that all has to be

1 figured in to what you do.

2 I have to tell you that when we go before
3 the CMS and the people who pay for what we do, they're
4 not very sympathetic with the fact that do you know
5 that because I practice nuclear medicine I have to do
6 a lot more paperwork than the internist or the
7 pediatrician. They don't understand that and they
8 think that we're in some ways padding what our time
9 is. But somebody has to do it whether it's me or my
10 tech or my administrative person or radiation safety
11 officer or health physicist, you name it. It has to
12 be done and just to be cognizant of that when you're
13 thinking about these regulations is what I wanted to
14 make sure was heard today.

15 MR. CAMERON: That's good and then
16 sometimes when we do when we go out with a proposed
17 rule, we ask people to address specific questions or
18 to keep things in mind when they comment. Perhaps
19 this might be one of those times where we really
20 specify what do you think the effect on access might
21 be, for example or whatever those questions are going
22 to be to really focus people on that. Let's go to Ed
23 and I think we should try to go to the various
24 audiences also at this point.

25 MR. BAILEY: I said I wanted to change

1 streams a little bit and I want to focus on
2 accelerators used for research. Unless you take into
3 account all of the activated material created in an
4 accelerator, you're going to create a real puzzle
5 factory and I did work for a company that built
6 accelerators.

7 Sometimes you're experimenting with a
8 beam. That's research because you're trying to
9 improve the bending magnets. You're trying to do
10 something. You're trying to create a better target.
11 You're trying to do all kinds of things. So that the
12 part of the beam tube that gets activated while you're
13 doing that research, I don't know how you would
14 separate that from what occurred during normal
15 production. Or if you had an accident or you lose a
16 magnet or whatever, is that not in research?

17 If we take that then and the discussion
18 about the medical isotope is wonderful except now
19 you're going to create I can have the same
20 accelerator, I'm doing research with it and part of
21 it's covered. But if it's being used straight for
22 production it's not covered and I don't know. You all
23 must be a lot smarter than I am if you think you can
24 figure out which one caused which and where you're
25 going to do on each accelerator, which products you're

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1 going to regulate and which you're not.

2 MR. CAMERON: Okay. Great. Thank you,
3 Ed. Pointing out another difficulty that needs to be
4 taken into account here. Anybody in the audience?
5 All right. All of you who did speak from the audience
6 if we could just make sure that you sign in on the
7 sheets so that Lindsey can get a correct spelling of
8 your name.

9 MR. COSCA: Jim Cosca, Eastern Isotopes.
10 We have 12 PET facilities, about 17 machines. We're
11 PETnet's little brother. Nice to see Roger here
12 today. One of the things that I haven't heard all
13 day is at what limits do we start regulating. There's
14 exempt quantity tables that are in there, Table B,
15 Part 30 that I don't know how they were established
16 back in 1972 or what the logic was.

17 Whereas the DOT tables for Type A
18 packaging, Type A quantities are established on what
19 the emergency responder gets in 30 minutes to get his
20 five rems for the year. Where that was a Q value
21 system. What was that actual risk to that emergency
22 responder?

23 When we're looking at what the intent of
24 Congress was it was to protect us from a terrorist
25 action of handling these materials. It also looks

1 like you have to do a Q value analysis on every single
2 isotope and say if this isotope in the hands of a
3 terrorist, is there a potential for it to be used in
4 a dirty bomb? Then you have to establish exemption
5 points far above Table B. Table B right now doesn't
6 include any accelerator produced and the data is so
7 old it's amazing. That's just one comment.

8 MR. CAMERON: Okay. Barbara, do you want
9 to say something on that?

10 MS. HAMRICK: Yes, I just want to respond
11 to that.

12 MR. CAMERON: Go ahead.

13 MS. HAMRICK: Actually, I think in the
14 legislation it does also talk about protection of
15 health and safety not just security and so that aspect
16 is going to be covered. In the suggested state
17 regulations, there are those limits that you're
18 talking about, the concentrations, the exempt limits
19 for the accelerator produced nuclides. So what we
20 were talking about earlier this morning, they were
21 able to just pull those concentrations and those
22 numbers out. Then they would have those available for
23 use.

24 MR. COSCA: Asking any health physicist at
25 the table, what built that Table B?

1 MR. BAILEY: I can tell you exactly how
2 that table was built. The quantity of material, there
3 were two calculations done for the exemption quantity.
4 One was direct exposure. The other was assuming that
5 the amount of material that came airborne in a certain
6 sized room and there was an inhalation and it was
7 related back to dose.

8 The unfortunate part and that procedure is
9 spelled out in the NARM guides published by the
10 conference because we did it purposely for the
11 accelerator produced materials. The problem with
12 those quantities and it's probably something people
13 don't want to hear is that those quantities were never
14 adjusted when we went from 500 to 100 or when we went
15 from 15 to 12 to 5 rem a year. So if you look at
16 those quantities, you'd better use the old methodology
17 or you won't have any exempt quantities that you can
18 measure.

19 MR. COSCA: So the Table B is generous.

20 MR. BAILEY: Yes.

21 MR. COSCA: The Table B is generous right
22 now not looking at the DOT Type A-1, A-2 value tables,
23 the Q value tables that they have there.

24 MR. BAILEY: The exempt quantity tables
25 are -

1 MR. COSCA: Are overly generous.

2 MR. BAILEY: Are overly generous in the
3 amount of material.

4 MR. COSCA: Okay. So we won't ask you to
5 reevaluate those.

6 MR. CAMERON: That's said on the record.
7 That's not a request to reevaluate.

8 MR. BAILEY: But I would note that the
9 parameters under which they were calculated were
10 really quite conservative because it would be
11 difficult for you to wrap yourself around and smear
12 around the source to get the external and so forth.

13 MR. COSCA: Well, I just oversimplify it.
14 If the A-2 value for F-18 is 10 curies and that's an
15 emergency responder getting five rems in a half hour
16 and I say the general public is 100 millirems, I would
17 take 150 of A-2 value and that's my exempt level. To
18 me that's an oversimplification.

19 But the A-1, A-2 table is built using the
20 Q value, all routes of inhalation all five. Some
21 health physicists had a lot of time on his hands when
22 he built those A-1, A-2 tables. There's a lot of
23 number crunching that went in there and I don't think
24 10 CFR recognizes that.

25 MR. CAMERON: Is there a second comment?

1 MR. COSCA: A second comment, yes. The
2 accelerators, the cyclotrons, are registered by the x-
3 ray departments in most states. Those are relatively
4 easy forms and the fees aren't that bad. They're not
5 asking questions on bolt efficiency studies and things
6 like that. The State of Illinois, Gary and his crew,
7 they really know their stuff where they ask the right
8 questions. They want to see our bolt efficiencies.
9 They want to see our decommissioning plans. They want
10 money out of our pockets up front.

11 As the little guy on the block versus our
12 friend across the table who has Siemens to back him up
13 for decommissioning, I don't, I need to come up with
14 \$300,000 and now \$500,000 because I have two machines,
15 \$500,000 cash flow in a CD bond. That was stifle the
16 PET industry throughout the country. Other
17 alternatives for bonding of course is corporate
18 guarantees. You're lucky you have Siemen in your back
19 pocket but I don't.

20 So there's a thing here and for some
21 reason the State of Illinois would not let us, we
22 couldn't talk our way out of it. They just said
23 you're going to post the bond. We don't care what you
24 say. And we could bring in the consultants. We could
25 bring the scientists. We could bring in samples. We

1 could bring in everything. No. They made up their
2 mind. We have to post the bond.

3 Now if the NRC comes up with a new reg
4 1556 Volume 157 Cyclotron Operation guideline and now
5 we have suggestion from NRC that bonds and surety
6 devices are required or strongly suggested for all
7 cyclotron operations, you're going to put PET
8 facilities out of business.

9 MR. CAMERON: Okay. I think we get that
10 point and let me test that hypothesis. Already having
11 to post the bond for State of Illinois under whatever
12 scheme we come with, not whatever but is it practical
13 to expect that there would be an additional bond
14 posting for companies such as this gentleman?

15 MR. MOORE: I don't think there would be.
16 I don't think that we would expect that there would be
17 additional financial assurance on top of per facility
18 in agreement states.

19 MR. COSCA: No, he's got me already.

20 MR. MOORE: But, Chip, it goes back to the
21 question of what is licensed or what is under our
22 jurisdiction. If we only have jurisdiction over just
23 the activated product at a cyclotron, then it's
24 unlikely that we would require financial assurance
25 because you have very little material.

1 MR. COSCA: And we're thinking about the
2 broad definition as was discussed.

3 MR. MOORE: If you take a broad
4 definition, you have a lot of activated material,
5 concrete, rebar, all that kind of stuff. You get into
6 decommissioning and decontamination issues and then we
7 probably would end up requiring financial assurance
8 and that would be by facility I think.

9 MR. CAMERON: The bond that you're talking
10 about in Illinois is to take care of the same type of
11 thing that --

12 MR. COSCA: Thirty years in the future.
13 When I go bankrupt, they have the money.

14 MR. CAMERON: So it's a question of there
15 would be, your concern is that there would be more
16 states that might be requiring this of you wherever
17 you operate.

18 MR. COSCA: All 50 states would. If the
19 NRC came out with level playing field consistent
20 regulations and you had determined you had an hour on
21 that target, that's enough to hit decommissioning
22 levels and you came up with that conclusion, then
23 we're going to be posting bonds everywhere. You will
24 put PET facilities out of business because these
25 people don't have the cash flow or the means to post

1 the bonds. They may have gotten away with it so far
2 in some states that weren't aware of the requirement
3 or enforced the requirement consistently. But you
4 will put PET facilities out of business if you come
5 across the whole country and say we want a bond from
6 everybody.

7 MR. CAMERON: Okay.

8 MR. MOORE: I'm not sure how our financial
9 assurance regulations compare to Illinois's. But I do
10 know under our financial assurance requirements we do
11 offer various options.

12 MR. COSCA: Avenues to do the bonding,
13 yes.

14 MR. CAMERON: Okay. Let's go back out
15 here to this gentleman. I know that Roger just wants
16 to tell you that Siemens is not going to be as big a
17 help as you think.

18 MR. MORONEY: We built that facility up
19 before she even bought it. So we've been down that
20 road.

21 MR. CAMERON: All right. So this point is
22 the one that Gary raised in terms of an interest.

23 PARTICIPANT: I'm just supporting Dr. Case
24 that too much regulation will stifle the industry.

25 MR. CAMERON: Too much regulation will

1 stifle the industry. Okay. Thank you, sir. Yes,
2 sir.

3 MR. FENNER: Roger Fenner with the State
4 of Tennessee. So far all the beams we've talked about
5 have been going in circles and every once and a while
6 they start going in a straight line. I would like to
7 ask about a couple of those. In Tennessee, we have a
8 free electron laser facility that produces no product
9 at the end of its cycle. All it does is produce a
10 laser that is then used for research. So would the
11 NRC be interested in that particular beam because it
12 is not there for any purpose of commercialization
13 unless you buy the purpose of waste? It produces lots
14 of activation, tons of activation. But it produces no
15 product for research, no product for anything else
16 except the laser. Now that's one aspect of it.

17 The other aspect is if a graduate student
18 comes along and starts playing with chicane and and
19 stuff like Ed was talking about later and starts
20 seeing the stuff being activated, can be reduced in
21 terms of the amount of activation and does research on
22 that for his graduate thesis, then does the NRC come
23 in and get interested in the thing?

24 The third prospect is if the laser that is
25 used goes upstairs to a medical suite and is used in

1 medicine and is used as a commercial use, the laser
2 itself, does that part then become interested of the
3 NRC in terms of what's being used with it? So the
4 beams are used in different ways and it's not
5 everything going in circles. They can be used in
6 straight lines and they can be used sometimes and they
7 don't produce something that is a product that is
8 activated. So it's something that you need to keep in
9 mind when you think of your information.

10 MR. CAMERON: Thank you very much. Does
11 that go to the definition of what is research?

12 MR. MOORE: Yes.

13 MR. CAMERON: All right. Thank you.
14 Let's go over here to Christopher and then we'll go to
15 the phones.

16 MR. GALLAGHER: Yes. Christopher
17 Gallagher with the American Society of Nuclear
18 Cardiology. I just had a question. I know I had
19 heard that the Society for Nuclear Medicine mentioned
20 California as a possible template because I know I
21 think part of this is to look at state models that
22 might be adopted. I'm not familiar with what
23 California does in terms of how it would affect
24 cardiac PET for example and I know that Sally Schwarz.
25 I guess Missouri is a nonagreement state. For

1 example, if you're in Missouri and the NRC comes up
2 with California as a template, how would that affect
3 Missouri?

4 MR. CAMERON: And California was one
5 example given but maybe, Ed, that would be instructive
6 if you could just quickly give us a read on that.

7 MR. BAILEY: Okay. What I would basically
8 tell you is that we have no specific regulations that
9 deal with how you operate a PET facility. We do in
10 the licensing process look at the handling systems and
11 the processing facilities that are associated with
12 them and we look at things like air emissions and so
13 on.

14 I have not heard of anybody in California
15 who even though they're paying California fees which
16 may not be quite as high as NRC's that has not put in
17 a facility because of cost. More often, it's how long
18 it takes to get something approved and that is a slow
19 process. So I would not encourage anyone to emulate
20 our speed in getting things processed.

21 We have made an effort in recent years
22 working with the nuclear medicine community to try to,
23 and we have a nuclear medicine council that comes in
24 and one of their jobs is to tell us of new things that
25 are coming about and we have our whole medical

1 licensing staff there and inspection and so forth and
2 we basically ask them the questions before these new
3 processes come online or we try to so that we've
4 already asked all the questions that we were going to
5 ask 50 different doctors or 50 different hospitals.

6 I think if you talk to some of the people,
7 the medical community from California, they have found
8 that very helpful to do that. That's the only part
9 that I would really suggest that you emulate.

10 MR. CAMERON: Okay. Thank you, Ed. Let's
11 go to make sure that we hear from the people on the
12 phones and in the TV room. Jill, do we have anybody
13 who wants to make a comment on this last conversation?
14 Jill.

15 PARTICIPANT: She may have ended at 4:00
16 p.m.

17 MR. CAMERON: Okay. That's Jill for us.
18 TV? Anybody in the room over there?

19 PARTICIPANT: Anyone have a comment? I
20 don't think we have any comments.

21 MR. CAMERON: Thanks. And we figured that
22 out. Thank you. Okay. Let's have three quick
23 comments to finish this out. Sally, go ahead.

24 MS. SCHWARZ: Just have a question about
25 decommissioning costs in California.

1 MR. BAILEY: They're among the most
2 reasonable in the United States.

3 MR. CAMERON: Okay, Ed. Thank you, Ed.
4 Could I have Derek and Rob? Rob's there. Derek is
5 going to come up. I just want to three. Can you just
6 make this quick, Roy, James and Lynne? Okay, Roy.

7 MR. BROWN: Yeah, real quick. I just
8 wanted to respond to Chris's question because this
9 gets into the game I suggested to play this morning
10 but we're not going to have time for unfortunately.
11 The way I understand it I'd like to get the State of
12 California's opinion on this and then NRC's opinion.
13 Take something specific that Chris mentioned like the
14 rubidium-82 generator. It's an accelerator produced
15 product. In California, it's licensed along with
16 everything else that the State of California does. It
17 doesn't handle a rubidium-82 generator any differently
18 than technetium generator. So it would be seamless
19 and in specific in the State of California.

20 In the case like Missouri, that's another
21 great example where right now you can probably bring
22 it into the State of Missouri fairly easily with
23 nothing more than a registration on your State of
24 Missouri form. So under the new scenario, I would
25 think Missouri would be one of those that may likely

1 choose not to become an agreement state. The
2 jurisdiction would fall back to NRC. So NRC may have
3 to regulate NARM and old byproduct material in the
4 State of Missouri. Is NRC prepared to do that and is
5 that your assumption too?

6 MR. MOORE: Yes, and I think it's
7 important for people who didn't understand that before
8 is that if the states that are not agreement states
9 now and we take over jurisdiction there and they don't
10 want to become agreement states for this limited
11 purpose, then the state is basically out of the
12 business and the NRC is going to do it.

13 MR. CAMERON: James.

14 DR. CASE: Yeah, I think a real important
15 question is how would the rules affect? I don't know
16 much about California's approach an agreement state
17 relative to Missouri which takes NRC's. Maybe you
18 could inform us. I'm glad to hear that you're offer
19 some of the most reasonable decommissioning rates of
20 any -- My question is that it still doesn't seem as if
21 and maybe you could give me a little bit of an idea
22 that if the bureaucracy takes an enormous amount of
23 time in California, they may have a well written or
24 well reasoned regulation but as a practical matter
25 becomes difficult to implement in a state like

1 California, in Missouri where potholes are a big deal,
2 it seems like we're going to be considerably slower
3 than we are. Maybe you could let us know or give us
4 a little insight as to how your regulation would look
5 if it were on a national scale.

6 MR. BAILEY: Okay. Now in Missouri, are
7 there PET production facilities?

8 MS. SCHWARZ: Yes.

9 MR. BAILEY: Okay. One?

10 MS. SCHWARZ: There are several.

11 MR. BAILEY: Okay. The real problem I
12 think in handling any pro view type facility is the
13 first one is the most difficult one of all generally
14 speaking and the more experience the people have both
15 as an applicant and as a reviewer, the quicker it
16 goes. I would think a state with a single PET
17 facility probably if they're not an agreement already,
18 they're not going to sign one of these agreements. I
19 can't see any reason for them to. So it would come
20 back then to NRC.

21 I don't know. Right now, things are
22 continuing along under the waivers. As the rules come
23 out, the states are going to have to look at it and
24 decide is this industry, do they have enough interest
25 in regulating it to put out the extra effort. Several

1 people have mentioned that the state's going to
2 require to register. The NRC is going to license and
3 then the state is going to be involved in the clean-
4 up. To me that is the epitome of asking for delays is
5 having two or possibly three different agencies
6 looking at the permitting and decommissioning of the
7 facility. So from my standpoint, I think I'd rather
8 have one agency doing it regardless of whether it's
9 NRC or the state agency.

10 MR. CAMERON: Okay. Thank you, Ed.
11 Quickly Lynne and then Tom Essig and then we will go
12 to Derek.

13 MS. FAIROBENT: Yes, I just have a
14 slightly different question for both Roger and Chris
15 based on something Chris said which is are you finding
16 then that you're putting more PET cyclotrons into
17 states that do not require financial assurance for
18 decommissioning and is that therefore then skewing the
19 access to patients for where PET is at currently?

20 MR. MORONEY: For me, Roger, no. It's
21 driven strictly by the market, how many scanners in
22 the area, is Eastern in there already. If I could
23 sneak in here real quickly on the comment about
24 licensing, sorry. We did recently license six months
25 ago a rubidium generator in California and I was

1 amazed it was turned around in like four weeks and
2 back out. They had a licensing guideline.

3 MR. CAMERON: Okay. Tom Essig.

4 MR. ESSIG: I just wanted to offer a
5 comment on when we're talking about broad versus
6 narrow perspective and what the Energy Policy Act was
7 intended to capture. I can only offer from an earlier
8 version of the statute when it was still a bill and
9 had been introduced by various members of Congress
10 that the word "discrete" was associated with both the
11 radium-226 and the accelerator produced material. And
12 somewhere along the way, the word "discrete" was
13 removed from the accelerator produced material.

14 So I don't know if the thinking was that
15 earlier on we would focus on the product more and
16 being that, it's kind of a discrete source, something
17 that could be removed and used for malevolent purposes
18 versus if you take the word discrete away, then you
19 possibly open it to a broader approach. It doesn't
20 answer any questions.

21 MR. CAMERON: If there's a prior version
22 of the bill where discrete was used with accelerators,
23 how much would that affect the discussion that we're
24 having right now?

25 MR. ESSIG: I was thinking it would focus

1 on the narrower approach.

2 MR. CAMERON: So it would focus it on the
3 narrower approach. Okay. We have Derek Widmayer of
4 the NMSS staff with us who's just going to quickly
5 address waste disposal. We have Rob Lewis here. What
6 I'd like to do is have Derek go and Rob go if we could
7 and then open it up for questions or discussion. It
8 might make it a little bit more efficient. Do you
9 want Rob to come up? Come on up, Rob. Go ahead,
10 Derek.

11 MR. WIDMAYER: Okay. I don't believe that
12 there are copies of these handouts. Is that correct?

13 PARTICIPANT: That's right.

14 MR. WIDMAYER: Okay and there are only two
15 slides of any significance. Last but not least, of
16 course waste disposal. I'm used to being last on the
17 agenda. My name is Derek Widmayer, Project Manager.
18 I'm in the Decommissioning Directorate of the Division
19 of Waste Management/Environmental Protection. That's
20 also in NMSS. And I mistakenly put my phone number
21 and my email address. I noticed that nobody else from
22 the NRC had done that today. So quickly write it down
23 before I change this slide.

24 I have two things that I want to cover,
25 broad background on waste disposal topics and then a

1 discussion of the issues. The background is basically
2 just discussing the provisions of the Energy Policy
3 Act and that was what there were some questions
4 earlier about that we tabled and now unfortunately
5 those people are no longer on the phone.

6 There are provisions in the Energy Policy
7 Act that specifically address waste disposal and the
8 background material that was handed out provides
9 additional explanation to these bullets. But
10 essentially one of the provisions makes sure that the
11 new definition of byproduct material, the things that
12 are added in, are not to be considered low-level
13 radioactive waste for the purposes of the Low-Level
14 Radioactive Waste Policy Amendments Act and the
15 intention of that is not to muddy the waters with
16 respect to the definition of low-level waste but to
17 just have no impact on the compacting process that
18 that law establishes. That's the reason for the
19 provision.

20 The second provision in the Act that
21 affects waste disposal is it says that regardless of
22 the fact that you're not calling it low-level
23 radioactive waste it ought to be disposed of in an
24 NRC-licensed facility which presumably means under
25 Part 61.

1 Then the third provision that's very
2 important is notwithstanding that second provision.
3 It's that these new materials in byproduct material
4 definition can be disposed of in facilities permitted
5 under Federal and state hazardous and solid waste
6 regulations which has the effect of hopefully not
7 impacting the current solutions that are used for the
8 disposal of these materials.

9 So I think that the person's issue that
10 was on the phone before was I understand if it's not
11 low-level waste where is it supposed to go and that
12 initial provision that I talked about is simply to not
13 affect the compacting process. Because of Part 61
14 actually does not use the definition of low-level
15 radioactive waste, it does appear in other NRC
16 regulations. But it doesn't actually appear in Part
17 61. So hopefully when we make all the necessary
18 amendments to the rules it will not be too confusing
19 anymore hopefully.

20 There were several waste disposal issues
21 that had arisen in the working group already. The
22 first one we've already touched on several times and
23 I don't think it bears repeating. Depending on how
24 the NRC decides to define accelerator produced
25 radioactive material and where our regulatory

1 authority begins, I think we'll have an effect on
2 waste disposal particularly in the areas that we were
3 talking about before where the beam and/or cyclotron
4 creates a lot of materials that are activated that to
5 one person's definition has nothing to do with the
6 actual materials that are being made radioactive for
7 benevolent purposes. And another issue I'll speak
8 about later will also talk about that.

9 Specifically the addition of radium-226 to
10 the definition of byproduct material may in fact have
11 a specific ramification on waste disposal. Back in
12 1986, the CRCPD asked NRC under this regulatory
13 framework that you invented for low-level waste, what
14 would you guys do with radium and NRC actually did
15 answer that in a technical memorandum. NRC said they
16 would add radium-226 to the tables that are in the
17 Part 61 waste classification system specifically
18 defining it the same way as they defined transuranic
19 waste.

20 One thing I might point out with that is
21 Part 61 of course was created and the rules are place
22 based on an ancient radioactive methodology. So
23 whether or not those numbers that were proposed back
24 in 1986 make sense to add now I think is an issue.
25 The other thing I have on this bullet is depending on

1 how NRC defines discrete sources and how that
2 definition turns out is the possibility that there
3 would be other sources that might need to have some
4 sort of specific regulation. I don't know of anything
5 off the top of my head but of course, uranium and
6 thorium and some of the longer-lived radionuclides
7 come to mind as far as whether anything needs to be
8 addressed if there's a broad-brushed definition of
9 discrete source.

10 Now I touched on this briefly. The table
11 in Part 61 is where there would seemingly be an impact
12 if we add radium. Now radium-226 is already addressed
13 in waste acceptance criteria at the State of
14 Washington's U.S. Ecology facility. That's another
15 option that could be used is to incorporate their
16 bases for disposal requirements and include that
17 somehow in Part 61. It may or may not impact the
18 table. As far as we've gotten so far, that radium-226
19 issue is really the only one that jumps out as far as
20 an impact on regulations.

21 Now with respect to the provision in the
22 law that allows that waste to be disposed of in a
23 solid or hazardous waste disposal facility, we're
24 still thinking about this of course but it's been
25 suggested that perhaps a provision in Part 20 that

1 allows that to occur would be the way to go. There
2 are already provisions in Part 20.2002 specifically
3 that we could use but that generally requires
4 individual applications and treatment of individual
5 situations. So there might be a reason to do a
6 blanket change to the regulation to allow these two
7 specific types of byproduct material to go into these
8 other facilities.

9 One reaction I've gotten to that already
10 is that's none of your business. So you don't need to
11 have that provision in your regulations. We'll have
12 to see how that goes.

13 As we were having all the discussions
14 today, I wrote down a couple other things that
15 probably belong on this chart now, one of which I had
16 already thought of that was the impact that our
17 redefinition of byproduct material might have on
18 CERCLA and CERCLA clean-up not that NRC necessarily
19 would be able to do anything about it. But we do
20 already have a memorandum of understanding with EPA as
21 to how clean-ups that are done under NRC authority are
22 handled and when we consult with EPA, there
23 potentially is an impact on what materials NRC
24 suddenly has jurisdiction over during a clean-up.

25 And specifically speaking of clean-up, we

1 talked already about the decommissioning funding. The
2 primary reason for the decommissioning funding
3 requirements in NRC regulations is because of the
4 waste and you have to calculate how much waste you're
5 think you're going to generate in the lifetime of your
6 facility and make sure you have adequate funding to
7 not only clean up your facility but to get rid of the
8 stuff you have to get rid of.

9 So if we were to have a broad definition
10 of the regulation for accelerator produced materials
11 in bullet no. 1 it does suggest that NRC might be in
12 the business of coming up with whatever
13 decommissioning funding requirements would be
14 necessary for an accelerator. That question might go
15 to jurisdiction and that's literally out of my
16 ballpark. But that question obviously is something
17 that we need feedback on.

18 Your comment about large accelerators
19 versus small accelerators, NRC does have a graded
20 approach as far as decommissioning funding assurances
21 and it would seem like it may just walk lock, stock
22 and barrel with the way that that's already defined.
23 Large accelerator would end up needing to do a whole
24 decommissioning plan and come up with how much waste
25 they're going to get. Others, smaller accelerators,

1 just have to have a certain amount regardless of the
2 waste that they're going to generate and those numbers
3 are not particularly high. That's my TF on waste
4 disposal.

5 MR. CAMERON: Very good, Derek. That's
6 very useful and let's get Rob on and then we'll go
7 back for questions and, Derek, we might impose upon
8 you since Rich Gianitti was not on the phone. Perhaps
9 it might be useful to call Rich Gianitti of
10 Pennsylvania to just tell him about what you were
11 saying. This is Rob Lewis, Spent Fuel Project Office,
12 NRC.

13 MR. LEWIS: Thanks. I am very interested
14 to know if anybody sees any pitfalls at all in the
15 transportation area for this legislation because our
16 initial view of this is that there's essentially no
17 impact on transportation resulting from expanding
18 NRC's regulatory authority into NARM.

19 The reason is that the DOT transportation
20 regulations on which our regulations are derived, if
21 you will, don't have anything to do with the Atomic
22 Energy Act authority and in fact, the Tables A-1, A-2
23 and the Transportation's Exempt table already have the
24 nuclides listed in the DOT rule and in the NRC rule
25 just because we wanted the table to be identical even

1 though we didn't have the authority. We don't want
2 people to have to look at two different tables that
3 are several pages long. So we put them in our rule
4 anyway last year. I mean they've always been in there
5 but we updated it last year.

6 And I think I'll leave it at that. I
7 think there's no impact. There's maybe some minimal
8 impact that's really only if in the rare case, there
9 was a Type B quantity. Part 71 would be directly
10 applicable to you now versus applicable by reference
11 to the DOT requirement that you use a Type B package
12 and let's something for theoreticians but in practice,
13 it's the same requirement anyway.

14 MR. CAMERON: Okay. Great. Thank you,
15 Rob. Let's go to James.

16 DR. CASE: Okay. I don't know. Just to
17 say this, you put up there regulate medical under Part
18 35. That stuff you put up there, I hope you're not
19 making the assumption that those things are
20 stipulated.

21 MR. LEWIS: No.

22 DR. CASE: I just want to make sure we get
23 to that because opening up the kettle of worms of Part
24 35 it took many years to resolve and doesn't cover
25 really what was the mandate here. I don't want that

1 sort of thing to be stipulated.

2 Now getting to the question of
3 transportation-related things, we spoke very early on
4 about where does NRC's authority get picked up and
5 where does it get dropped off in the whole process.
6 Is it out of the cyclotron and into the syringe and
7 somehow when it's being transported it's under
8 somebody else. Could someone try to walk me through
9 that model? If what I want to do is extract some
10 material from the cyclotron and now I put it into a
11 car and I drive it across town and now it's in
12 somebody else's facility and they're going to compound
13 it with some new F-18 flow agent, some kind of shake
14 and bake, like tetraphosmin and now inject it, where
15 do you see NRC's authority coming into play, out of
16 play, maybe back into play again in that whole
17 delivery scheme?

18 PARTICIPANT: It's the same way.

19 DR. CASE: But then do you have
20 overlapping authorities is my question.

21 PARTICIPANT: (Off microphone.)

22 MR. CAMERON: Let's get Rob back.

23 MR. LEWIS: It's has always been subject
24 to DOT. It would continue to be subject to DOT and
25 agreement statement regulations. There's an exemption

1 for physicians transporting their own material that
2 applies for the NRC requirements that may be
3 applicable in that case. But I guess the DOT
4 requirements as long as it's in furtherance of a
5 commercial enterprise the HAZMAT regulations for DOT
6 would apply to it.

7 DR. CASE: But it would also now have NRC
8 as well in a nonagreement statement like Missouri. Is
9 that right?

10 MR. MOORE: There's only one point in that
11 process where NRC itself doesn't have jurisdiction
12 over part of the process and that's the transportation
13 end of it itself and the Department of Transportation
14 actually regulates the transport of the material and
15 Rob could explain this better. But the transport
16 itself comes under DOT regs. So the transport from
17 one point, from point A to point B, is regulated under
18 the DOT regs but the material itself comes under NRC's
19 jurisdiction in the hypothetical case that you laid
20 out. Rob.

21 MR. LEWIS: That's right. That's the way
22 I understand it.

23 MR. CAMERON: Let's go to Barbara.

24 MS. HAMRICK: I'm just going to clarify on
25 that point and this varies from state to state because

1 our California Highway Patrol has authority to enforce
2 the Department of Transportation regulations. So that
3 framework already exists.

4 MR. CAMERON: That's a delegation.

5 MR. MOORE: And actually we do too. We
6 have an MOU with the Department of Transportation to
7 cite against DOT regulations. So we can enforce
8 against DOT regulations but the authority is with DOT.

9 MR. CAMERON: Lee, do you want to talk to
10 this point before we move?

11 MR. COX: Sure. North Carolina has the
12 same thing. We incorporate their regs and our regs by
13 reference and we have reinforced the DOT.

14 MR. CAMERON: Okay. Ralph and then Lynne.

15 MR. LIETO: Well, I was just going to say
16 to answer Rob's inquiry I don't see any effect in
17 terms of transportation on medical users. The one
18 point that I wanted to just make to Derek is that in
19 reading the Energy Act there is a lot of confusion out
20 there with that reference that it's not low-level
21 radioactive waste. It's very confusing to those
22 trying to read it and not understand the nuances of
23 what this is, the intent of that reference is.
24 Because just taking it at face value, it's like this
25 doesn't make any sense.

1 So I think as NRC goes along, I think you
2 really need to explain that reference and that the Act
3 actually, it appears to me in the addition bullets
4 that you had, actually provides for some additional
5 mechanisms to dispose of NARM that would be available
6 to users. Again, I think that's a positive aspect
7 that needs to be better communicated to the community.

8 MR. CAMERON: And Barbara, quickly.

9 MS. HAMRICK: Yes, I was part of a group
10 that we also drafted proposed legislation on this
11 issue with the HPS and Scott might be able to speak to
12 this better. But the specific intent of that is just
13 as he stated that people were already disposing of
14 radium not under the LLRW scheme. So for example,
15 California could take its radium to Washington and
16 dispose. Whereas under the compact system we could
17 not. In fact, in some states, permittee or licensee
18 can dispose in RCRA facilities already radium
19 materials and so the intent of the HPS in asking to
20 keep that in was to not eliminate any avenues that
21 already existed for disposal.

22 MR. CAMERON: Okay.

23 MR. BAILEY: And OAS.

24 MS. HAMRICK: And OAS, that's correct.

25 MR. CAMERON: All right. Lynne.

1 MS. FAIROBENT: Derek, I just have a
2 slight different question and it's been so long since
3 I've focused on levels of activity in waste
4 definitions.

5 MR. WIDMAYER: That's an advantage to you.

6 MS. FAIROBENT: We'll trade afterwards. Do
7 you foresee any discrete radium sources that may fall
8 into the category of greater-than-Class-C and that
9 would not in fact fall under Part 61?

10 MR. WIDMAYER: I believe that there are
11 such a thing, yes.

12 MS. FAIROBENT: That's what I thought.

13 MR. CAMERON: Okay. I want to try to get
14 us to wrap up with some process issues here and I
15 listed some of them that were raised earlier but I
16 think it's very important. James brought this up.
17 This were some points that Scott had picked up based
18 on what Barbara had said earlier in terms of what we
19 need to do in terms of this regulatory regime.

20 It's not what NRC is proposing right now.
21 It's more of a strawman for discussion and I'm not
22 even sure what this particular point was. I would ask
23 Scott if he wanted to revisit this and get any
24 reactions from people around the table. Define
25 discrete. Change definition of byproduct material.

1 Add accelerator produced and radium to Part 20 tables
2 and regulate medical under Part 35. Do you want to
3 say anything about this?

4 MR. MOORE: Sure. In terms of formulating
5 the rule, this would be the least invasive approach to
6 coming up with a rulemaking and as far as the last
7 bullet, regulate medical under Part 35, we could go
8 into Part 35 as necessary but in a limited number of
9 places pick up in Part 35 PET and any other uses of
10 accelerator produced but make no other changes to Part
11 35.

12 We have an existing regulatory structure
13 for medical under Part 35. It seems to be working to
14 the extent that's possible with the community and I
15 think we would propose one option which is to include
16 PET and other accelerator produced material in that
17 structure to the extent possible.

18 MS. HAMRICK: And in 33 states now that's
19 the way that material is regulated already.

20 MR. CAMERON: Okay. James.

21 DR. CASE: Yeah, but Part 35 took six,
22 seven years to actually get through the rulemaking
23 process and Congress gave you 18 months to get through
24 this particular process. I think though you may want
25 to use a surgeon's approach to adjusting that. But

1 what Roy was saying seemed to be a much more broad
2 discussion of training and regulations and I think
3 it's opening up that whole kettle of fish that
4 potentially if you open up 35 which I think is beyond
5 the scope of your statutory authority again, really
6 it's more appropriate to stay in 20 than to start
7 going over into 35. I think that's probably how I
8 would say.

9 If you want to try and get through it,
10 it's not going to be physically sitting down and
11 scrawling out a regulation that's going to make this
12 a slow process. What's going to make this a slow
13 process is if you have a rule which the ink is still
14 wet in 35 but now you're going to go back to the
15 states and say, "Hey, guess what? We've just fiddled
16 around with it again" and all of the societies are
17 going to be worrying about that as well and all the
18 societies and their training regulations. I think
19 then you're going to open up a Pandora's box which
20 definitely you're not going to do in 18 months.

21 MR. MOORE: Can I be specific about what
22 I meant under regulate medical under Part 35?

23 MR. CAMERON: Yes.

24 MR. MOORE: I didn't mean add new parts to
25 Part 35. I meant under the existing parts in Part 35,

1 100, 200, essentially regulate the accelerator
2 produced under 100, 200 and any other existing parts,
3 not add new portions to Part 35.

4 MR. CAMERON: Okay. And I just want to
5 make sure that we hear from Gloria Romanelli but keep
6 in mind that we did hear two proposals that would have
7 been far-reaching today. One was Roy's let's try to
8 eliminate these, I'm calling them, dysfunctionalities.
9 And we also heard a suggestion from Ralph to be
10 creative, think out of the box. We heard another
11 perspective on that from James which is to be very
12 surgical to use his term. This is Gloria Romanelli.
13 Gloria, please tell us what your concerns are here.

14 MS. ROMANELLI: Gloria Romanelli with the
15 ACR. The only comment I wanted to make has to do with
16 process. My concern is it's 45 minutes past the
17 posted time on the notice. The people who were on the
18 conference call have been cut off. ACR's
19 representative is no longer at the table. SNM's
20 representative is no longer at the table. HPS
21 representative's is no longer at the table. What I
22 would like to do is have NRC post these questions and
23 give the societies an opportunity to provide a written
24 response if this is being seen as the medical
25 community's input into this process. I understand

1 there will be other processes during the rulemaking
2 but I feel like a lot of people aren't going to have
3 an opportunity to bring their views to the table
4 because we are past the posted cut-off time of this
5 meeting.

6 MR. CAMERON: And that's true and I think
7 that this was one opportunity. But there is a written
8 comment period that runs with this where people will
9 have an opportunity to look at the transcript.

10 MR. MOORE: I guess I can address the
11 opportunities for input. This was one opportunity and
12 we built it in actually under a very tight schedule to
13 receive input. There's also an opportunity when the
14 proposed rule goes out and we built in an opportunity
15 if the Commission agrees when the rule is with the
16 Commission to post it on the web. It remains to be
17 seen whether the Commission agrees with that.

18 You make a good point that we're past the
19 point when the meeting was set to end. I think we can
20 probably accommodate written comments until the end of
21 next week. So if anybody in the room would like to
22 provide written comments we can receive them until the
23 end of next week and we could accommodate those in our
24 rule development process. But beyond the end of next
25 week, I can't tell you that we could accommodate them

1 within the time schedule.

2 MS. HAMRICK: Who should those be sent to?

3 MR. MOORE: Those should be sent to
4 Leslie.

5 MR. DELLIGATTI: This is Mark Delligatti.
6 Those should be sent to Leslie Kerr.

7 MR. CAMERON: All right.

8 MR. MOORE: It's in the Federal Register
9 that announced the meeting.

10 MR. CAMERON: We have a few more cards
11 around the table. Lynne, you had yours.

12 MS. FAIROBENT: Yes. Scott, just on your
13 strawman for consideration and if you follow Gloria's
14 suggestion perhaps of posting some questions on the
15 Medical users tool kit by the end of this week, then
16 people can respond. I would not overlook the fact
17 that regardless of what may be done in Part 35 there
18 are considerations that we have to look at in Part 30
19 and Part 32 as well.

20 MR. MOORE: That's a good point and one
21 thing we've been thinking of is there are couple
22 things we didn't touch on in this meeting. One is
23 security issues and another is industrial issues.
24 Certainly, there are issues like cobalt-57. There are
25 industrial devices out there and the rule will have to

1 pick up those issues as well.

2 MS. FAIROBENT: Yes, and my concern is in
3 Part 32 where you regulate the suppliers for the
4 pharmaceuticals.

5 MR. MOORE: That's correct.

6 MS. FAIROBENT: I just don't want to lose
7 sight that from a user's standpoint Part 35 is where
8 the regulations will primarily, I think, be adjusted
9 to include a broader definition of byproduct. But I
10 don't want to lose sight that there are other parts in
11 the Part 30 chain that also need to be looked at and
12 modified consistent with whatever the decisions are
13 down the pike.

14 MR. MOORE: Great point.

15 MR. CAMERON: Okay. And Ralph and Felix.

16 MR. LIETO: A couple of points and
17 questions. I wanted to assure Dr. Case that the ACMUI
18 has no intention of looking at training experience in
19 the future. So that rest assured, that we don't want
20 to make changes there although it will stay in Part
21 35.

22 One of the points though is that I think
23 there are going to have to be made, a lot of specific
24 changes will have to be made in Part 35 to incorporate
25 some of the NARM aspects for the nonagreement states.

1 One thing just shooting from the hip here has to do
2 with cobalt-57 sources which are relatively large
3 radioactive sources if you will and there are multiple
4 numbers of those used for QC purposes in nuclear
5 medicine. So there may be a need of some aspect of
6 Part 35 needing to be adjusted to make that more
7 flexible for nonagreement states.

8 One question I had also to the
9 conscientious subject about when would the transcript
10 be available for this. Do you have a time frame for
11 that? I'm just wondering with this short -- I'm just
12 thinking that people might want to take a look at that
13 to see where they might need to make comments on it
14 and that was just a thought.

15 MR. MOORE: The transcript itself I think
16 we can get it up on the web probably next week. I
17 think we get it back within three to five days and
18 then we can get it up on the web within a couple days
19 after that.

20 MR. CAMERON: I'm looking at Lindsey and
21 our contract, our delivery on this is three days.
22 Okay. Good. So we can get that up on the web so that
23 if people wanted to look at that and make additional
24 comments for the period of time for anything but
25 especially the period of time when their

1 representative had to leave they could do that.

2 MR. MOORE: And then next week we would
3 need comments by in writing.

4 MR. CAMERON: All right. Good. Mark, I'm
5 sorry.

6 MR. DELLIGATTI: Mark Delligatti. I
7 appreciate your interest in seeing the transcript but
8 please if there's anything you think you may have even
9 talked about fully today send it to us in writing if
10 you have any concern because the clock is ticking and
11 Congress doesn't allow us to stop the clock. So
12 please if you have anything that you want to get to
13 us, if you thought of specific parts of the regs for
14 instance that you think we need to look at to change,
15 get that information to us because whether it's in the
16 transcript or we get it from you separately, we can
17 only use it if we get it by the end of next week.

18 MR. CAMERON: All right. Felix.

19 MR. KILLAR: Actually, Lynne picked up a
20 couple points I thought I wanted to mention. You need
21 to look at Parts 30 and 32 as well. But I also think
22 you need to look at Part 40 as well because it's the
23 base for source material. So you need to go beyond
24 the 30 parts but you need to look at 40 as well and no
25 one has mentioned Part 40.

1 MR. CAMERON: Thanks, Felix. Scott.

2 MR. KIRK: Thank you. Scott Kirk. Ruth
3 McBurney left but she asked for me to make a statement
4 for the Health Physics Society and as Barbara has
5 mentioned, the Health Physics Society and the
6 Organizations of Agreement States did draft some model
7 legislation on this issue as well that we had
8 submitted to Congress. One of the key things that we
9 didn't mention which Barbara noted was is that we
10 thought that waste disposal options, what we looked at
11 was opening the doors and one of the key things that's
12 missing here is what we had proposed is an equivalency
13 statement for 11(e)2 to allow these new materials,
14 11(e)3 and 4 materials so that it would open up the
15 use of uranium mill tailing sites for disposal of
16 radium. That's also consistent with the suggested
17 state regulations under Part N. So we think there's
18 a very good nexus here to take another look at
19 disposals of some of these radium maybe at the mill
20 tailing sites.

21 One of the things that was missing in the
22 presentation was there's another option for disposal
23 and that was at any site as you had mentioned, Derek,
24 that NRC had licensed but it also says for any
25 facility that's safe. So we think that further opens

1 up the door. But because there wasn't that
2 equivalency statement that we had proposed, the issue
3 that's still on the table is that DOE hasn't yet
4 agreed to take title to those sites at the end of the
5 life of those facilities.

6 So what we would really encourage is for
7 NRC to begin some deliberations with DOE and maybe
8 begin some development of a memorandum of
9 understanding to develop some generic waste acceptance
10 criteria specifically for the radium but maybe other
11 radionuclides that would go hand-in-hand with the
12 suggested Part N regulations because we think if that
13 MOU is signed and agreed to by DOE and NRC then it
14 will also address that issue. That's my comment.

15 MR. MOORE: Scott. As I understand it
16 though and you and I talked during one of the breaks,
17 you don't envision that any regulatory change is
18 needed for that. Right? You envision that as an
19 implementation issue that only an agreement between
20 NRC and DOE would be needed.

21 MR. KIRK: Correct. And there's currently
22 some deliberations right now. I think the National
23 Mining Association and the Fuel Cycles Facility Forum,
24 they submitted a white paper to move this forward as
25 well and there's also an NRC policy that talks about

1 disposals of non-11(e)2 materials. So there's already
2 a box to carry this on but again we just wanted to
3 make the point that we think now is the time for NRC
4 to actually begin maybe development of an MOU with DOE
5 to move this further along and again that would be an
6 implementation issue.

7 MR. CAMERON: Great. And thanks for
8 backing up on Health Physics. Anybody else? Okay.
9 This is the EPA.

10 MR. SETLOW: I'll try and keep this brief.
11 I hadn't expected to be talking about this. Loren
12 Setlow with Radiation Protection Division of EPA. In
13 regards to the last set of comments, the use of radium
14 mill tailing impoundments, EPA had established the
15 standards for materials to be disposed in these
16 facilities and they were subsequently adopted by NRC
17 and then certainly DOE for their acceptance ultimately
18 as the final repositor and licensee for these
19 facilities.

20 One of the problems about using these
21 facilities for additional disposal of radium is that
22 because of the high amounts of radon it may result in
23 if there is too much of this material the premature
24 closure of a number of the facilities because they may
25 wind up exceeding the radon standards that have

1 already been promulgated of 40 CFR 192 and then
2 subsequently in the NRC standards.

3 So this is a very important issue and in
4 addition to that, the Generic Environment Impact
5 Statement which was developed by the NRC for the
6 uranium mill tailing impoundments and their regulation
7 did not include in their premise the acceptance of
8 materials such as these. So we had provided letters
9 to NRC previously in response to National Mining
10 Association proposals to expand the use of these
11 facilities for decommissioning materials and other
12 low-level waste and so on. To say that if in fact
13 this was the ultimate intention of NRC to expand these
14 uses, then we believe that this would also require an
15 additional evaluation under NEPA because of a change
16 in the original intent for use of these facilities
17 that had undergone a larger public review and a larger
18 impact statement. So we've been on record on that
19 previously.

20 MR. CAMERON: Okay. And I just need to
21 ask Scott and Derek whether there's something that
22 needs to be clarified here. In Scott's comments, it
23 seemed like he was referring to a broader set of
24 disposal options than those that you presented, Derek,
25 that are in the Act and I don't know if that's true or

1 not. But do we need to go back? Do you need to
2 clarify anything about what is actually permitted
3 under the Act?

4 MR. MOORE: As I understand it, what Scott
5 has suggested is that the Act gives some broader
6 disposal options as Scott reads the Act and those
7 could be put in place as Scott sees it through an
8 agreement between NRC and DOE. But it doesn't require
9 regulatory change. So I've encouraged Scott to talk
10 to the Division of Waste Management Environmental
11 Protection.

12 MR. CAMERON: Okay. That's great.

13 MR. MOORE: But as far as what we need to
14 do in the rule space and development of the rule, it
15 doesn't require us to make any regulatory changes and
16 I don't know what DOE's position on it is and frankly,
17 I'm not sure what NRC's position is on that within the
18 Act itself either.

19 MR. CAMERON: Okay. Final comment on this
20 from Ed and I just want to review some of your process
21 suggestions. Ed.

22 MR. BAILEY: The statement about adding
23 other material, if I'm not mistaken the impoundments
24 are designed and evaluated with a certain source term.
25 So whether that source term comes in as dirt from a

1 rare earth processing facility or uranium mill, as
2 long as the source term is not exceeded, there
3 shouldn't be a problem.

4 Now some of the other things, and I would
5 suggest that if you looked at the oil and gas industry
6 thing, all the studies I have seen indicate in fact
7 that the radium is bound up tighter in those than it
8 is in any of the mill tailings and so is the radon.
9 So there shouldn't be a real problem. That's just a
10 comment on why I don't think you have to go back
11 through the whole process. But maybe you do.

12 MR. CAMERON: Okay. There were a number
13 of process points made today. One was the transition
14 issue but I think Mary raised that right off the bat.
15 And as part of that transition, I know that Sally and
16 others were concerned about what are the implications
17 for nonagreement states.

18 We heard that people would like to have
19 earlier access to draft rule language somehow. Leslie
20 pointed out that while the Commission is reviewing
21 this it is going to be on the web so that people can
22 get prepared for it for commenting if the Commission
23 agrees to it.

24 We heard that the comment period should be
25 60 to 90 days. We're presently contemplating a 45-day

1 comment period.

2 And Roy Brown and others brought up the
3 collaborative process in terms of identifying and
4 working with differences in state regulations. Scott,
5 I know that you have some concerns about how much we
6 can do along those lines because of Scheduler and
7 perhaps Federal Advisory Committee Act concerns. But
8 again, all comments on this. I know we are over time.
9 Do we want to stop now or do you want to see if
10 there's any final comments on any of these process
11 issues?

12 MR. MOORE: I think that's up to the
13 attendees. I have some specific information about how
14 to get information into us, but I think that's up to
15 you.

16 MR. CAMERON: Well, let's hear from Maria
17 and then why don't we turn it over to you.

18 DR. KELLY: I just was taken by the number
19 of people who said that a lot of these definitions are
20 used in a number of different agencies and I would
21 just want to say that I think that should be part of
22 the transition is having all the agencies using the
23 same language and definitions so you're not held to
24 regulations that are interpreted differently by
25 different regs.

1 MR. CAMERON: Okay. Thanks, Maria.
2 Anybody else? I think we're ready to wrap up. Go
3 ahead, Mary.

4 DR. MOORE: Just as an overview comment,
5 with the objective in mind. and I understand you are
6 requesting guidance and concerns, I keep coming back
7 to the kiss principle that the simpler it is the
8 cleaner it is, the greater the probability of quality,
9 enhanced safety, lower cost and improved efficiency so
10 there are no delays keeps coming to the forefront.

11 I think and I may be speaking heresy here
12 but I think the limitations that the Act has put on
13 this operation is one of the things that is the
14 biggest roadblock to having streamlined easy to
15 enhance compliance. But you have to play the cards
16 you were dealt and I understand that and in trying to
17 work within that tight frame as long as the overview
18 of everybody and I'm sure it is by all the heads that
19 are bobbing that everybody is trying to get to the
20 same goal. I applaud you for that and I just ask you
21 to continue your efforts in that regard. Thanks.

22 MR. CAMERON: And, Scott, do you want to
23 close us out. I just would thank everybody for their
24 comments and for following the groundrules. I'll turn
25 it over to Scott for any final comments.

1 MR. MOORE: Sure. I'd ask first that if
2 you do have any written comments you submit them in
3 writing by the end of next week and that you also call
4 Leslie and inform her that you've submitted written
5 comments and that you also email the written comments
6 to her at this address so that we have them
7 immediately. There is Leslie's telephone number and
8 her email address.

9 I'd like to remind everybody about the
10 meeting feedback forms if you could submit them if you
11 wish as well.

12 I guess the final comments that I'd add
13 are the task before us in the rulemaking group is a
14 monumental one. We essentially have about seven to
15 eight weeks to write a proposed rule. With your input
16 at the end of next week, we'll have six and a half to
17 seven weeks to write the proposed rule and get it out
18 to the agreement states by January 3rd.

19 We're actually getting it out to the
20 agreement states after the Christmas holidays so that
21 they won't be getting it during the Christmas holiday
22 season and then they have to turn it around very fast
23 as well. They're only getting the set limit of 30
24 days which makes it very tight for them.

25 So it's a very daunting task for us and

1 them. Our staffs are going to have to work very hard
2 to do it. But we're working to the legislative
3 mandate which is not negotiable. Congress gave us
4 that date and we've worked a schedule that will work
5 to it and we will meet it. We're trying to build
6 opportunities within that schedule for dialogue with
7 the key stakeholders such as we've had today.

8 I think what we've heard today has been
9 very helpful to us. It's given us a lot of input. We
10 have to figure out how to incorporate that into the
11 proposed rule itself and we'll look at what you all
12 submit to us over the next week and a half to feed it
13 into the rule. We have a working group working on the
14 rule. We have a steering group that will advise us as
15 well. And we'll get input from the states and other,
16 the ACMUI, along the way. So we really appreciate the
17 input we've received. Thanks.

18 MR. CAMERON: And we thank our ACRS/ACNW
19 help over there. He did a great job and thank you to
20 Lindsey also. Did someone leave their glasses? I
21 thought maybe Dr. Dillehay had left his glasses.
22 Anyway, thanks for coming all this way and talking.
23 Off the record.

24 (Whereupon, at 5:09 p.m., the above-
25 entitled matter was concluded.)

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