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UNITED STATES

NUCLEAR REGULATORY COMMISSION

Organization of Agreement States Meeting

October 3, 2000

Double Tree Suites

181 Church Street

Charleston, SC 29401

P R O C E E D I N G S

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EDWARD BAILEY: We are going to try something new and we will see how it goes. It is sort of a thing that the conference used a couple of years ago. When they suggested it I thought it was the most ridiculous damn thing that I had ever heard. I was simply amazed at how well it went off with everybody getting up and saying two, or three minutes, or whatever. They went through every state in the conference. I thought that went off so well that we are going to try to do that with the different working groups.

So, to start off what I have alluded to, I am going to read off the name of the working group and, if there is somebody here from that working group, just stand up and tell us how you are going to meet this year or in what decade. We just want a little summary of what is going on.

I want to apologize to NRC, because I am not going to read all of the NRC people's names. We would be here all afternoon just doing that. These will be put out. Your name will be prominently displayed. The main reason that I am not going to do it is that I can't pronounce some of them.

So, the first one is Control of Solid Materials. If there is someone here from NRC who would like to, stand up and

1 give a few minutes on it.

2 CHIP CAMERON: Control of Solid Materials Working
3 Group. Steve?

4 STEVE COLLINS: I am not from NRC.

5 CHIP CAMERON: Do you want a state person? Is there
6 any preference?

7 EDWARD BAILEY: I didn't see a state person.

8 CHIP CAMERON: Steve Collins?

9 STEVE COLLINS: Steve Collins, Illinois. I will
10 address it, because -- I am not on the working group, but I am
11 on the steering committee that looks at everything that the
12 working group does. That group did a whole lot. Basically
13 they are going back and are going to have to redo a part of it
14 under contract, because of a conflict of interest on the part
15 of the contractor. To the best of my knowledge, there wasn't
16 anything technically wrong found with the contractor's work,
17 but the conflict of interest problem is going to cause them to
18 have to redo that.

19 The work is continuing. The commission has directed
20 the NRC staff to continue research, so that when the process
21 does get going again there will be additional research
22 available. They are continuing this process for other

1 materials, other than the four that were originally looked at.

2 EDWARD BAILEY: Thank you. And, I apologize to you,
3 Steve, because I didn't put those two together. Steve Collins
4 is the state person on the Control of Solid Materials Steering
5 Group. The next one that I have is Sealed Sources and Devices.
6 Actually we are -- the states are really well represented on
7 that. Will Wright from Arizona has retired --

8 KATHY ALLEN: Joe Klinger.

9 EDWARD BAILEY: Joe Klinger, Illinois; Clayton Brant,
10 New York; and Walter, North Carolina. Klinger is here and he
11 has not spoken much, so --

12 CHIP CAMERON: Joe?

13 JOE KLINGER: Thank you, Ed. Joe Klinger, state of
14 Illinois. I am a member of this S. S. & D. group. I went to
15 one meeting. Gib Vincent went to the second meeting and that
16 is the meeting that really did most of the work.

17 So, what is the scoop all about? A couple of years
18 ago, up in New Hampshire, I gave a presentation. It was after
19 several states went through the IMFET process and there was a
20 less than pleasurable experience in the S. S. & D. area. I
21 remember North Carolina, Texas, Illinois -- several of us. It
22 was not pretty.

1 So, what we did -- NRC took it to heart and we put
2 together this working group. In April of 1999, we got together
3 and we decided what we wanted to work on. Some of the things
4 that we wanted to work on were the S. S. & D. reviewer
5 qualifications, the second S. S. & D. reviewer, the concurrent
6 review issue -- you know, was that a complete review? And
7 various changes to the management directive 5.6 in the area of
8 S. S. & D.'s.

9 In July of 1999, Gib Vincent, from my staff, went to
10 a meeting with somebody from North Carolina, the NRC staff, and
11 I think that Bill Wright was there as well. They went through
12 the whole process. They -- they spent two days and came up
13 with recommendations. Apparently their recommendations just
14 kind of languished around a while. I talked to Don Cool about
15 this this morning. He said that it kind of went into a black
16 hole for a while and then he resurrected it.

17 So, they came up with this report and it went to MMSS
18 management -- Don Cool, correct me if I am wrong, but he wasn't
19 really comfortable with some of the recommendations. Where we
20 thought that it was too rigid before -- if there was one hit on
21 one S. S. & D. review it was unsatisfactory. And so, we wanted
22 to put some flexibility in it. So, Don had a problem. He

1 didn't agree with it.

2 So, what does he do with it? In the old NRC, before
3 the alliance, before -- you know, the old way of doing it, it
4 would have come back to the group -- said I don't agree, fix
5 it. What he has done this time, he has gone to the OAS
6 Executive Committee and said we have unresolved issues. Would
7 you please take a look at this? In sixty days give us your
8 comments. That is where we are on that issue.

9 EDWARD BAILEY: Okay. Any questions for Joe? Okay.
10 Thank you. The next one that I have is Jurisdictions/Source
11 Material. And, Ken Weaver from Colorado is our person working
12 on that. Jake, you have something to report, right? You all
13 have been busy.

14 JAKE JACOBI: Just two things. One is that, I think
15 that it was last week that, they had their first meeting. And,
16 it really is a majority of the organizations, maybe Paul can
17 help me, but -- besides NRC there is DOE, EPA, OSHA, and just
18 about any other agency that might be involved in either worker
19 safety or environmental issues regarding source material.

20 The issue is, I think that it was pretty well -- if
21 any of you didn't get the Rad Rap or are not on it, let me know
22 and I will see that you get a copy. The issue is that there

1 are certain levels of source material that are not regulated
2 now, but they are a hazard. The question is who gets control,
3 who should be controlling, and should we be controlling those
4 quantities of material below .05 percent.

5 It really gets quite complicated. If it is a worker
6 issue and no environment, do you turn it over to OSHA? Should
7 the states be involved? To complicate the issue just one step
8 forward, many many times, it looks like, when you are dealing
9 with the source materials down at the those levels you have
10 Radium. That is a bigger hazard and maybe we should be
11 involved anyway. This is the issue that they are trying to
12 address.

13 I know that Ken has been sending out a little
14 information and he asked me to have you all please respond when
15 it talks about where we should go, and how we should could go.
16 Out of all these agencies there is only one state rep.

17 EDWARD BAILEY: I can give those agencies. They are
18 EPA, OSHA, DOE, DOT, DOI, and the U.S. Army Corps of Engineers.
19 So, we may need to get some more people in that working group
20 in case they decide to vote on something.

21 CHIP CAMERON: Just one clarification, some of these
22 issues that are being talked about, Trish Holahan is going to

1 be covering during her presentation. Maybe she will be a
2 resource to answer questions about it.

3 EDWARD BAILEY: When we looked at this we said, okay
4 -- traditionally or historically NRC has gotten up and had one.
5 So, we decided, hey, we have some people that are working on
6 it. Let's let them have their few brief minutes of fame and
7 glory. We know that there is enough fame, blame, and shame to
8 go around. Okay. The next one is Malancroft's Lessons Learned
9 and Bill Kirk from Pennsylvania is, I guess probably the CRCPD
10 person on that. I don't remember.

11 BILL KIRK: We shifted that off. I wasn't able to
12 take that, participate in that. So we shifted it off to Paul
13 Fesser. He is not here, so I don't know exactly what has
14 happened on that.

15 EDWARD BAILEY: Okay. Maybe --

16 CHIP CAMERON: Any --

17 EDWARD BAILEY: -- Trish can in her presentation --
18 are you planning to mention it?

19 PATRICIA HOLAHAN: Actually I wasn't going to on that
20 one, but maybe Don --

21 CHIP CAMERON: Don, do you want to give us --

22 EDWARD BAILEY: Maybe an over feel?

1 DR. DON COOL: Five seconds on this. Cindy Peterson,
2 from our region three office, is actually leading up this
3 particular effort. Most of you are probably aware that this
4 spring Malancroft's Maryland Heights Manufacturing Facility had
5 a rather serious extremity overexposure. One of the workers on
6 their production line actually picked up and held in his
7 fingers, for some twenty plus seconds, a nineteen curie
8 Malitech generator tube, not inside the shield, the generator.

9 We did an AIT and are continuing the process of
10 inspection and potential enforcement activities with the
11 licensee. Part of this was also, as we looked at this, to go
12 back and ask ourselves what pieces of the program were or were
13 not working. Did we have the right focus, in terms of safety,
14 the way we were doing the inspections.?

15 There were also some issues related to jurisdiction
16 because the Malancroft facility also has a number of
17 accelerators. One of several of the outcomes of this was that
18 there were additional over exposures identified, some of which
19 were both non- ADA and ADA materials.

20 So, there is an effort ongoing now to see whether we
21 had the right focus, if we were looking at the right things for
22 manufacturing, and to try to help define some of these

1 jurisdictional issues. This will go, this coming spring, into
2 a broader look at our whole inspection and licensing program,
3 which I understand some folks were also being signed up for.

4 EDWARD BAILEY: Just one more example of if you are
5 an Agreement State you look at the whole picture. I strongly
6 encourage NRC to become an Agreement State.

7 Instead of trying to get these posted, I am just
8 going to pass them around and let you all look at them, that
9 way everyone will get a chance to look at them.

10 The Part 40 Rule Making Activity Working Group. We
11 have Bill Sinclair from Utah. This is the one that is going to
12 take the big overview.

13 BILL SINCLAIR: I think that Chris is going to talk
14 about this. We actually haven't had a meeting yet, but there
15 is one scheduled October 17th and 18th, I believe. So, we are
16 getting ready to start those discussions. As those discussions
17 proceed we will be getting a lot of information out.

18 EDWARD BAILEY: Great. The next on is Event
19 Reporting and we have two state people on it, Robert, and
20 somebody help me, Desaro. In the south, we would make that
21 three to five syllables. Also we have Helen Watkins from
22 Texas. Anybody from the states have any further update on

1 that? Is this going to be in one of the updates from NRC?

2 KATHY ALLEN: ED?

3 EDWARD BAILEY: Oh, Linda McClane, from NRC Region
4 Four.

5 LINDA MCCLANE: Thank you. I have some information
6 that I received from Kevin Graham. He is the co-chair of the
7 working group and Bob Dansero, from the New York Department of
8 Health is the other co-chair.

9 The working group has met three times so far. Our
10 charter was just approved on September 6th. There was a delay
11 in the approval of the charter, because there was some possible
12 leakage between the National Materials Working Group and the
13 Event Reporting Working Group. So, there were some delays to
14 the petition for our charter, but we did get it approved on
15 September 6th.

16 The other membership, as you mentioned, is Helen
17 Watkins. We have Kevin Shane, who is sitting next to me.
18 Research and our incident response center is also in. I am the
19 regional representative. Helen Watkins represents the CRCPD.

20 We are looking at the Nuclear Material Events
21 Database, the Agreement State reporting requirements, and
22 elements of a generic issues program. You probably have all

1 received a questionnaire. We sent them out to all the states
2 and all four regions. We received twenty-one responses from
3 the states and all four regions sent their responses in. I am
4 not prepared to talk about what we found from that yet, but we
5 will be putting that information in the report.

6 We have five task. I won't go over them all. I am
7 sure that we will talk about it later. Our schedule is pretty
8 quick. We are going to have the final report that will be out
9 in March 2001. There is still a lot to look at.

10 I have four questions that I wanted to read, so that
11 you can think about them. Things that I think you might be
12 able to help us on, if I can find them. Some of these are some
13 statistic areas that we were talking about. Should NRC delay
14 posting event reports on the web site? Should NRC have one
15 agency Y tracking system? Should MNAD be available to the
16 public? Should we share event data with IAEA database? Those
17 are just some of the issues that we are going to be looking at.
18 I know that some of the states have been interested and are
19 apposed.

20 EDWARD BAILEY: That reminds me. I told Kevin that I
21 would encourage the eleven states to respond to the
22 questionnaire. If we go forward on this alliance, we are going

1 to have to pitch in. So, I encourage all of you that have not
2 returned the questionnaire to do so. Let's make it a hundred
3 percent. We got a hundred percent on the definition of
4 radioactive material and I think that we should strive to have
5 a hundred percent of the states respond.

6 NRC has a little more leverage over the regions than
7 they have over us. That is, they got all four regions to
8 respond, so we can all participate in this. Okay? And, if you
9 don't know if you responded -- somewhere I have a list of those
10 who have not responded. I will try to remember to bring it
11 down tomorrow.

12 The next one, there are a series of them on new regs
13 Volume ten, Volume twelve. I think that I have a CP for volume
14 fourteen, which is has Richard Penlight from Louisiana and
15 David Fogel from Texas. I don't think that either one of them
16 are here. So, we will wait to get an update from NRC, or if
17 someone from NRC wants to tackle that.

18 CHIP CAMERON: Does anybody want to say anything
19 about that?

20 EDWARD BAILEY: Okay. Volume fifteen, sixteen,
21 seventeen, and eighteen are all NRC people, as are nineteen and
22 twenty. And, there is a new reg coming out for XXX rated

1 movies. This is going to be a quadruple X rated new reg. So,
2 I am not sure what the expected date is on that.

3 Generally Licensed Devices. There are two, two
4 people, John Fenney from New Jersey and Carl Trump from
5 Maryland. Does anybody want to address that one?

6 Part 35 Medical. This has been around almost as long
7 as the Agreement States, I think. David Walter -- actually he
8 was in Kindergarten when he was first -- so, David if you want
9 --

10 DAVID WALTER: This is David Walter from Alabama. I
11 gave up counting how many meetings we have had. It has been
12 over three years since we had our first meeting in August of
13 1997. We met last in 1999. Officially there has been no
14 change since March.

15 We took -- I want to give a little aside to you on
16 this. I know that a number of the states are waiting for this
17 rule to come out and be finalized. We are all aware of the
18 fact that the affirmation vote has not yet come. I am sure
19 that Donald has more to talk about in his presentation about
20 that, but the SR6 committee for Part D did meet last week.

21 We have been through two comment periods. We were
22 going through the peer review. I would like to let you guys

1 know that I am very proud that we got almost two hundred, if
2 not more, on this peer review. In three days, there's one
3 hundred and eighteen sections to this rule, our group got
4 through all one hundred and eighteen sections and all the
5 comments. We were able to finish up getting answers for all of
6 that.

7 Now it is just a matter of compilation and a couple
8 of additional things that needed to be added, not right now, in
9 the NRC rule. We let them know about it as well to see if they
10 wanted to include that. It had to do with cadavers that happen
11 to have radioactive materials still in them. What do you do as
12 a licensee, if a patient checks themselves out and they don't
13 meet the criteria for release yet? I am hoping that we will be
14 able to get things lined up, but I am not going to do anything
15 more to our part until a final decision is made by the NRC.

16 EDWARD BAILEY: One comment. We have had several
17 patients incinerated with diagnostic quantities of radioactive
18 materials, some of which were hospitalized and some of which
19 weren't. L.A. County has been involved in several surveys and
20 they will contaminate the crematorium, and the second person to
21 be cremated after them, and on and on.

22 Who is responsible for that person then? We have

1 gotten into some real interesting legal battles, particularly
2 where hospitals have had people with diagnostic scans and then
3 die. This is particularly occurring in Gallium and so forth.
4 So, we have had them remove organs, save those organs, and all
5 kinds of things. It is a good problem to work with.

6 PEARCE O'KELLEY: Ed, can I make a comment?

7 EDWARD BAILEY: Sure.

8 PEARCE O'KELLEY: When I was at Oak Ridge, in a five
9 week course, one of the questions was: what do you do when
10 somebody dies and they are contaminated? Well, the answer from
11 the audience was bury them deeper. So, I just thought that I
12 would let you all know that.

13 EDWARD BAILEY: We have a rather large Jewish medical
14 center in California, Cedars-Sinai, and they have had one
15 patient die there. They were able to convince the family to --
16 only one. Right. It is the hospital where movie stars go to
17 have babies and die. But anyway, they have raised very
18 interesting questions to us in regards to burial. If you are
19 an Orthodox Jew, you must be buried before sundown. If you
20 don't think that gives us a little bit of a pucker, because
21 Cedars-Sinai is a pretty big hospital. One of these days, we
22 are going to have to face that issue. Okay. I have taken more

1 time than I should.

2 The next one is Part 35 Medical Steering Group. Tom
3 and Bill have been on that steering group for a while.

4 TOM HILL: I have nothing to add to what David said a
5 minute ago in the working group.

6 EDWARD BAILEY: Then there is the Part 35 Guidance
7 Document with Robert from Ohio. Okay. 10CFR 30.20 Proposed.
8 David King, South Carolina? I am sorry. I am going to screw
9 up your name, Sulifu Dakubu, Massachusetts, William Hutchinson,
10 Ohio, and additional membership to be determined. I presume
11 since it is proposed that they haven't had a meeting yet.

12 Integrated Materials/MPET Lessons Learned, a proposed
13 group, Terry Fessy, Washington, Bill Sole, Texas, and
14 additional membership to be determined. I don't think that
15 they have met yet.

16 And, the ASNT Radiography Certification Process, Dan
17 Endal, Texas, Charles Guzman, Illinois, George Giles, Iowa.

18 Does anyone -- Generic Event Assessment Proposed?
19 There will be an Agreement State representative to be named and
20 a CRCPD person to be named.

21 Risk Assessment and Management Proposed. Agreement
22 State rep to be determined. National Materials Steering Group,

1 Bob Hallisie and I inherited that job. Then the National
2 Materials Program, I think that you have heard from them today.
3 So, I don't think we have to go into that again. That will
4 conclude the working groups. Yes, Steve?

5 STEVE COLLINS: Steve Collins, Illinois. I have
6 worked with Skip Guzman and Jan Endal a little bit on the ASNT
7 Certification of Radiographers. Where that stands right now is
8 a request for information has been sent to ASNT, saying that we
9 need this following information before we can finish evaluating
10 ASNT's request for recognition of their x-ray only exam and
11 their combination exam under 1034 appendix -- ah, the three
12 appendi that apply. They have already been recognized and have
13 reciprocity with all of the other certifying entities, but for
14 x-ray NRC has no authority.

15 So, for the combination test, basically they haven't
16 done the cyclometric stuff or they haven't submitted that
17 information yet. You have got to give a certain number of
18 tests and have enough people to answer each question before you
19 have the data to submit it. The problem is that they haven't
20 submitted the data yet. I am not sure that they have enough to
21 submit for that evaluation to be done by this committee.

22 Therefore, there is no basis on which the other

1 certifying entities can grant reciprocity. So, they have been
2 giving those exams and the other certifying entities are
3 getting to the point where people have took the ASNT x-ray exam
4 and they are going to be saying that is too bad. You are going
5 to go and take the Texas test from us, because we won't grant
6 reciprocity on that other one, because there is no basis to
7 grant reciprocity yet. That is the issue that is holding it
8 up.

9 Another thing that we just identified that all of you
10 need to look at is your regulations. Once they submit this
11 information, the G-34 group will got through that evaluation
12 process and probably provide a comparable level. When they do
13 that some of you in your regulations, or maybe all of you, may
14 have something that says you will recognize anyone who gives
15 the test through the conference, other words the text test, or
16 you will recognize anyone who has been approved by NRC. Your
17 regulations currently would exclude ASNT, even though the G-34
18 had approved them.

19 EDWARD BAILEY: And your point is?

20 STEVE COLLINS: My point is, Illinois and Jan Endal
21 are already working on some model language to try to solve this
22 for you. Once this letter comes out or maybe before hand, we

1 can give you some model rules regulations that will fix your
2 rules. So, that your rules will match and grant ASNT what they
3 really need once they have approval.

4 EDWARD BAILEY: Thank you very much, Steve. And, I
5 want to thank all of you and remind you that at this break we
6 will have the poster on licensing states up. I encourage all
7 of you to go be and take a look at it.

8 CHIP CAMERON: Do you want Bob to --

9 EDWARD BAILEY: Sure. Let Bob --

10 CHIP CAMERON: Okay. This is Bob Gallagher.

11 BOB GALLAGHER: What I have brought with me today is
12 just the activities of the G-20 or the licensing state
13 designation for the conference. It is a presentation that was
14 presented down in Tampa. It was brought here in the hopes that
15 of the thirty- one states that are here at the meeting, only
16 fourteen are currently licensing states and we have one review
17 state. It is an effort to market the licensing state concept
18 to this group.

19 CHIP CAMERON: Okay. Thanks, Bob. At 3:15 be back
20 from the break.

21 (Recess.)

22 CHIP CAMERON: Our next session is going to be on

1 Medical Rules. There are three different subjects here. One
2 is going to be covered by Don Cool. The next one is going to
3 be with Kathy Allen. She is going to put a chart up on
4 Intervascular Graphic Therapy. There are going to be some
5 questions for you. Then we are going to have Ruth McBirnie do
6 the PET discussion.

7 At any rate, let's go to Don. I think that we all
8 know that he is the Division Director of the Division of
9 Industrial and Medical Nuclear Safety at NRC. I will turn it
10 over to him and then we will have questions.

11 DONALD COOL: I am hoping that all of you can hear.
12 Let's go ahead to the first slide that means anything here.
13 Today, I am going to speak briefly to you on a hodge podge of
14 different things related to medical type activities. We will
15 touch briefly on what is going on with Part 35, although David
16 really told you most of it already. We will talk a little
17 about some of the activities that are related to implementation
18 that we are starting to think about and look forward to. In
19 anticipation that Aubrey was going to bring it up, we will talk
20 a little bit about 45CFR Part 61 and the whole question of what
21 you have got to report and where you have to report it.

22 Let's go on to some of the key issues, just to remind

1 you very briefly. In Part 35 there were a number of issues
2 that seemed to float up to the top and there were various
3 discussions back and forth. Notifications and reporting, given
4 the time that we have today, I am not going to try to go into
5 the details of how the commission came out on that. The staff
6 provided to the commission in February, seemingly a long, long
7 time ago -- it was actually -- he gave it to them in about
8 August of last year. In February of this year, the commission
9 said, okay. We are comfortable with the rule text that you
10 have put together. Please come together and provide the whole
11 complete package that has to go along with the administrative
12 procedure act rule making.

13 The staff sensitivity commission at the end of May,
14 00118, which was the entire package, I think that at least
15 momentarily the record for the size. It was literally along
16 the lines of this thick. It included all the statements of
17 consideration, some six hundred plus pages. The rule text
18 itself, when you print it out in that double space, the way you
19 are suppose to send it for the federal register, that is a
20 hundred plus pages.

21 The regulatory analysis plus the volume of the draft
22 final new reg support of implementation guides, all of that

1 went off to the commission. The commissioners spent a great
2 deal of time examining that. They have all submitted their
3 initial verdict to the office of the secretary. Everybody was
4 happily running around getting ready for an acclamation
5 session, which is one where the commissioners get together in a
6 public meeting. They canceled that on the morning of the
7 meeting. There are a couple of small issues that they are
8 trying to resolve.

9 They do not go to the basic text or any of the
10 fundamental issues that have been developing all along. But
11 rather there are some questions related to the embryo/fetus.
12 There were some questions between the commissioners themselves.
13 Those for various reasons, not the least of which have been
14 travel issues, have not been resolved. So, we are waiting.
15 The staff is waiting, just as everybody else is waiting with
16 all sorts of eagerness, in hopes that someday this will
17 actually come out.

18 Now, when the commission votes, that doesn't mean
19 that it is going to show up in the Federal Register the
20 following week. What it means is that the staff will actually
21 get to prepare the package and send it down to the office of
22 management and budget for the review of the record keeping and

1 reforming part of it. Assume that they are going to take their
2 full ninety days before they will approve the record keeping.
3 They did not review the proposed rule. The NRC can not legally
4 publish the regulation until it has been approved by OMB. So,
5 even assuming that we have an affirmation vote within the next
6 couple of weeks, I would not expect a rule to actually be
7 published in the Federal Register until sometime early next
8 year, simply because of logistic steps that are necessary and
9 of course the steps to actually have it become affective and do
10 the implementation.

11 The other piece that I have got, we have been going
12 along and moving with a medical policy statement that also
13 would go to the commission at the same time. The commission in
14 fact approved that. That has now been published in the Federal
15 Register.

16 Now, I will move on to the implementation issue.
17 This is sort of, where are we going from here. First thing
18 that I want to look at is a pilot program that we have just
19 started within the inspection arena intended to focus upon
20 safety, being more risk informed, performance based. Yes,
21 certainly we are interested in compliance with the
22 requirements.

1 But, we are trying to develop a new more focus
2 approach where we go in and we look at some performance
3 factors. How have they been doing in executing their program
4 and basically doing what a lot of the more experienced
5 inspectors do. You walk in. You walk around for a few
6 minutes. You talk to people. You have some basic data. We
7 all have experienced inspectors, who know within the first half
8 an hour if there will be significant issues and where to start
9 poking.

10 Let's move to the next slide. The mission of
11 temporary instruction to our region. That temporary
12 instruction gives them the special process to go ahead and look
13 at their performance. And then dig deeply into particular
14 areas that appear to have problems and not dig so deeply into
15 area where performance has been good and there is no indication
16 of difficulty. We are using this as a method to see if we can
17 focus our inspections. We intend to run it for about a year
18 and evaluate the results. Also, to build those results and
19 experiences into the inspections that will be done as Part 35.

20 And, as we start to build it next year, and I
21 mentioned it a few moments ago, we are working with the working
22 group a reconsideration of our whole fundamental inspection

1 program. Are we looking at the right things? Are we asking
2 the right questions? Are we looking at the things that pose a
3 risk?

4 We are moving along to implementation activities
5 related to the rule itself. The agency, of course, has a lot
6 of things that it is going to have to do in terms of doing more
7 with the activities and training for our inspectors and
8 reviewers. We need to continue to work closely with you, with
9 Dave Walter's group, to continue to move forward. There is an
10 effort which is already underway to start the process for the
11 recognition of the specialty boards, so that when it comes time
12 with an affective date, we will not have a disconnection from
13 the training. I have already sent out a number for an
14 invitation for those medical sessions that already recognized,
15 asking them if they wish to be recognized and to get basic
16 information, so that we can post those on our web site.

17 We are looking at developing communication plans,
18 going out and talking with our licensees. The agency is going
19 to be Agent Charlie and responding to questions that will
20 inevitably come up as you go through your rule and people get
21 into it. The more people that come looking, what am I actually
22 going to do when the more detailed questions start to arise

1 about our technical assistance process. You will have revise a
2 section manual chapter, activity.

3 We are going to need to be looking at some of our
4 Sealed Source and Device Certificates. One of the things that
5 we did with the regulations was move to nuisance as around on
6 the S. S. & D. registry sheet, rather than being constrained
7 with something that might have happened to have affected your
8 license position for other license. It should be much more
9 flexible. If you go look at the records in the S. S. & D. you
10 will find everything from all uses to under -- then you find
11 five lines of very specific tiny tiny fine print.

12 There are a number of those sorts of activities where
13 we are working with the manufactures and distributer in order
14 for a research sheet. This is one of the things that we will
15 get into working with those of you that have S. S. & D.
16 programs in your state, to make sure that we can all rely on
17 that basis of information, as a basis for how people are
18 learning to use the devices.

19 Update things in the Technical Training Center that
20 are used for -- and corresponding changes in Nuclear Material
21 Events Database, because it will no longer be in the
22 administration. It will be in some other, there will be

1 changes in categorization, so that they can do proper research.

2 All right. Let's get back to Aubrey's issue, real
3 quick here. I know I am zipping through things real quickly.
4 45CFR Part 61, otherwise known as the Healthcare Integrity &
5 Protection Databank. That is a mouthful. I dare you to say it
6 three times quickly. The rule actually became effective
7 October 26th of 1999. I think that, Aubrey, you Governor
8 office made an inquiry as to the actual effective date.

9 What it basically says is that there is reporting
10 that is required from federal agencies. State agencies are
11 responsible for licensing and recertification, and the delivery
12 of medical care. Ah, now, exactly what does that mean? I think
13 that is an extremely good question, which we do not yet have a
14 very good answer for.

15 So, right now, we are in the process of examining
16 what our role will be. It has become clear to us, and the
17 letter which I think was sent out to the states, the
18 determination by our general counsel's office, that we, in
19 fact, were under an obligation under that regulation to report.
20 What isn't yet defined is exactly what we will report.

21 The regulation says that enforceable actions have to
22 include civil judgements, criminal investigations, actions

1 taken by the agency. That is pretty broad. It doesn't give
2 you a real good idea of what to do. So, one of my staff went
3 to the web site. There is all sorts of stuff on their web
4 site. I can give you that web site address, if anyone wants
5 it. There are also some examples. After you read the pages of
6 examples, let me assure you that you will come away almost as
7 confused as when you first hit the web site. None of them have
8 any clear connections to how radioactive materials are used and
9 regulated in the practice of medicine.

10 There are a number of parallels and that is what we
11 are trying to start drawing upon now. The things that we are
12 looking at, and this is strictly a staff consideration at the
13 moment. We haven't vented it through any local veto until we
14 get comfortable ourselves -- things like our confirmatory
15 action letters, then we take the licensees in order to insure
16 that actions are taken which are necessary to protect safety.
17 Certainly orders are confirmatory orders, I will probably be
18 part of it.

19 Enforcement actions -- probably NRC's severity level
20 three, maybe three is with several pounds. We don't want to
21 get into the mode of tossing a report for every severity level
22 four non-sighted violation, four and five might be ones that

1 you leave with inspector observations. Then things that we
2 look at will be related to application/amendment denials. The
3 big issue then is an order related to non- payment of fee. We
4 are having to put in a report for that.

5 Furthermore, it is not just necessarily the physician
6 or the hospital -- and there are some wonderful questions about
7 whether you are reporting as an individual or a supplier -- but
8 think about the entire chain of sequences which gets the
9 radioactive material from where it was produced into the
10 individual. Manufacturers, radio pharmacies, the hospital
11 radio pharmacies, and a number of others, all are covered by
12 this act and would be required reporting. So, if you took
13 action against a radio pharmacy, independent radio pharmacy,
14 that would also, as best as we can determine right now, require
15 reporting of information into the database.

16 As Aubrey told you during the business meeting, there
17 are a number of decisions that you have to go through. Who is
18 going to report? Who is going to have permission to extract
19 the information? As well as the things like, what are you
20 going to report? That is part of the process that we are going
21 through at the present time. There are several questions that
22 still need to be resolved.

1 Chip, I probably used just about my ten minutes.
2 That very briefly covers the things that I wanted to touch on.
3 I would be glad to answer questions.

4 CHIP CAMERON: Great. Let's go to Ed and then we
5 will go to Pearce. Ed?

6 EDWARD BAILEY: Don, I am sure that in your
7 investigation of this you have made contact with the agency and
8 discussed with them what they need?

9 DON COOL: Several times already.

10 EDWARD BAILEY: And that doesn't help any?

11 DON COOL: Hasn't yet. That doesn't mean that it
12 won't. We haven't actually gone down and gone face to face.
13 My staff people have been talking to the people who are really
14 responsible for it. This was done by the HHSIG. So, they have
15 a certain lense that they are looking through, which doesn't
16 necessarily lend itself very well to answering the kind of
17 questions that we have to ask ourselves. I think that there is
18 going to be great benefit, I am not sure whether through Rad
19 Rap or otherwise, continuing to try and come to some common
20 understanding of what the concept needs to be for things that
21 are reported.

22 CHIP CAMERON: Let's go to Pearce and then to John.

1 Pearce?

2 Pearce O'Kelley: Don, is there any penalty for
3 failure to report? And, is this going to be guidance given to
4 us now from NRC on how to comply with this? And, what is the
5 level of compatibility?

6 DON COOL: That is three questions. Let me see if I
7 can get them in order. Is there a penalty? There is. It
8 ranges somewhere between a slap on the wrist to having yourself
9 posted on the web site for failing to comply. If you are a
10 non-governmental organization there are in fact some fines and
11 other things associated with that.

12 Is it something where the NRC is going to put out
13 guidance? Right now, I am not looking at something where we
14 would put out guidance. Although I think that it would be very
15 important for us to have some common understanding. And, given
16 that it is an HHS writing, as far as I know, there is no NRC
17 compatibility designation. You are all on your own.

18 But I also note that you are probably not the only
19 ones in your state who have to deal with this, depending on
20 where you are in your organization. The board that is handling
21 licensing actions for physicians, the health department, and
22 maybe the others, are also going to have to be playing this

1 game.

2 CHIP CAMERON: Great. Just to underline that, the
3 states have flexibility to interpret this whatever way --

4 DON COOL: Absolutely.

5 CHIP CAMERON: All right.

6 DON COOL: Absolutely. There is nothing that
7 mandates that NRC has to be the same as the states or that the
8 states have to be the same as each other. You may have your
9 health department or someone already fairly well along. You
10 may want to piggy back on where ever you find it or you may
11 want to go back and ask them if they ever realized that it was
12 there.

13 CHIP CAMERON: All right. Let's go to John and then
14 we will go over to Bill and Aubrey. John?

15 JOHN ERIKSON: Website.

16 DON COOL: Website. www.npdb-hipdb.com.

17 CHIP CAMERON: Okay. Bill and then Aubrey. Bill?

18 BILL DUNDULIS: Rhode Island. Is there any explicit
19 or implicit obligation that in addition to informing this
20 national database, is there an explicit or implicit duty to
21 also notify whatever the state entity is that is responsible
22 for licensing and disciplining physicians?

1 DON COOL: This regulation, I don't believe, has that
2 sort of information transfer to another organization. It is in
3 essence saying that, if you are an organization that is doing
4 licensing and inspections this is a resource that you can go to
5 and check as you take action to determine whether or not the
6 organizational individuals have had any reported to it.

7 To also note, to kind of correlate an answer to that,
8 the reports that you send in, a copy of that or at least
9 notification, is provided to the individual or organization,
10 who is reported. I think that there is some provision to
11 determine if there is certain pieces of factual accuracy or
12 not. So, you are also not under obligation to send it to
13 whoever the action was taken on. It is simply: you enter the
14 data, via the Internet, to the database. Whatever you put in
15 is what is in. That is it. When you enter it in, whatever key
16 strokes are put in, whatever little summary they put in, that
17 is what is going to be in the database.

18 CHIP CAMERON: Aubrey and then Bob. I guess this is
19 one way to keep the attention off the Part 35.

20 AUBREY GODWIN: It is real easy to get into the
21 business. You go to the website and they have all the forms
22 right there on the website. You can print up in living color,

1 if you so desire. You complete them and send them in. It
2 costs you nothing to register to be an inputer. You have to
3 meet certain legal qualifications.

4 Once you on there, as a part of the package, they
5 also ask for your credit card or other funds transfer
6 mechanism, so that you can request data, if you are authorized
7 to request data. If you are checking to see whether people are
8 qualified to be licensed by your.

9 Apparently they are getting more serious. Apparently
10 someone showed up in our state and did a briefing for all the
11 licensing agencies, that is how I got involved. They said that
12 after a certain date they are going to start putting their
13 names in the voter register and notifying the governor that
14 this organization is not complying. If you want your name in
15 front of the governor in that context have at it.

16 CHIP CAMERON: Thanks, Aubrey. Bob?

17 BOB WALKER: Yeah. If you happen to license
18 radiology techs in your program and have had fixed clauses --
19 you might want to think twice.

20 CHIP CAMERON: Let's go to Pearce.

21 PEARCE O'KELLEY: Don is there a time limit on when
22 the data has to be entered? Is it after the resolution? Do

1 you have an opportunity to change the data that you put in
2 there?

3 DON COOL: It is in the regs, but right off the top
4 of my head I don't remember. There is certain preliminary
5 actions that I do believe have to be entered as well as final
6 action. I believe there is a provision for updating, although
7 I am not completely sure how that mechanism works.

8 CHIP CAMERON: Very good. Does anybody out here in
9 the audience have any comment on the HHS databank or even Part
10 35 questions for Don before we go? Ed?

11 EDWARD BAILEY: Mine goes back to Part 35. We have
12 been approached by the medical community to consider something
13 next to self-inspection, but it is really not self-inspection.
14 There are professional practice programs and one to the
15 suggestions that have been made to us is to get one of these
16 medical institutions that participates in one of these
17 voluntary programs and successfully completely that program --
18 would the state consider extending the inspection interval on
19 those facilities.

20 We are talking about, discussing, I guess that is the
21 same thing, extending our three year inspection to five years
22 with all facilities that are participating in those, if they

1 passed it. Then, if we got notice that they had failed it, we
2 would immediately inspect it. And, it will include some review
3 of these practice audits and what they really look at. We are
4 discussing it. I am not saying that we are headed that way.
5 At least it is something new and different. In the judgement
6 of some in the medical community, those audits are much better
7 at getting to, not only patient safety, but the quality of care
8 for the patients.

9 CHIP CAMERON: As a source of information for the
10 group, Don, during the public meetings on the development of
11 Part 35 the medical community put forward a proposal such as
12 that and that they were going to try to develop an initiative
13 on this to present to the NRC or the states. I was wondering
14 if you have seen anything on that?

15 DON COOL: What transpired during the Part 35
16 development was, mediation was in fact brought up, I believe by
17 the American College of Radiology representative. We sort of,
18 as in the past, we passed on it, it wasn't something that was
19 in the regulations that had to do with the program and they
20 agreed with that. What Ed has laid out here is a variation.

21 What they had initially tossed on us was if they had
22 this practice audits, why don't you just not inspect us as long

1 as we continue to pass it. There was a lot of discussion and
2 wringing of hands. There was some sort of back and forth about
3 the legal implications about information availability and so
4 on. There were a number of questions that were put on the
5 table. At this point, I don't believe that they have come back
6 to us with a more specific proposal. I have heard the issue
7 before.

8 This is another place where something is merging,
9 where we have an opportunity. Ed happens to have gotten the
10 first balloon, sort of the first balloon tossed out there. We
11 all should think about it. If they get one, they will come
12 looking for the rest of us real quick.

13 EDWARD BAILEY : Their initial proposal to us was
14 exactly the same and, one benefit of the benevolent dictator, I
15 can just say no. We won't do that, but we might consider
16 something else. So, we came to this thing of simply extending
17 the interval. We will see. We are going to talk about it.
18 The initial reaction from my staff was we can't do that. So, we
19 are trying to get them to loosen up and not be quite so tight.

20 CHIP CAMERON: Thank you. Thank you, Don. I think
21 that we are ready to go on to the next one. Kathy Allen is
22 going join us now to ask us some questions about IVB.

1 KATHY ALLEN: When we went out to set this up we
2 asked what kind of things did people want to hear about and one
3 of the big things was this IVB thing. We tried to figure out
4 who could come up here and talk about this and wahoo.

5 We started looking at the people who actually want to
6 use this. Every cardiologist has a different approach, a
7 different desire, a different need. We couldn't find one that
8 was willing to represent these all. So, I am going to make you
9 guys do it, actually.

10 I went to the Health Society Meeting that Ed
11 mentioned earlier. There was a session on medical uses of
12 specifically IVB. They started talking about all these
13 different uses. They have got activated stents, coated stents,
14 IR-192, Sr-90, P-32 solid, P-32 as a liquid, which they want to
15 stick in a balloon, and all kinds of other things. I mean they
16 are serious about this kind of stuff.

17 So, rather than me telling you guys what is going on,
18 I think that you guys are really the more expert or you have
19 members of your staff that are much more involved in this. So,
20 yeah, I kind of slipped on my working group hat again. So, I
21 would just like to know who is already working on this. We are
22 going to put this on the chart. Then I am going to send that

1 on through Rad Rap or whatever you want. Who is already
2 working on this? I know that there are lots of states involved
3 in looking at these things and also approving the sealed
4 sources and substitutes.

5 Okay. Let's see a show of hands for Activated/Coated
6 stents. California, Rhode Island, Massachusetts. Any one else
7 involved in Activated/Coated states?

8 BILL DUNDULIS: Kathy, a clarification on Rhode
9 Island. We have had one licensee approach us for early phase
10 IVB non-human use on an incorporating P-32, you know, into --
11 as a stent. It is very early. In fact, we are still
12 negotiating with them on the licenses. It is probably at least
13 several years away from human trial.

14 KATHY ALLEN: Okay. Let's skip down to IR-192.
15 California, Louisiana, Texas, Georgia, Rhode Island, Arizona,
16 Arkansas, Florida, Massachusetts, Maryland, Oklahoma. Anybody
17 else? Do I have you all right now? Okay. I will go to the
18 next category. Sr-90? Texas, California, New York, Arizona,
19 Georgia, Illinois, Arkansas, Florida, Massachusetts. Okay. Are
20 there any others? P-32? Maryland, Oklahoma, Florida, New
21 York, Texas, Illinois.

22 CHIP CAMERON: A question from Rhode Island?

1 BILL DUNDULIS: Kathy, as I outlined before, P-32 is
2 going to be somehow incorporated into a stent. We are not sure
3 if it is going to be coated or what. It is going to be solid
4 P-32.

5 CHIP CAMERON: Any other P-32 solid states not up
6 here?

7 Kathy Allen: Okay. Let's move on to P-32 liquid.
8 P-32 liquid? California. All right. Anybody else?

9 CHIP CAMERON: Anybody else? Any states in the
10 audience?

11 KATHY ALLEN: Does NRC have any experience with any
12 of this stuff?

13 DON COOL: As far as I know, we are not actually
14 doing any S. S. & D. reviews in any of those right now. But, I
15 do have several members of staff trying to follow what the
16 manufacturers are doing in essentially every one of those
17 categories. Bob Arison of my staff is doing a full time job
18 trying to track the Intervascular stuff right now.

19 KATHY ALLEN: I am assuming that the states that
20 spoke up, you are working on guidance or how to incorporate
21 approval of users and that type of thing, correct? Okay.

22 RUTH MCBIRNIE: Excuse me.

1 KATHY ALLEN: Yes?

2 RUTH MCBIRNIE: Is this going to be something that
3 the ACMUI is going to pick up at the next meeting?

4 DON COOL: Yes.

5 RUTH MCBIRNIE: So, we will be discussing it at our
6 November meeting.

7 KATHY ALLEN: Great. Any other funky new uses that
8 we should look at?

9 EDWARD BAILEY: There is another one, but I can't
10 remember what it is.

11 CHIP CAMERON: David, did you offered probably the
12 most information. So, let's get that on the transcript. This
13 is David Walters.

14 DAVID WALTERS: They are also looking at, just
15 beginning to start looking at a solid Itrium-90, Strontium-90
16 beta source for this. But, they are just getting started on
17 that right now. Rab Itrium- 86 has been talked about, but it
18 is not currently active to my knowledge.

19 CHIP CAMERON: Any other comments or information for
20 Kathy on this? One comment from Massachusetts.

21 SALIFU DAKUBA: I can't off-hand remember who is
22 making it, but it is in the form of clinical trials. The

1 original device is from somewhere, I am not sure where. I will
2 have to look up and see the origin of the device.

3 CHIP CAMERON: Okay.

4 KATHY ALLEN: Okay. Well, I will go ahead and type
5 this out and put it out on Rad Rap in another form. That way
6 everyone will know who else is working on it. So, if you want
7 to sort of share some resources. Obviously, I am not an expert
8 on the topic being used, but this is obviously a very big
9 change in technology. We all need to stay on top of it.
10 Thanks a lot for your systems and help.

11 DON DUNDULIS: Kathy, one thing, for those that
12 aren't members of the Health Physics Society -- I can't
13 remember if it was this month or last month, there an article
14 where somebody did an assessment of, you know, the typical
15 doses that are involved to workers and patients in the
16 surrounding rooms. That was in the Health Physics Journal or
17 the Occupational Supplement, within the last couple of months.
18 It looks like it might have some good background information,
19 based on what kind of doses to expect.

20 KATHY ALLEN: I am actually kind of hoping that,
21 maybe the next time we meet or maybe at the steering meeting,
22 there maybe people who actually kind of use this and said we

1 have looked at it and these are the key issues that we need to
2 look at. We can all look at down the list and say, wow, look
3 at that. There are a bunch of issues, but I would rather wait
4 and see what kind of things people actually bring together.
5 Joe, do you have a comment?

6 JOE KLINGER: Yes. For those people that are working
7 on a S. S. & D. -- who has actually issued an S. S. & D. for
8 this? I thought that Texas did? Georgia, what is the status
9 of that one?

10 TOM HILL: We issued an S. S. & D. for clinical
11 trials only.

12 JOE KLINGER: Is anyone else close to issuing?

13 RAYMOND MANLY: Maryland also issued for clinical
14 trial.

15 CHIP CAMERON: All right. Thank you, Kathy.

16 EDWARD BAILEY: Just a point of clarification: if
17 they are going to broke medical licensees, what you have to
18 necessarily do in S. S. & D., because they can generally any
19 form of materials -- okay. What is the practice that is
20 generally going on with that?

21 TOM HILL: Tom Hill, Georgia. I think that you have
22 to have an S. S. & D. sheet at their in hold. We have approved

1 one hospital to use it in clinical trials. I understand that
2 they were looking at -- possibly with other hospitals around
3 the country that might fall into that same category that were
4 considering it. We issued the S. S. & D. so they could -- we
5 thought it would be useful to the states.

6 DON COOL: This is Don Cool. Most of the
7 circumstances that we have run into has been a broad scope
8 licensee. We have had a couple limited scope folks who thought
9 that the general provision for medical research would some how
10 allow them to do this without having the broad scope authority.
11 We have been having some rather interesting interactions with
12 those particular folks, trying to get them to understand that
13 simply because they have gotten an agreement with one of the
14 donors to do some clinical trials didn't mean that they were
15 free and clean to do whatever they so chose.

16 CHIP CAMERON: Okay. Thank you. Thanks, Kathy. The
17 last medical issue that we have is the PET. Ruth McBirnie,
18 from Texas, is going to talk to us about that.

19 RUTH MCBIRNIE: This is PET as in Positron Emission
20 Tomography, rather than Puppies, Egrets, and Turtles. I have
21 got more questions than answers. I had my Chief of Medical
22 Licensing write out a few of the issues that are involved in

1 doing this, regulating PET, especially mobile PET. The first
2 of which is the proper of Florin 18, FEG on the radioactive
3 materials license. The only new drug applications for FDG is
4 -- it therefore does not fall into what we call the group
5 authorization, although we are now changing our rule to take
6 that out. But, we do put it on as a line item on the license.
7 We also limit the use in a specific individual.

8 We told a group of ACGME, that is the American
9 College of Graduate Medical Education, program directors of
10 nuclear medicine training programs. They recommended a nominal
11 amount of additional training and experience to use PET
12 pharmaceuticals rather than the regular diagnostics, about
13 three days additional was recommended. There have been notices
14 sent from the regulating community that we have seen. Major
15 teaching institutions have responded to offer PET update short
16 courses for you, from several days to a week in length.

17 Some of the other issues that are involved in adding
18 amendments to the licenses. There are different areas of use.
19 It could be a coach in a parking lot. It could be a new room
20 for a scanner. It could be an additional injection room or it
21 could be an inoculated quiet waiting room.

22 The placement of the coach may or may not be on the

1 property that is under the control by the licensee. The most
2 convenient placement of the coach could be on another person's
3 property or that of the medical center. It is not been
4 advisable to have doses of PET in heavy carrying cases. Some
5 of these are up to one hundred and twenty pounds. They move to
6 and from the hospital in a coach. Have the licensee decide on
7 or the other for logistics. I am hoping that it is shipped
8 there and not have to look at it's shielding, counting
9 equipment, decon supplies, waste storage, patient holding and
10 so forth.

11 You have quite a bit of difference in the shielding
12 that is required, the HVL in lead. For Technesium-99M it is
13 that .3 millimeters. For Florin 18 it is 5 millimeters. You
14 have got the annialation radiation 9-11 KEV, two of those
15 coming off.

16 Different administration devices. They have been
17 using tungston syringe shields, different dose calibrator
18 settings, to get a precise calibration. Recommending a thesium
19 137 check for them. Additional shielding needed for the
20 L-block. Those calibrate waste storage to afforded the same
21 protection used in standard nuclear medicine.

22 The patient can't leave the area due to short

1 distribution time. It is about thirty minutes. And, of course,
2 the short half-life of the isotope. It is about two and a
3 half, two hours.

4 Reviewing the radiation safety officer's
5 responsibility, especially for mobile coaches that are removed
6 from the premises. The shipping containers are bigger and
7 heavier, so counter space may apply, may need alterations.

8 Public area exposure may not have been considered for
9 a higher energy damage with the patient waiting requirements.
10 The dose rate is about five times greater than with the
11 Technesium.

12 PET drugs must be compounded under the Food and Drug
13 Administration Modernization Act. Those technically are
14 prepared for a specific patient, by a specific authorized
15 physician user. How would that be accomplished with patients
16 and APU's scattered across the horizon or tele-radiologied to
17 virtually anywhere.

18 Mobile PET may very well be paving the road for
19 violation to state and federal drug laws. With mobile PET
20 there are significant disadvantages to assigning every
21 individual the role of radiation safety officer. The
22 technologist will have a significant conflict to shut down his

1 own van in the event of a spill, when reimbursement exceeds
2 over \$2,300 per exam. Few technologist have experience with
3 specifically with PET. The anywhere authorized physician user
4 would simply be that, anywhere except on the coach and thus not
5 available to truly evaluate a radiation safety concern. The
6 corporate licensee or radiation safety officer is located at
7 places unknown and will have widely varying duties, depending
8 on the number and activity of the coaches riding hot, in
9 whatever state they are operating.

10 Effort needs to be taken to inform and educate the
11 state boards for pharmacy for interstate distribution of drugs,
12 licensing institution for commercial distribution, and
13 understanding compounding rules for pharmacies.

14 Then there are other concerns dealing with the actual
15 cyclotron in the production of these PET pharmaceuticals. So,
16 there would be a need for a pharmacist to be physically present
17 to dispense the drug, not just the operator of the cyclotron.
18 An extensive lead time needed for the placement and operation
19 of accelerators of all types.

20 There has been problems with the use of the Rabitrium
21 generator, which are now known as the Firestone Tires of PET.
22 With all the recalls recently, as eight out of fourteen centers

1 have reported leaks.

2 The last thing is the state hospital licensing rules
3 have provisions for hospital based operations that should be
4 reviewed to see if a mobile coach will meet those requirements.
5 These are just some of the issues. I am so glad that Terry
6 Frazee has stepped up to lead us in a group to put all this
7 together into some guidance. I will one of my licensing people
8 to help with that. I hope that this has given some food for
9 thought and some discussion.

10 CHIP CAMERON: Thanks, Ruth. Does anybody need
11 further information from Ruth or want to share information? Ed
12 Bailey?

13 EDWARD BAILEY: Yeah. Ruth brought up training.
14 There is a new group of physicians who are interested in this
15 particular mode or I don't know what the proper word is --
16 modality, okay. That is the psychiatrist and they get, ah, ten
17 hours of training with this. You may begin to get requests
18 from psychiatrist or psychiatric groups in hospitals that want
19 to use PET.

20 We have one center that specializes in the brain
21 imaging in mass murderers. So, every time they find a new mass
22 murderer they come to us with this.

1 AUBREY GODWIN: Do they operate at that prison?

2 EDWARD BAILEY: No. It is a strange arrangement. It
3 is at a university that has a medical center, but the cyclotron
4 and the imaging is not under the nuclear medicine. It is at
5 the regular academic university. The psychiatrist, or whatever
6 they are, the brain people are running it.

7 CHIP CAMERON: Okay. We are going to go to Bill Kirk
8 and then we will go to David Walter.

9 BILL KIRK: We were a bit surprised on the fifth
10 mobile PET operation that we licensed to find that the health
11 department had a regulation that says there will be no mobile
12 PET licenses. We asked them where that came from and they said
13 when we did those regs we didn't know what it was and it
14 sounded complicated. So, we thought it out to be done away
15 with. They are changing the regs now.

16 CHIP CAMERON: That is the way regulations happen, I
17 guess. We will go to David Walter and then we will come back
18 to Cheryl. David?

19 DAVID WALTER: David Walter, Alabama. You mentioned
20 on the training aspect that it was for three days. Can you give
21 me some information on what additional training it was suppose
22 to cover?

1 RUTH MCBIRNIE: It has to do with these specific
2 isotopes --

3 DAVID WALTER: Strictly radiation safety --

4 RUTH MCBIRNIE: That is correct.

5 DAVID WALTER: -- because of exposure possibilities?

6 RUTH MCBIRNIE: Right.

7 DAVID WALTER: Okay. Thank you.

8 CHIP CAMERON: Cheryl Rogers?

9 CHERYL ROGERS: Cheryl Rogers, Nebraska. Nebraska has
10 already licensed a mobile PET facility. So, now I need to go
11 get Ruth's list and find out if we did everything right. We
12 have already done our initial inspection and the main problem
13 that we found was that they didn't have the waste properly
14 shielded.

15 The way we licensed the mobiles in Nebraska is under
16 that companies licensed. I had noticed from the Rad Rap
17 conversations that quite a lot of you still license the fixed
18 facility. So, I am not quite sure what all the controversy is,
19 because the way it works in Nebraska seems to work quite well.
20 We have quite a few of the mobiles. So, I will try to keep in
21 on this discussion.

22 CHIP CAMERON: Okay. I think that we are going to go

1 to Arkansas?

2 JARRED THOMPSON: Jarred Thompson, Arkansas. We are
3 getting ready to issue a local PET license to one of Ruth's
4 licensee, about coming into Arkansas only with the camera. The
5 PET material will be delivered to the licensed facility,
6 injected into the patient, and then scanned out in the van.
7 Then, the van is not suppose to be kept in Arkansas on the
8 weekends. It is suppose to driven back to Texas. It is the
9 kind of different thing that you see. Why they did that, I
10 don't know.

11 The RSO will be the nuclear medicine technologist who
12 is actually just doing the scan. All of his license, all the
13 PET license we have is for the germanium continuaters for the
14 camera. That is all that he is licensed for in Arkansas.

15 CHIP CAMERON: All right. Kentucky?

16 EDWARD LOHR: I am Ed Lohr, Kentucky. We have gotten
17 licensed so that they come and do the work on the van only and
18 have the isotope delivered to the facility. But, recently we
19 have had a company that wants to inject on the van itself.
20 They are sighting a study that was done, had to do with the
21 quiet time after the injection to the patient, not moving the
22 patient from the quiet room out to the van. I was wondering if

1 anybody had heard any of that or had any experience with that?

2 CHIP CAMERON: Thank you, David. Thank you, Ruth.

3 There is a number of other rule making activities that are
4 going on at the NRC and we have asked Trish Holahan the branch
5 chief of rule making to briefly run through all of these effort
6 for us. Then we will open it up to discussion. I believe that
7 there are four topics.

8 PATRICIA HOLAHAN: Just to clarify, these are not all
9 the rule makings that we have going on. Can everybody hear me?
10 Okay? Okay. I am going to try and go through these relatively
11 quickly. You heard a little bit about some of them earlier.
12 So, I will try to be as brief as I can. Then I will open them
13 up for questions.

14 The first one that I would like to cover is Part 40.
15 Really what we are talking about here there are several
16 different initiatives on going. I am going to try to clarify
17 which ones we are doing. I would like to clarify that this is
18 separate from another initiative that we have ongoing, which is
19 to create a new Part 41.

20 Some of the background -- the next slide -- is that
21 as we heard yesterday, the definition of unimportant quantities
22 is based on national security. Whether it is a useful source

1 of fissionable material, rather than health impact. That has
2 been defined as <.05 percent by weight one- twentieth of one
3 percent of the material is considered unimportant quantity.

4 In front of these circumstances, the material under
5 the Event License and Protection, as well as general licenses,
6 may result in doses that could exceed limits. Also we have had
7 many pages where specific licensee has requested transfer
8 material under 40-51, B-3 and 4 to exempt persons to dispose of
9 low level source material. In February of '99, in response to
10 one of these cases, the commission issued direction to provide
11 recommendations to improve the licensing of source material in
12 Part 40.

13 In addition to these issues that are ongoing, we also
14 received a petition from LES and the state of Colorado that
15 requested that the exemption in Part 40 for general licensees
16 be re-examined to make sure that they were required to perform
17 Part 2011. Specifically they asked that the exemption in 4022
18 be revoked for entering any general licensee that had the
19 potential to exceed the public limits could exceed the limits
20 -- with a person monitoring or with a prior area posting. And,
21 that they would then have to comply with the requirements of
22 Part 19 and 20.

1 As a result of these activities -- the next slide --
2 we submitted a paper last November, titled Exceptions Part 40
3 for Materials <.05 percent, Options and Other Issues Concerning
4 the Control of Source Material. As part of that the staff
5 recommended four things. First of all, that we would develop
6 more risk informed performance based regulations for the use of
7 source materials, again using the main four strategic goals of
8 maintaining safety, looking at efficiency, appropriateness, and
9 reducing unnecessary regulatory burden. Also, the
10 recommendation was to explore the best of approach of delaying
11 the responsibility of the NRC and other agencies with
12 responsibility in this area of low level source material. To
13 improve the control and distribution of source materials
14 through general licensees and finally there was a
15 recommendation that the staff could consider requiring prior
16 commission approval for transfers of licensed materials.

17 As a result of that the commission did issue a
18 direction and a staff requirement memorandum last March to deal
19 with three specific tasks. As a result of this we have
20 established two working groups with the Agreement States
21 participants and the CRCPD representatives. We heard a little
22 bit about those previously. So, let me quickly go through the

1 three individual tasks.

2 The first one was to alligniate the interaction with
3 EPA, OSHA, and the states to explore the approach to aliniate
4 the responsibility of NRC. As part of that we were suppose to
5 consult, confer, work closely with DOE, the Army Corps of
6 Engineers, DOT, the Department of the Interior, and come
7 forward with a plan, or come back to the commission with a plan
8 to address some of these jurisdictional issues.

9 As you heard, the first working group meeting was
10 held last week. Ken Weaver, who is on that group, has been
11 fairly active on Rad Rap trying to into it with everybody with
12 regards to what are the responsibility of the state. The other
13 aspect of that working group meeting is that they finalized the
14 charter, which included the identification and priority
15 organization of options. So, there is to be a tele-conference
16 with the working group this Thursday, October 5th.

17 The second task was to develop a proposed rule
18 amending 40-51 to require prior commission approval for
19 transfers of <.05 percent of source material. That rule is not
20 to the commission. It was sent out to the Agreement States
21 for, as a draft for a proposed rule for a comment period. The
22 criteria is that the doses are not expected to exceed 100mrem

1 per year, but the commission will be informed if doses exceed
2 25mrem per year.

3 The third aspect of it is to develop a rule making
4 plan to improve the control and distribution of source material
5 to -- general licensees. So, this is a major rule making plan
6 to look at the other aspects of Part 40 and making sure that
7 the general license requirements in this rule making plan will
8 also address the petition.

9 Again, Bill Sinclair is representing the Agreement
10 States on that and Steve Collins is the representative of CRCPD
11 on that working group. As Bill mentioned, the first working
12 group meeting is planned this month.

13 So, really that is where we are. I would now like to
14 move on to a couple of other activities that we have going on.
15 The next one is Part 71. This is another rule making that we
16 have. The focus of this was, or the initial part of it was to
17 make the current transportation regulations compatible with
18 ST-1, which are the '96 IAEA transportation safety standards.
19 However, in going through and beginning to look at this rule
20 making, in addition to the eleven ST-1 changes, we also
21 identified eight NRC initiated changes that would effect
22 domestic shipments of materials.

1 We have been using an enhanced public participation
2 process which has had three public meetings so far. One has
3 been a round table meeting at Rockville in August. In the last
4 two weeks we have had a town hall meeting in Atlanta and
5 another town hall meeting in Oakland last week.

6 We published an issues paper on the 17th of July.
7 The public comment period ended last Saturday. Like I said, we
8 had the three public meetings and we did have Agreement States
9 participants at both the Rockville meeting as well as the
10 Atlanta Meeting. I apologize, I haven't gotten to the
11 participant list to see if anybody was able to make it to the
12 Oakland meeting.

13 So, we are now working to get a proposal developed.
14 We have contracted to look at all the public comments that we
15 have gotten on the issues paper. The proposal is due to the
16 commission in March of 2001, but we are planning to have a
17 draft of the proposal to the states before that, probably in
18 the January time frame.

19 As I said, there are nineteen issues. The key issues
20 that seemed to generate the most discussion at the public
21 meetings are listed on the next slide. One is what --
22 characterizes the adoption changes, tests, and experiments

1 authority. Let me just clarify, of the four issues on the
2 slide, two of them are NRC identified issues and the latter two
3 are to be compatible with ST-1. The adoption of changes and
4 tests, what this allows is for the reactors and for the spent
5 fuel certificate holders. They are allowed to make certain
6 changes to the design or do certain experiments without prior
7 NRC approval. This became problematic specifically for the
8 dual purpose cap that are both for storage for spent fuel and
9 also an approved transportation. So, the issue was to look at
10 Part 71 to see if we would allow this type of change authority
11 for spent fuel transportation packages, not only for the dual
12 purpose cap, but also for the central transportation packages.

13 The next issue, the double containment of Plutonium
14 was in response to a petition for rule making which basically
15 requested that we eliminate the current regulations in 71-63,
16 which requires the use of double containment for Plutonium.
17 The rationale was that this isn't based, it is not required for
18 any other isotope. It is not based on the A1-82 values and
19 there is no comparable requirement in the international
20 standards.

21 The third issue is the radionuclide exemption values.
22 Currently the exemption value and the requirements is 2,000

1 picocuries per gram and it is not isotope specific. New IAEA
2 standards has radionuclide specific values for event materials.

3 And, then there is several new and revised Part 71
4 definitions to be compatible with ST-1. Very quickly, they are
5 confinement systems -- criticality safety index look first for
6 radioactive materials, 2-a requirements, and the definition of
7 a package.

8 On the next slide, Most of the Part 71 rule changes
9 that we are looking at are in the NRC only categories, but
10 several of the sections to include the changes of definitions
11 are items of compatibility. Currently Part 71 is compatibility
12 C. So, we would certainly like any input.

13 I am going to skip over the next two slides, because
14 they are the listing of all the specific nineteen issues. If
15 you want to hear more about that, I will be happy to go through
16 them later.

17 Switching gears a little bit, we also have a rule
18 making with relation to Part 34. This is one that has been in
19 response to a petition for rule making from the Amersham
20 Corporation. It was noticed that as we received comments --
21 there were several workshops held on it. We did have several
22 representatives working with us on developing the rule making

1 plan. Unfortunately, it has slipped somewhat in the schedule
2 and we are trying resurrect this to get this back out again and
3 back out on the street. Specifically the petitioner requested
4 that we remove all references to associated equipment from the
5 NRC regulations. Because only the registration devices that
6 are required in 30-32 and 32-310.

7 I am going to skip over the next slide which just --
8 if you will maybe just put it up. That just sort of indicates
9 what the sections are that they are focusing on. Currently
10 34-20 does require criteria for associated equipment.

11 Next slide. The petitioner has proposed that we
12 revise 34-20 to eliminate the requirement to register
13 associated equipment and provide for licensee certification of
14 associated equipment that is fit for use. Currently in the
15 rule making plan under the options that we are looking at we
16 are proposing a classification of radiography equipment based
17 on a risk basis. So, we would be looking at -- Category A
18 would have, would include the camera and various associated
19 special features. Category B, which is on the next slide,
20 would include some of the other equipment that wouldn't be
21 considered in the same category as far as the risk perspective.

22 In terms of how we are proposing to handle that, the

1 next slide, for Category A, it would need to be either
2 registered or licensed. The current 34-20 would continue to
3 apply. And, all the other equipment in the Part 34 Category A
4 would remain essentially unchanged. For the Category B
5 equipment, it wouldn't require registration or licensing, but
6 it would require certification by the manufacturer licensee
7 that the equipment meets the performance criteria.

8 Where are we? We need to get the class rule making
9 plan out to the Agreement State representatives that are on the
10 group. Then we need to get the class rule making plan out to
11 all the Agreement States for comment. Again, we hope to do
12 that by November or December of this year. And, get a final
13 ruling on the plan in 2001. So, no. I haven't already done
14 it.

15 The last rule making that I quickly wanted to cover
16 is one that address new dosimetry technology. On the next
17 slide, the current regulation, Part 20, there is a requirement
18 that personal dosimeters that are processed to determine dose
19 must be processed by an accredited NVLAP processor. However,
20 in Part 34, 36, and 39 there are very specific requirements
21 that specify the use of film badges and TLD's for NVLAP
22 processing.

1 The problem that arose with that is that there are
2 some new technological advances. In specific the optically
3 stimulated thermoluminescent dosimeter that also requires
4 processing to determine dose. The problem was that some of the
5 licensees wanted to use this, but were limited by the current
6 requirements to use either film badges or TLD's. Also there is
7 the possibility of other dosimetry technology coming in the
8 future.

9 The intent of the rule making is to make those
10 changes to Part 20 in the requirements, but in the specific
11 Part 34, 36, and 39 is to delete these limitation in the use of
12 film badges and TLD's, and to allow the use of any dosimeter
13 that requires processing to determine dose, and provides that
14 the dosimeter processor does hold NVLAP accreditations, and at
15 monthly intervals for film badges, and quarterly for TLD's
16 still require they be processed, and also quarterly for all
17 other dosimeters.

18 On the next slide, the proposed compatibilities,
19 there is no change in this from what the existing requirements
20 are. So, category C for personal monitoring. Category D, for
21 the ones in Part 36 and Part 39. As I said, that is not a
22 change from the current compatibility requirements.

1 Where we are is -- because this was determined to be
2 a non-controversial rule making we have gone by a direct final
3 rule process. It was signed by EO last week. So the Direct
4 Final Rule and the Proposal will be published in the Federal
5 Register for, probably by the end of this week or next week.
6 When we do a Direct Final Rule there is a proposal that is
7 published for a thirty day comment period. If no significant
8 and adverse comments are received then the Direct Final Rule
9 will be affective seventy-five days after publication. If we
10 do have what is determined to be significant and adverse
11 comments then we will withdraw the Direct Final Rule and go to
12 a normal -- whatever process is appropriate.

13 So, that is a quick rundown of four of the rule
14 makings that we have ongoing. I know that -- if I can just
15 take one minute more, earlier I think that Ed had asked about
16 some of the guidance documents. The Part 20 guidance document
17 will be published in the draft next month. Our numbers are now
18 final. We are discussing by the end of the year publishing the
19 final Volume 12. Bankruptcy should be published next month as
20 will the -- the general licenses guidance document will be
21 published once we publish the Final Rule. The Final Rule is
22 still with L & B for approval.

1 CHIP CAMERON: Thanks for that overview, Trish. Four
2 very different topics. Who wants to start us off with either a
3 question or a comment on these area? We will go to Kirk first.

4 KIRK WHATLEY: I may have just missed this, but just
5 for my clarification. Did I see your slides say that a license
6 would be required to transfer any source material that contains
7 <.05 percent?

8 PATRICIA HOLAHAN: No. What the rule is that
9 specific licensees that are licensed and have materials that is
10 <.05 percent, then need to come in and get approval before they
11 transfer it to an exempt person.

12 KIRK WHATLEY: What about all that source material
13 that isn't <.05 percent? What is the difference?

14 PATRICIA HOLAHAN: Right now that issue is not -- I
15 mean that if it is, if it is possessed by an exempt person,
16 there is no requirement for them to come in and ask us for a
17 transfer. It is just looking at those issues where it's -- it
18 is licensed material and it is being transferred to an exempt
19 person.

20 KIRK WHATLEY: Just one quick follow up. Are you
21 also looking at the Magnesiumthoric alloy in general licensing?

22 PATRICIA HOLAHAN: Yes. That will be part of the

1 individual plan that we are looking at.

2 CHIP CAMERON: Okay. David Walter and then Cheryl
3 Rogers.

4 DAVID WALTER: David Walter, Alabama. I want to make
5 sure that I got verified on this too. I thought that I heard
6 you say that in the dosimetry rule, you were going to allow
7 anything other than film badges to be processed at a quarterly
8 limit or each quarter. That is to say, if they are not wearing
9 a film badge, if they decide to go the OST or OSL, they can go,
10 and they are a radiographer, they can go to a quarterly
11 monitoring?

12 PATRICIA HOLAHAN: No. We weren't -- I may have
13 summarized that a bit too much. If -- for film badges it will
14 be monthly processing, which is what it currently is. For the
15 TLD's -- we haven't made a change to the timing within the
16 current requirements.

17 DAVID WALTER: So, radiographers will still be
18 required to have a monthly dosimeter exchange?

19 PATRICIA HOLAHAN: Yes.

20 DAVID WALTER: Thank you very much.

21 CHIP CAMERON: Okay. Cheryl?

22 CHERYL ROGERS: Cheryl Rogers, Nebraska. This is on

1 the transportation and we did not make comments. I don't know
2 if we missed our opportunity or not. I was curious about the
3 radionuclide exemption values. You know, that seems like a lot
4 of work to go risk informed on a nuclide basis. What kind of
5 comments are you getting on that?

6 PATRICIA HOLAHAN: We are getting comments that -- a
7 variety of comments on it. I think that one of the concerns on
8 going on a nuclide by nuclide basis is what will this capture
9 in addition to what is already caught. Also, from a lot of you
10 we get concerns raised about us easing up on our regulations.
11 Certainly there is some concern there as to -- if we are
12 lowering the limits. So, we haven't gotten through all of the
13 comments, but we are definitely getting a lot of comments on
14 that specific issue.

15 CHIP CAMERON: All right. Let's go to Cindy Jones.

16 CINDY JONES: Cindy Jones, NRC. Is there any mention
17 in the NVLAP rule regarding DOLAP's and if we would like to use
18 DOLAP accredited facilities?

19 PATRICIA HOLAHAN: Not at this point in time. We did
20 recognize that there is a need for the DOLAP, but we could not
21 go a Direct Final Rule, if we were going through DOLAP, because
22 there was an expectation that it would get comments on that.

1 So, we are going to be developing a rule making plan to address
2 the DOLAP issue.

3 CHIP CAMERON: Anything else on this rule making?
4 Trish, thank you for doing that and covering that for us.

5 (Recess.)

6 CHIP CAMERON: We had a, I guess the best way to
7 describe it is, an interesting discussion last year and Jim
8 Kennedy from the NRC is here to tell us what progress has been
9 made since last year.

10 EDWARD BAILEY: Before Jim starts, I would like
11 everybody to know that the U.S. Army Corps of Engineers was
12 invited to participate in this meeting. I went back to them
13 and asked if they were going to have someone there? I got a
14 very kind message back from the USACE saying that we forgot
15 about it and now it is too late for any of us to come.

16 JAMES KENNEDY: Thank you. It is my pleasure to be
17 here today to talk to you and give you our views on the FUSRAP
18 program. Many of you I know from waste disposal and I also see
19 a lot of new faces.

20 I have three main messages today. The first is that
21 NRC doesn't have jurisdiction under current law to regulate
22 either on-site clean up of FUSRAP materials or off-site

1 disposals of FUSRAP materials. The second is that if Congress
2 wants us to regulate the FUSRAP program we are ready to assist
3 them in lending legislation to help make that happen. The
4 final is that whether if you agree with what the Corps has
5 done, particularly with radioactive materials in hazardous
6 waste facilities or not, they have at least added to the
7 conversation, advanced the conversation on more risk informed
8 disposal of low activity waste. So, I will be talking some
9 about that.

10 Next slide. Here are the topics that I am going to
11 talk about first, a little bit of background on the FUSRAP
12 program. Next. Interest in NRC regulation FUSRAP, that is
13 really an understatement. We have had lots of letters and so
14 forth from different folks arguing that we should be regulating
15 the FUSRAP program. Next. I am going to go over briefly the
16 Director's Decision that was issued in March of 1999,
17 concerning our lack of jurisdiction over on-site clean ups of
18 FUSRAP sites. Next. I will give you our current view on
19 regulation of off-site disposal of mill tailings in the FUSRAP
20 program. Then, I am going to jump off sort of a level and
21 compare low activity waste in general, not just mill tailings
22 from the FUSRAP program, but also unimportant quantities of

1 source material, like 75 percent source material, low end of
2 low level waste. Finally, I am going to talk about some
3 related issues, even more probably, regarding risk informed
4 disposals of low activity materials.

5 First, background on program. I think that most of
6 you probably know that the Manhattan Engineering District and
7 the Atomic Energy worked on nuclear materials for the nation's
8 early atomic energy and weapons program during the 1940's
9 through the 1960's at different sites around the country. Many
10 of the sites have radiological contamination, principally
11 uranium, thorium and radium mill tailings. There is also some
12 low level waste and TENORM at some of the FUSRAP sites too.

13 DOE began the FUSRAP program in 1974. Eventually
14 forty-six sites were in the program. Twenty-five have been
15 completed to date and twenty- one are still left to clean up.
16 DOE managed the FUSRAP program until 1997 under Atomic Energy
17 Authority. At the end of 1997, Congress transferred the
18 administration of the program from DOE to the Army Corps of
19 Engineers.

20 Next slide. That is a map that I took off the Army
21 Corps web site. What that map doesn't show and is the most
22 controversial issue right now, I think, is the four disposal

1 sites where the Army Corps has been sending waste. One is down
2 in Texas. They have sent a lot out to Utah. Some have also
3 gone, one train load went to California. And then there has
4 been some that has been sent to a hazardous waste site up in
5 Idaho, near Boise.

6 Next slide, please. We have had a lot of interest in
7 NRC picking up regulation of the FUSRAP program. We have had
8 letters from CRCPD, various state officials, commercial firms,
9 on the hazardous waste sites advocating that we shouldn't
10 regulate it, various legislatures. There was also a Senate
11 hearing back on July 25th, where we gave testimony. I will
12 talk in a little bit about that. And, finally, some of the
13 environmental groups, especially the Natural Resources Defense
14 Council, who submitted a petition to us about two years ago
15 asking us to regulate the Army Corps implementation of FUSRAP.

16 Let me talk about that now. It is really two issues.
17 NRC regulation of the on-site clean up and NRC regulation of
18 the off-site disposals.

19 Next slide. With respect to on-site clean ups, we
20 issued a Director's Decision that was actually signed by Dr.
21 Paperiello, who was the director at that time. In it we
22 addressed the issue of NRC's regulation of on-site clean up.

1 He stated that we lacked the authority for on-site clean ups.
2 That the Corps clean ups are being conducted pursuant CERCLA,
3 which waived permit requirements for on-site activities. We
4 also pointed out that Congress gave NRC no money and no
5 personnel for an oversight goal when the transfer was made back
6 in late 1997. We said, as I said earlier, that if Congress
7 believes that NRC should regulate the on- site clean ups, we
8 stand ready to assist Congress in amending legislation to that
9 ends.

10 Next slide. With respect to off-site disposal of
11 FUSRAP mill tailing, as I mentioned earlier, the Corps practice
12 has been to use RCRA hazardous facilities, in a few cases, for
13 disposal of mill tailings and low activity waste. Earlier this
14 year, back in February or March, we received two petitions
15 requesting that we regulate off-site disposal of mill tailings
16 from FUSRAP sites, particularly the material already in RCRA
17 hazardous waste facilities. They were submitted by EnviroCare
18 of Utah and the Snake River Alliance, which is an environmental
19 group out in Idaho. Those petitions have been combined into
20 one. They both ask for the same thing and they were both
21 submitted at the same time. We are working on that Director's
22 Decision right now. That Director's Decision will be issued

1 soon. It will have a definitive agency position on where we
2 stand with respect to regulation of off-site disposal. The
3 views that I am giving today, our views today, are what we had
4 to say at the July 25th hearing, Senate Hearing, before the
5 Environment and Public Works Committee. That was also given by
6 Dr. Paperiello. Dr. Paperiello was there, along with a number
7 of other folks.

8 Here are our views that we presented, NRC views.
9 These are the views that we gave at the Senate Hearing on July
10 25th, that Uranium Mill Tailings Radiation Control Act applied
11 to mill tailings produced at facilities under license at the
12 affect date of the UMTRCA or licensed thereafter. Second, those
13 tailings produced at facilities, such as FUSRAP sites, not
14 under NRC license at that time or thereafter, have not been
15 regulated by the NRC. And finally, Corps disposal of Freon mill
16 tailings in RCRA hazardous waste facilities is subject to the
17 authority of the EPA or state permitting agencies.

18 Now, at the hearing, I am going to talk about this
19 chart. At the hearing there were basically two categories of
20 testimony. First there was testimony that dealt with the legal
21 issues, which addressed what UMTRCA says, what the Atomic
22 Energy Act says, and how the law should be interpreted about

1 whether NRC has authority over these mill tailings. The other
2 category of testimony at the hearing though was of more
3 interest to me, because I am not an attorney, and that is
4 having to do with the risk posed by disposal of low activity
5 waste and different kinds of waste disposal facilities, mainly
6 mill tailings and RCRA hazardous waste sites.

7 This next chart, what that is a comparison of the
8 relative specific activity on different kind of materials. At
9 the top is soil. Next is radium mill tailing or 11e(2) by
10 product material. Then it is low level waste. What most will
11 notice about low level waste is that it has an enormous range
12 of specific radioactivity. As somebody pointed out yesterday,
13 I think in connection with reactor vessel disposal, what is
14 interesting about low level waste is that after a few hundred
15 years all of the top of that bar is going to be very low. Next
16 is NARM and TENORM. I also put down exempt source material,
17 that is <.05 percent source material. And finally, spent
18 reactor fuel is by a class by itself.

19 There is a couple things to point out on this chart.
20 We could talk about this chart for a long time, but first,
21 there is a lot of overlap at the low end, that is mill
22 tailings, soil, low level waste overlaps mill tailings. Not

1 only that, but one other thing that is not shown in this chart
2 is that in many of those cases where there is an overlap of
3 statistic radioactivity the radionuclide are the same, uranium,
4 thorium, and radium, not in all cases, but in many cases.

5 Second is that all categories of waste have pretty
6 wide ranges in their specific radioactivity. It is largest of
7 course for low level waste. It is large for TENORM and it is
8 even large in mill tailings and it's source material. One of
9 the reasons for that is that once a material takes on a name,
10 like mill tailings, even if it is mixed with soil it still
11 maintains that name. The name is important, because the name
12 determines how it is regulated, what controls need to be
13 applied to it, and where it is being disposed of.

14 The other -- let me bring this back to the Army Corps
15 for a minute. One of the things that the Army Corps has done
16 that has caused a lot of controversy is taken some of the
17 uranium mill tailings or 11e(2) by product material and
18 disposed of it in the same manner that TENORM is disposed of,
19 that is in RCRA hazardous waste sites. We can argue about what
20 the appropriate number is for that, whether it is 2,000
21 picocuries per gram or -- but that is one of the issues that
22 they forced. They have sort of broken down some of the walls

1 that have been put up by the regulations and laws, not
2 everybody has liked that.

3 Next. I don't want to go too far a field here, but I
4 do want to connect these FUSRAP disposals with some broader
5 issues that we have ongoing regarding risk informed disposal of
6 low activity waste. One of them is the Jurisdictional Working
7 Group on Low Level Source Material. It has some federal
8 agencies and some state officials that are looking at how to
9 better manage and regulate <.05 percent uranium and thorium.

10 Next is a revision to 10CFR 40 for transfers for
11 unimportant quantities of source material. We have a rule
12 making in process that will work on these transfers. Right now
13 there is no dose limit when a exempted quantity of source
14 material is transferred to an un-licensed person. Sometimes
15 the dose can be a few rem's. We are putting into place a rule
16 that proposes a 100mrem per year.

17 Next is the 10CFR Part 41 rule making that has to do
18 with developing a separate section just for uranium mills.
19 That is a very large rule. It addresses many different issues.
20 One of the issues that it addresses is the expanding use of
21 tailings containers for disposal of other materials like some
22 quantities of source materials, low-level waste, hazardous

1 waste, and so forth.

2 Another related activity is that the National Academy
3 of Scientists has a proposed study that they are just getting
4 underway. We actually committed to providing a little bit of
5 funding for it in the last few months. It is on low activity
6 radioactive waste. Originally it was their study of the states
7 and compacts. Since then it has been expanded to include all
8 kinds of radioactive waste, particularly those at the low end.
9 They are particularly interested more risk informed disposal of
10 low activity radioactive waste. Probably there are some EPA
11 efforts under way. The EPA is also looking into TENORM. They
12 have got a TENORM team. Finally, EPA over the years has
13 developed some guidance on TENORM.

14 Just to summarize, I talked about our Director's
15 Decision on the 10CFR on NRDC. We don't believe that we have
16 authority to do that. Secondly, our current view is that we can
17 not regulate off-site disposal of FUSRAP waste. We have got a
18 Director's Decision in process for EnviroCare and the Snake
19 River Alliance that should be coming out in the near future.
20 Third, a number of efforts are under way to get us more risk
21 informed decision making for low-level waste disposal.
22 Finally, we are ready to assist Congress, if Congress tells us

1 to regulate any of the FUSRAP programs.

2 CHIP CAMERON: Jim, before we go to open discussion
3 let's go to Carl. Also on the Part 41, Cheryl Rogers, in a few
4 minutes, is going to sort of tee that up for us. Carl?

5 CARL PAPERIELLO: Yeah. I obviously signed the
6 Director's Decision that was signed, up until now I have signed
7 as Director of NMSS. I did represent the agency and give the
8 agencies testimony at the Senate Hearing in July.

9 Let me just reflect on the thing. I am not a lawyer
10 and honestly much of what we did was determined by our office
11 of general council, not by the technical people. That is not
12 bad, I am just saying. My reflection, because I read the law
13 quite often in preparation for this, is that I think that the
14 law was defective. I think that Congress split the world in
15 1978 into two pieces. They said, okay, everybody that is
16 inactive, anybody that doesn't have a license, DOE, you fix it.
17 Congress envisioned the material being stabilized and being
18 place, which is what we are doing on title one sites. Title
19 two says the NRC, for anybody that you have under a license,
20 you are going to take care of and you are responsible for.
21 That is the reason why we are not responsible for FUSRAP sites.
22 Congress split the world that way. I don't think that in 1978

1 Congress ever envisioned what occurred in the year 2000 or
2 1999. That is not unusual. That is how we got where we are.
3 So, you know, it's -- it's -- you know, we can't very well tell
4 Congress this. You can imply it, but you don't outright say,
5 you screwed up when you wrote the law.

6 One of the things that I did find, there was all of
7 this about this being horrible. You are transferring it to
8 RCRA. I did a lot of work on the Internet and I keep finding,
9 depending where you are, material is going into RCRA sites. It
10 is not universal, but a number of RCRA sites take TENORM,
11 principally from oil and gas. We all know -- Ed, I agree with
12 you. What is the difference? TENORM and FUSRAP material that
13 are mill tailings are the same radionuclide. I told Congress
14 that. They are similar. They are similar. Yes.

15 Let's look at the other -- we have and let's talk
16 about uranium. Let's suppose that you just had source material
17 and it was <.05 percent. You could turn around and send that
18 to a vineyard in California. Right? They don't have a license
19 and if it is <.05 percent you could transfer it to somebody who
20 is exempt.

21 EDWARD BAILEY: That is a big if.

22 CARL PAPERIELLO: I am agreeing with what you said

1 earlier today. This is the reason why we are trying to address
2 the <.05 percent. We are going to bubble gum for our
3 licensees, for the specific licensees, we are going to bubble
4 gum. We are not going to let them transfer material <.05
5 percent without us knowing what in Gods name they are doing.
6 But it does create a hystereses, because if somebody has
7 material that they never had to have a license they are all
8 right, but once you have a license you are in trouble. I will
9 admit that is what we are doing. We are bubble gumming it
10 until we can solve the problem. To solve the problem we are
11 going to have to somehow put all of this material in the same
12 box. You just can't get a solution if you turn around and say,
13 well, if it is uranium that resulted from digging up cooper ore
14 and processing it for cooper, and you never got above .05
15 percent by weight uranium, you can throw it wherever you want.
16 But, if you turned around and you dug up uranium or if you dug
17 up the same ore even and processed it for uranium, it now
18 becomes mill tailing. If you have dug up the ore and processed
19 it for something else, but you got uranium above .05 percent it
20 now becomes low level radioactive waste, which can happen. We
21 have licensees that are dumb enough to tell us that they have
22 done something like that. You have got to put this all in the

1 same box.

2 The issue of us and FUSRAP deals with a legal issue.
3 It deals with something that -- our attorney said you don't
4 have it. If I look at the law, I think that the law is just
5 flawed. Congress didn't envision this situation. They thought
6 that the world could be just cut in half in 1978 and they were
7 wrong.

8 CHIP CAMERON: Thank you, Carl, for putting those
9 issues on the table for us. Let's go to Ed for the states
10 perspective.

11 EDWARD BAILEY: Up until this point it has been a
12 very friendly meeting, that may change. I will be very happy
13 when we are able to release our report of the investigation of
14 the waste that went from Tondawonda, New York to Buffalo and
15 California, because a lot of the facts that you are hearing are
16 the facts as told by the USACE. I think that we will find that
17 some of the information and the characterization of the waste
18 has not been accurately presented up to this time. Because of
19 the legal ramifications, I hesitate to get into any discussion.
20 Some of you might have picked up some of the things that
21 occurred.

22 I do have to correct one statement, which I think I

1 can do without getting into problems. It wasn't one train load
2 of waste. It was several trains over about a six month period.
3 Greater than eighty train car loads, more than two hundred and
4 forty truck loads of waste that were shipped all the way across
5 the United States to be disposed of at a RCRA hazardous waste
6 site. A RCRA hazardous waste site which comes no where close
7 to meeting the criteria for a low-level waste site or uranium
8 mill tailings. I think that before we just go and say these
9 are an okay kind of site you really need to do some of the dose
10 analysis and compare how those sites perform doing the same
11 analysis techniques that we do for a low-level waste site. I
12 think that we will find that there are some significant
13 shortcomings in the RCRA sites when it comes to projected
14 off-site doses and the sliding that is allowed for those kinds
15 of sites.

16 CHIP CAMERON: Would any of you, besides these
17 specifics of these -- one of your big criticisms of this whole
18 process is that the RCRA sites are not suitable for the
19 disposal of this type of waste.

20 EDWARD BAILEY: I am not saying that all of the sites
21 are unsuitable. I am not saying that they are unsuitable of
22 some of these kinds of waste. In fact, one of the utilities in

1 California came to us to dispose of some slightly contaminated
2 oils out of a reactor. We agreed that that was an acceptable
3 way, an alternate method of disposal. That was acceptable. We
4 have done this on several other occasions for other disposal of
5 both AEA material and non-AEA material. What has not been done
6 is these sites have not been evaluated on a site wide basis to
7 except any particular value of material going in to them, as a
8 low level waste site would have to be.

9 CHIP CAMERON: Okay. I just wanted you to clarify
10 that so that people can keep track of what the major issues are
11 from the states point of view here.

12 EDWARD BAILEY: Can I ask one other question here. I
13 guess you are the attorney, but -- this material was not
14 regulated by NRC and therefore the disposal can not be
15 regulated by the NRC and if you can go anywhere that you want
16 to, does that mean that if DOE owns a cobalt tele-therapy unit
17 that DOE can dispose of that source anywhere that they want to?
18 You don't regulate it.

19 JAMES KENNEDY: Our position is that it has to go to
20 a facility that it is authorized to be disposed of. That is --

21 EDWARD BAILEY: But it is not licensed material.

22 JAMES KENNEDY: It is not licensed material -- in the

1 case of FUSRAP it is not licensed material.

2 EDWARD BAILEY: In the case of the cobalt 60
3 tele-therapy unit that I just made up, it is not licensed
4 material --

5 CHIP CAMERON: Carl, use this.

6 CARL PAPERIELLO: The question is where would it go?
7 It would go to somebody who would either be regulated by the
8 NRC or regulated by the -- you know, the law -- by product
9 material is by product material -- this is -- this is -- we
10 keep talking about 11e(2). This is 11e(1). 11e(2) was created
11 by the Mill Tailing Act --

12 EDWARD BAILEY: Wait a minute. You are making an
13 assumption that it is 11e(2) material. It may not be. For
14 example, we know that there is one site on the FUSRAP list that
15 was NRC licensed site that never was involved in the Manhattan
16 Project.

17 CARL PAPERIELLO: 11e materials -- that is why -- I
18 understand that. I had a case years ago with a long argument
19 about what was there was source material or 11e(2) material.
20 In fact, the licensee used both. At that time I was just an
21 inspection section chief. I didn't appreciate why all the
22 lawyers were arguing over whether or not it was source material

1 or 11e(2). Now I understand it is because of -- you know, the
2 different thing. The position of the agency was as mill
3 tailing, FUSRAP material, mill tailing, we don't have
4 jurisdiction over it.

5 EDWARD BAILEY: You also don't have jurisdiction over
6 by product material owned by DOE. It is the same --

7 CARL PAPERIELLO: Well, DOE owns it.

8 EDWARD BAILEY: DOE, I believe, still owns the FUSRAP
9 material.

10 CHIP CAMERON: I can go on record saying that they
11 didn't take ownership of the material when they got the
12 transfer of jurisdiction. Let's get some other problems.

13 BILL SINCLAIR: Jim, you didn't mention that as part
14 of the FUSRAP disposal program that some of the material also
15 went to at least one uranium mill for alternate feed
16 processing. I was wondering if you were making a distinction
17 that wasn't disposal in the end or not.

18 JAMES KENNEDY: Well, I was trying to keep it simply
19 first off. Both of you have brought up valid issues. One
20 thing that you are talking about is low-level waste. I was
21 talking about mill tailing. That is another issue. You are
22 talking about alternate feed. That is an issue. The court has

1 -- what they have done is that they have taken some
2 contaminated material, mill tailings, sent it to the
3 International Uranium Corporation, that has a uranium mill out
4 in Utah, and processed it for the residual uranium, which is
5 not very much. What they do is they extract the uranium, they
6 distill it, and then they dispose of all the mill tailings.
7 So, as Bill will quickly point out, it is a way to get rid of
8 -- not only to extract uranium, which isn't a whole lot, but
9 also to get rid of the tailings from the FUSRAP program.

10 BILL SINCLAIR: The other complicating factor to that
11 was that because FUSRAP material had origin that was
12 classified, it was very confusing that the position was taken
13 that once it enters the gate, and is processed, it becomes
14 11e(2) by product materials again. So, it becomes a different
15 category. It is very confusing from a regulatory standpoint.
16 I am not sure what it is now.

17 CHIP CAMERON: Are there recommendations for the NRC
18 on what the NRC should do to try to resolve any problems that
19 the states see here? Aubrey?

20 AUBREY GODWIN: There is another little problem that
21 is floating around in all this mess. Typically there is an
22 analysis performed by some laboratory, so I asked the question

1 of the Corps of Engineers, since they took a grand total of
2 twenty-six samples to determine if this material was below the
3 limit -- on all eighty-four train car loads -- you know, just
4 how good were these laboratories? They came back and said they
5 are all certified. They were certified for water. None of
6 them are certified for solids. They quoted a whole bunch of
7 water procedures that they had used to analyze the material
8 with. I on questioning the Corps of Engineers -- you know, I
9 pointed out that they had water certification and did they
10 adjust their levels for solids -- that is a rather important
11 correction factor that you might add -- they talked about
12 radium 228. I was interested in which method they used and how
13 did they count that. Did they use an ingrowth method? Did
14 they allow the ingrowth to complete itself or did they
15 calculate alphas? With alphas, again the thickness of the
16 sample is a major consideration on your accounting.

17 The Corps of Engineers thought that was so important
18 -- I wrote them in December. They wrote me back that they had
19 not worried about it until I reminded them that I needed an
20 answer to my letter. So, you can tell that they are really on
21 top of figuring out if the laboratories were right. They are
22 going to ask the laboratories to provide some of this data. My

1 guess is that they will be somewhat close to right, but maybe
2 not as good as you would like. It is important to look at the
3 laboratory data and the quality control work that the
4 laboratory does when you start looking at these environmental
5 samples, particularly when you are using radium, uranium, and
6 thorium series for a decision.

7 CHIP CAMERON: Let's go to --

8 EDWARD BAILEY: Can I ask one more question?

9 CHIP CAMERON: Yeah. Sure.

10 EDWARD BAILEY: Aubrey is on the Southwest Low- Level
11 Waste Compact. We haven't really heard any discussion about
12 what happens when this pre '78 wastes go from one compact to
13 another. It seems like all of a sudden we come into -- you are
14 generating new waste for that compact, by bringing it, by
15 hauling it in.

16 AUBREY GODWIN: In terms of the Southwest Compact --

17 EDWARD BAILEY: I know the problem --

18 AUBREY GODWIN: -- copied the federal law, so 11e(2)
19 get exemption from it. However, should your investigation
20 reveal that this is not 11e(2) then the Corps of Engineers and
21 the federal government is in violation of federal law. You
22 could probably proceed that way.

1 CHIP CAMERON: All right. Let's go to Ruth McBirnie
2 from Texas.

3 RUTH MCBIRNIE: Ruth McBirnie, Texas. We have been
4 -- our agency has been put into the position lately, and it is
5 taking up a lot of time, of verifying that the material truly
6 is exempt source material, or exempt material of some sort, in
7 order that it can go to a RCRA type landfill. The RCRA
8 landfills that are in Texas that are wanting to take it can not
9 take any radioactive material that would require a license to
10 possess. So, we are only allowing exempt material to go there.
11 In -- in considering the .05 percent by weight in any mixture
12 for soils, rubble, and that sort of thing, it is pretty easy,
13 if they have a good sampling analysis. The latest request has
14 been for piping, large equipment, file cabinets, and so forth,
15 which are contaminated which is above .05 percent, if you just
16 look at the contamination itself. They want to average the
17 material. However, we have in our regulations contamination
18 limits for release of unrestricted use. We are using that
19 criteria to say whether or not that material is truly
20 unrestricted or exempt. We are having a lot of conversations
21 back and forth.

22 This particular material however came from an NRC

1 licensed facility, rather than a FUSRAP site. NRC has done some
2 sort of analysis and we are trying to work with them on that,
3 on how they came up with the fact that it is truly unimportant
4 source material. As far as what we would recommend, I think
5 that in developing regulations on unimportant source material
6 is to have some sort of consistency on what is truly exempt,
7 what can be disposed of at alternate places, and then what can
8 be released for unrestricted use in playgrounds and so forth --
9 similar to what is being done with NORM.

10 CHIP CAMERON: Thank you, Ruth. Kirk?

11 KIRK WHATLEY: This is just one -- there is another
12 side to this that we have dealt with lately and that is not
13 associated with disposal, but it is the importation of it,
14 thorium and uranium. It really creates a problem trying to
15 determine the percent by weight. That is not an easy control
16 to set, not easy to do. It takes a lot of time. 7 to 10
17 picocuries per gram of thorium, which is about twenty percent
18 or .05 percent by weight will set off the alarms. We have done
19 a lot of running around chasing after stuff.

20 In Aubrey's wisdom, before he left -- we have RCRA
21 site, prohibits disposal material without a background. Think
22 about that. It means you can't take dirt there from anywhere

1 in the state. It comes in by the barge load in Mobile.

2 The Department of the Army uses tons and tons of it
3 to sand blast ten thousand tanks, plus tanks that they are
4 rebuilding everyday. They are talking about they want to send
5 --

6 CHIP CAMERON: Thanks, Kirk. Jim, based on the
7 comments that you have heard, have you anything to add or
8 anything that you want to say about this?

9 JAMES KENNEDY: No.

10 CHIP CAMERON: Anybody else out here?

11 BARBARA YOUNGBURG: I am Barbara Youngburg from New
12 York State. I work for Paul Mitchell. I just wanted to bring
13 you up to date on what New York State has done. In March,
14 probably -- you have all heard that the courts there issued a
15 decision for the Lindy site and adopted clean up criteria for
16 uranium of about 700 picocuries per gram for the surface and
17 3000 picocuries per gram for below fifteen centimeters. They
18 also threw in a lot of statements. They would remove
19 everything about 600 picocuries per gram uranium.

20 So, they did their work plans to start work at the
21 site. The work plan tells the -- well, the contractor wrote
22 the work plan and it says they will segregate everything that

1 the excavate into clean and contaminated piles. Anything below
2 600 picocuries per gram uranium is clean, anything above is
3 contaminated and is going to be shipped off-site. They are
4 demolishing several buildings on the site. Some of which were
5 built on contaminated soil. So, they aren't contaminated.
6 They have been surveyed. We have been out there and surveyed
7 them too. But they started looking around for local landfills
8 where they could dispose of this clean material.

9 We got calls from one of our RCRA D facilities, a
10 regular old garden variety municipal solid waste landfill
11 called up and said, can we take this clean stuff? That
12 prompted the department to do an emergency rule making to close
13 that regulatory gap on this material. What we did was amend
14 our regulations that regulate the disposal of radioactive
15 materials to make them apply to basically, we just lifted the
16 definition of 11e(2) material out of the Atomic Energy Act and
17 said that stuff -- wherever the NRC doesn't regulate it. So,
18 this kind of things can't go to New York State landfills,
19 because we have a handle on that.

20 EDWARD BAILEY: Can I ask Barbara a question? If I
21 remember correctly, 600 picocuries of uranium exceeds .05
22 percent by weight.

1 BARBARA YOUNGBURG: Yes. It does.

2 EDWARD BAILEY: Am I also correct that the Lindy site
3 was licensed by the State of New York for a contamination that
4 was on-site in 1978.

5 BARBARA YOUNGBURG: It was on their Labored Park
6 License for a while, the contamination was. That is true.

7 EDWARD BAILEY: I am not sure, since this was in part
8 a uranium mill, why it wasn't gobbled up into Title One or at
9 least interpreted to be under regulation at that time.

10 CHIP CAMERON: Barb, you don't have an answer for
11 that, right?

12 BARBARA YOUNGBURG: No.

13 CHIP CAMERON: All right.

14 STEVE COLLINS: Steve Collins, Illinois. I would
15 like for all of you just to think about the waste that was just
16 described from New York, if it is not federally regulated or
17 regulated by NRC, is it below your exempt concentrations or
18 quantities in your rules that require people to get a license
19 if it is above certain amounts. I would tell you that it is
20 above those amounts. So, as soon as Corps of Engineers get
21 through cleaning up the site and walks away, they have to get a
22 license from New York to possess that material left.

1 CHIP CAMERON: Good question. Anybody else? I think
2 that we all heard enough issues raised for the NRC to ponder.
3 We just thank Jim for the presentation. Cheryl, I am just
4 going to turn this over to you.

5 CHERYL ROGERS: Cheryl Rogers, Nebraska. That is
6 what I get for asking to put something on the agenda. The new
7 Part 41 rule making really only affects, as far as I can tell,
8 seven states, four Agreement States and three Non-Agreement
9 States. The states that it could potentially affect is anyone
10 that has a uranium, thorium processing going on in your state.
11 As you have heard this recent discussion, you just might never
12 know when it might come and impact your state. So, stay awake.

13 Part 41 proposed, request for comments on the
14 proposed rule making plan was announced in the State and Tribal
15 Programs, 00-074. It is due approximately October 25th.

16 I have my CRCPD hat on right now, as the Chair of
17 Part U, which is the group that is suppose to do the parallel
18 rule making with the NRC. My main task is to look around and
19 make sure that I know what all the various states that are
20 affected, the seven states, might have views on this. Also to
21 make sure that we have adequate state representation on the
22 rule making group. My understanding is that NRC has not made

1 it to the step of asking for representation, but we think that
2 they will be going to the CRCPD because they have the priority
3 rule making group and potentially to the OAS.

4 The new Part 41, the main focus is to upgrade the
5 uranium and thorium processing for facilities, but as Jim
6 Kennedy just pointed out, there are other issues. Using the
7 mill tailing impoundments for materials similar to 11e(2) and
8 processing material other than nature uranium ores. The
9 commission has said yes, if they meet the same requirements go
10 ahead. There is a long laundry list of requirements and for
11 the processing that they will not use the economic test, which
12 is what I believe is what Utah is pushing. That affects both
13 Agreement States and Non-Agreement States.

14 The other big issue is that since it -- the
15 regulation of ground water, that line does not cut down whether
16 you are an Agreement State or a Non- Agreement State. You may
17 want to go talk to your people who regulate ground water.
18 Alice Rogers from Texas has been busy about informing me what
19 relying on the EPA regulation might mean and where some wholes
20 in that might be.

21 The fourth issue, which affects Non-Agreement States,
22 is the concurrent jurisdiction issue. In the past the NRC has

1 let the Non-Agreement States have jurisdiction over the
2 non-radiological component. They are reversing that decision,
3 which has been kind of a twenty year policy. I am not entirely
4 sure who that affects. I believe that it could be the State of
5 Wyoming, the State of Utah. It is kind of a grab bag. Right
6 now we have seven states, but it seems to be -- it could
7 possibly reach its tentacles to your state.

8 If you don't have a ensitu facility or a uranium mill
9 you are probably off the hook at the moment, unless one of
10 these waste disposal comes up. When Ed was having all his
11 troubles, I checked to see if I had an RCRC facilities. I
12 thought that I was off the hook for a while.

13 CHIP CAMERON: Thanks for putting those issues in
14 front of us, Cheryl. Does the NRC want to comment at all on
15 any of the issues that Cheryl mentioned?

16 PATRICIA HOLAHAN: Trish Holahan, NRC. I think that
17 Cheryl kind of characterized them all. The main issues that
18 are in there are basically -- the purpose of doing the Part 41
19 was to try and consolidate all the regulations into one part.
20 That is the real focus. Yes. We do have the draft rule making
21 plan that is going out to the Agreement States and the
22 Non-Agreement States for comments because some of the issues do

1 cross and have an impact on the Non-Agreement States as well.

2 CHIP CAMERON: Thank you, Trish. Anyone else?

3 (Whereupon, the meeting was concluded.)

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