UNITED STATES

NUCLEAR REGULATORY COMMISSION

Organization of Agreement States Meeting

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Double Tree Suites

181 Church Street

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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
give a few minutes on it.

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

STEVE COLLINS: I am not from NRC.

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

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

CHIP CAMERON: Steve Collins?

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

The work is continuing. The commission has directed the NRC staff to continue research, so that when the process does get going again there will be additional research available. They are continuing this process for other
EDWARD BAILEY: Thank you. And, I apologize to you, Steve, because I didn't put those two together. Steve Collins is the state person on the Control of Solid Materials Steering Group. The next one that I have is Sealed Sources and Devices. Actually we are -- the states are really well represented on that. Will Wright from Arizona has retired --

KATHY ALLEN: Joe Klinger.

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

CHIP CAMERON: Joe?

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

So, what is the scoop all about? A couple of years ago, up in New Hampshire, I gave a presentation. It was after several states went through the IMFET process and there was a less than pleasurable experience in the S. S. & D. area. I remember North Carolina, Texas, Illinois -- several of us. It was not pretty.
So, what we did -- NRC took it to heart and we put together this working group. In April of 1999, we got together and we decided what we wanted to work on. Some of the things that we wanted to work on were the S. S. & D. reviewer qualifications, the second S. S. & D. reviewer, the concurrent review issue -- you know, was that a complete review? And various changes to the management directive 5.6 in the area of S. S. & D.'s.

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

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

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

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

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

The issue is, I think that it was pretty well -- if any of you didn't get the Rad Rap or are not on it, let me know and I will see that you get a copy. The issue is that there
are certain levels of source material that are not regulated now, but they are a hazard. The question is who gets control, who should be controlling, and should we be controlling those quantities of material below .05 percent.

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

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

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

CHIP CAMERON: Just one clarification, some of these issues that are being talked about, Trish Holahan is going to
be covering during her presentation. Maybe she will be a resource to answer questions about it.

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

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

EDWARD BAILEY: Okay. Maybe --

CHIP CAMERON: Any --

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

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

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

EDWARD BAILEY: Maybe an over feel?
DR. DON COOL: Five seconds on this. Cindy Peterson, from our region three office, is actually leading up this particular effort. Most of you are probably aware that this spring Malancropt's Maryland Heights Manufacturing Facility had a rather serious extremity overexposure. One of the workers on their production line actually picked up and held in his fingers, for some twenty plus seconds, a nineteen curie Malitech generator tube, not inside the shield, the generator.

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

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

So, there is an effort ongoing now to see whether we had the right focus, if we were looking at the right things for manufacturing, and to try to help define some of these
jurisdictional issues. This will go, this coming spring, into a broader look at our whole inspection and licensing program, which I understand some folks were also being signed up for.

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

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

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

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

EDWARD BAILEY: Great. The next on is Event Reporting and we have two state people on it, Robert, and somebody help me, Desaro. In the south, we would make that three to five syllables. Also we have Helen Watkins from Texas. Anybody from the states have any further update on
that? Is this going to be in one of the updates from NRC?

KATHY ALLEN: ED?

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

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

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

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

We are looking at the Nuclear Material Events Database, the Agreement State reporting requirements, and elements of a generic issues program. You probably have all
received a questionnaire. We sent them out to all the states and all four regions. We received twenty-one responses from the states and all four regions sent their responses in. I am not prepared to talk about what we found from that yet, but we will be putting that information in the report.

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

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

EDWARD BAILEY: That reminds me. I told Kevin that I would encourage the eleven states to respond to the questionnaire. If we go forward on this alliance, we are going
to have to pitch in. So, I encourage all of you that have not returned the questionnaire to do so. Let's make it a hundred percent. We got a hundred percent on the definition of radioactive material and I think that we should strive to have a hundred percent of the states respond.

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

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

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

EDWARD BAILEY: Okay. Volume fifteen, sixteen, seventeen, and eighteen are all NRC people, as are nineteen and twenty. And, there is a new reg coming out for XXX rated
movies. This is going to be a quadruple X rated new reg. So, I am not sure what the expected date is on that.

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

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

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

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

We have been through two comment periods. We were going through the peer review. I would like to let you guys
know that I am very proud that we got almost two hundred, if not more, on this peer review. In three days, there's one hundred and eighteen sections to this rule, our group got through all one hundred and eighteen sections and all the comments. We were able to finish up getting answers for all of that.

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

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

Who is responsible for that person then? We have
gotten into some real interesting legal battles, particularly where hospitals have had people with diagnostic scans and then die. This is particularly occurring in Gallium and so forth. So, we have had them remove organs, save those organs, and all kinds of things. It is a good problem to work with.

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

EDWARD BAILEY: Sure.

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

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

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

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

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

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

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

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

Risk Assessment and Management Proposed. Agreement State rep to be determined. National Materials Steering Group,
Bob Hallisie and I inherited that job. Then the National Materials Program, I think that you have heard from them today. So, I don't think we have to go into that again. That will conclude the working groups. Yes, Steve?

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

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

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

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

EDWARD BAILEY: And your point is?

STEVE COLLINS: My point is, Illinois and Jan Endal
are already working on some model language to try to solve this
for you. Once this letter comes out or maybe before hand, we
can give you some model rules regulations that will fix your rules. So, that your rules will match and grant ASNT what they really need once they have approval.

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

CHIP CAMERON: Do you want Bob to --

EDWARD BAILEY: Sure. Let Bob --

CHIP CAMERON: Okay. This is Bob Gallagher.

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

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

(Recess.)

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

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

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

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

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

The regulatory analysis plus the volume of the draft final new reg support of implementation guides, all of that
went off to the commission. The commissioners spent a great
deal of time examining that. They have all submitted their
initial verdict to the office of the secretary. Everybody was
happily running around getting ready for an acclamation
session, which is one where the commissioners get together in a
public meeting. They canceled that on the morning of the
meeting. There are a couple of small issues that they are
trying to resolve.

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

Now, when the commission votes, that doesn't mean
that it is going to show up in the Federal Register the
following week. What it means is that the staff will actually
get to prepare the package and send it down to the office of
management and budget for the review of the record keeping and
reforming part of it. Assume that they are going to take their full ninety days before they will approve the record keeping. They did not review the proposed rule. The NRC can not legally publish the regulation until it has been approved by OMB. So, even assuming that we have an affirmation vote within the next couple of weeks, I would not expect a rule to actually be published in the Federal Register until sometime early next year, simply because of logistic steps that are necessary and of course the steps to actually have it become affective and do the implementation.

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

Now, I will move on to the implementation issue. This is sort of, where are we going from here. First thing that I want to look at is a pilot program that we have just started within the inspection arena intended to focus upon safety, being more risk informed, performance based. Yes, certainly we are interested in compliance with the requirements.
But, we are trying to develop a new more focus approach where we go in and we look at some performance factors. How have they been doing in executing their program and basically doing what a lot of the more experienced inspectors do. You walk in. You walk around for a few minutes. You talk to people. You have some basic data. We all have experienced inspectors, who know within the first half an hour if there will be significant issues and where to start poking.

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

And, as we start to build it next year, and I mentioned it a few moments ago, we are working with the working group a reconsideration of our whole fundamental inspection
program. Are we looking at the right things? Are we asking the right questions? Are we looking at the things that pose a risk?

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

We are looking at developing communication plans, going out and talking with our licensees. The agency is going to be Agent Charlie and responding to questions that will inevitably come up as you go through your rule and people get into it. The more people that come looking, what am I actually going to do when the more detailed questions start to arise
about our technical assistance process. You will have revise a
section manual chapter, activity.

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

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

Update things in the Technical Training Center that
are used for -- and corresponding changes in Nuclear Material
Events Database, because it will no longer be in the
administration. It will be in some other, there will be
changes in categorization, so that they can do proper research.

All right. Let's get back to Aubrey's issue, real quick here. I know I am zipping through things real quickly.

45CFR Part 61, otherwise known as the Healthcare Integrity & Protection Databank. That is a mouthful. I dare you to say it three times quickly. The rule actually became effective October 26th of 1999. I think that, Aubrey, you Governor office made an inquiry as to the actual effective date.

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

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

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

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

Enforcement actions -- probably NRC's severity level three, maybe three is with several pounds. We don't want to get into the mode of tossing a report for every severity level four non-sighted violation, four and five might be ones that
you leave with inspector observations. Then things that we
look at will be related to application/amendment denials. The
big issue then is an order related to non-payment of fee. We
are having to put in a report for that.

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

As Aubrey told you during the business meeting, there
are a number of decisions that you have to go through. Who is
going to report? Who is going to have permission to extract
the information? As well as the things like, what are you
going to report? That is part of the process that we are going
through at the present time. There are several questions that
still need to be resolved.
Chip, I probably used just about my ten minutes.

That very briefly covers the things that I wanted to touch on.

I would be glad to answer questions.

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

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

DON COOL: Several times already.

EDWARD BAILEY: And that doesn't help any?

DON COOL: Hasn't yet. That doesn't mean that it won't. We haven't actually gone down and gone face to face.

My staff people have been talking to the people who are really responsible for it. This was done by the HHSIG. So, they have a certain lense that they are looking through, which doesn't necessarily lend itself very well to answering the kind of questions that we have to ask ourselves. I think that there is going to be great benefit, I am not sure whether through Rad Rap or otherwise, continuing to try and come to some common understanding of what the concept needs to be for things that are reported.

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

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

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

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

But I also note that you are probably not the only ones in your state who have to deal with this, depending on where you are in your organization. The board that is handling licensing actions for physicians, the health department, and 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.
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?
DON COOL: This regulation, I don't believe, has that sort of information transfer to another organization. It is in essence saying that, if you are an organization that is doing licensing and inspections this is a resource that you can go to and check as you take action to determine whether or not the organizational individuals have had any reported to it.

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

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

AUBREY GODWIN: It is real easy to get into the business. You go to the website and they have all the forms right there on the website. You can print up in living color,
if you so desire. You complete them and send them in. It costs you nothing to register to be an inputer. You have to meet certain legal qualifications.

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

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

CHIP CAMERON: Thanks, Aubrey. Bob?

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

CHIP CAMERON: Let's go to Pearce.

PEARCE O'KELLEY: Don is there a time limit on when the data has to be entered? Is it after the resolution? Do
you have an opportunity to change the data that you put in there?

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

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

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

We are talking about, discussing, I guess that is the same thing, extending our three year inspection to five years with all facilities that are participating in those, if they
passed it. Then, if we got notice that they had failed it, we would immediately inspect it. And, it will include some review of these practice audits and what they really look at. We are discussing it. I am not saying that we are headed that way. At least it is something new and different. In the judgement of some in the medical community, those audits are much better at getting to, not only patient safety, but the quality of care for the patients.

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

DON COOL: What transpired during the Part 35 development was, mediation was in fact brought up, I believe by the American College of Radiology representative. We sort of, as in the past, we passed on it, it wasn't something that was in the regulations that had to do with the program and they agreed with that. What Ed has laid out here is a variation. What they had initially tossed on us was if they had this practice audits, why don't you just not inspect us as long
as we continue to pass it. There was a lot of discussion and 
wringing of hands. There was some sort of back and forth about 
the legal implications about information availability and so 
on. There were a number of questions that were put on the 
table. At this point, I don't believe that they have come back 
to us with a more specific proposal. I have heard the issue 
before.

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

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

CHIP CAMERON: Thank you. Thank you, Don. I think 
that we are ready to go on to the next one. Kathy Allen is 
going join us now to ask us some questions about IVB.
KATHY ALLEN: When we went out to set this up we asked what kind of things did people want to hear about and one of the big things was this IVB thing. We tried to figure out who could come up here and talk about this and wahoo. We started looking at the people who actually want to use this. Every cardiologist has a different approach, a different desire, a different need. We couldn't find one that was willing to represent these all. So, I am going to make you guys do it, actually.

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

So, rather than me telling you guys what is going on, I think that you guys are really the more expert or you have members of your staff that are much more involved in this. So, yeah, I kind of slipped on my working group hat again. So, I would just like to know who is already working on this. We are going to put this on the chart. Then I am going to send that
on through Rad Rap or whatever you want. Who is already working on this? I know that there are lots of states involved in looking at these things and also approving the sealed sources and substitutes.  

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

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


CHIP CAMERON: A question from Rhode Island?
BILL DUNDULIS: Kathy, as I outlined before, P-32 is going to be somehow incorporated into a stent. We are not sure if it is going to be coated or what. It is going to be solid P-32.

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

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

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

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

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

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

RUTH MCBIRNIE: Excuse me.
KATHY ALLEN: Yes?

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

DON COOL: Yes.

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

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

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

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

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

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

SALIFU DAKUBA: I can't off-hand remember who is making it, but it is in the form of clinical trials. The
original device is from somewhere, I am not sure where. I will
have to look up and see the origin of the device.

CHIP CAMERON: Okay.

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

Thanks a lot for your systems and help.

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

KATHY ALLEN: I am actually kind of hoping that,
maybe the next time we meet or maybe at the steering meeting,
there maybe people who actually kind of use this and said we
have looked at it and these are the key issues that we need to look at. We can all look at down the list and say, wow, look at that. There are a bunch of issues, but I would rather wait and see what kind of things people actually bring together.

Joe, do you have a comment?

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

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

JOE KLINGER: Is anyone else close to issuing?

RAYMOND MANLY: Maryland also issued for clinical trial.

CHIP CAMERON: All right. Thank you, Kathy.

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

TOM HILL: Tom Hill, Georgia. I think that you have to have an S. S. & D. sheet at their in hold. We have approved
one hospital to use it in clinical trials. I understand that they were looking at -- possibly with other hospitals around the country that might fall into that same category that were considering it. We issued the S. S. & D. so they could -- we thought it would be useful to the states.

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

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

RUTH MCBIRNIE: This is PET as in Positron Emission Tomography, rather than Puppies, Egrets, and Turtles. I have got more questions than answers. I had my Chief of Medical Licensing write out a few of the issues that are involved in
doing this, regulating PET, especially mobile PET. The first of which is the proper of Florin 18, FEG on the radioactive materials license. The only new drug applications for FDG is -- it therefore does not fall into what we call the group authorization, although we are now changing our rule to take that out. But, we do put it on as a line item on the license. We also limit the use in a specific individual.

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

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

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

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

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

The patient can't leave the area due to short
distribution time. It is about thirty minutes. And, of course, the short half-life of the isotope. It is about two and a half, two hours.

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

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

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

Mobile PET may very well be paving the road for violation to state and federal drug laws. With mobile PET there are significant disadvantages to assigning every individual the role of radiation safety officer. The technologist will have a significant conflict to shut down his
own van in the event of a spill, when reimbursement exceeds over $2,300 per exam. Few technologist have experience with specifically with PET. The anywhere authorized physician user would simply be that, anywhere except on the coach and thus not available to truly evaluate a radiation safety concern. The corporate licensee or radiation safety officer is located at places unknown and will have widely varying duties, depending on the number and activity of the coaches riding hot, in whatever state they are operating.

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

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

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

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

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

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

We have one center that specializes in the brain imaging in mass murderers. So, every time they find a new mass murderer they come to us with this.
AUBREY GODWIN: Do they operate at that prison?

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

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

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

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

DAVID WALTER: David Walter, Alabama. You mentioned on the training aspect that it was for three days. Can you give me some information on what additional training it was suppose to cover?
RUTH MCBIRNIE: It has to do with these specific isotopes --

DAVID WALTER: Strictly radiation safety --

RUTH MCBIRNIE: That is correct.

DAVID WALTER: -- because of exposure possibilities?

RUTH MCBIRNIE: Right.

DAVID WALTER: Okay. Thank you.

CHIP CAMERON: Cheryl Rogers?

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

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

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

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

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

CHIP CAMERON: All right. Kentucky?

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

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

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

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

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

Some of the background -- the next slide -- is that
as we heard yesterday, the definition of unimportant quantities
is based on national security. Whether it is a useful source
of fissionable material, rather than health impact. That has been defined as <.05 percent by weight one-twentieth of one percent of the material is considered unimportant quantity.

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

In addition to these issues that are ongoing, we also received a petition from LES and the state of Colorado that requested that the exemption in Part 40 for general licensees be re-examined to make sure that they were required to perform Part 2011. Specifically they asked that the exemption in 4022 be revoked for entering any general licensee that had the potential to exceed the public limits could exceed the limits -- with a person monitoring or with a prior area posting. And, that they would then have to comply with the requirements of Part 19 and 20.
As a result of these activities -- the next slide -- we submitted a paper last November, titled Exceptions Part 40 for Materials <.05 percent, Options and Other Issues Concerning the Control of Source Material. As part of that the staff recommended four things. First of all, that we would develop more risk informed performance based regulations for the use of source materials, again using the main four strategic goals of maintaining safety, looking at efficiency, appropriateness, and reducing unnecessary regulatory burden. Also, the recommendation was to explore the best of approach of delaying the responsibility of the NRC and other agencies with responsibility in this area of low level source material. To improve the control and distribution of source materials through general licensees and finally there was a recommendation that the staff could consider requiring prior commission approval for transfers of licensed materials.

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

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

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

The second task was to develop a proposed rule amending 40-51 to require prior commission approval for transfers of <.05 percent of source material. That rule is not to the commission. It was sent out to the Agreement States for, as a draft for a proposed rule for a comment period. The criteria is that the doses are not expected to exceed 100mrem
per year, but the commission will be informed if doses exceed
25mrem per year.

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

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

So, really that is where we are. I would now like to
move on to a couple of other activities that we have going on.
The next one is Part 71. This is another rule making that we
have. The focus of this was, or the initial part of it was to
make the current transportation regulations compatible with
ST-1, which are the '96 IAEA transportation safety standards.
However, in going through and beginning to look at this rule
making, in addition to the eleven ST-1 changes, we also
identified eight NRC initiated changes that would effect
domestic shipments of materials.
We have been using an enhanced public participation process which has had three public meetings so far. One has been a round table meeting at Rockville in August. In the last two weeks we have had a town hall meeting in Atlanta and another town hall meeting in Oakland last week.

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

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

As I said, there are nineteen issues. The key issues that seemed to generate the most discussion at the public meetings are listed on the next slide. One is what -- characterizes the adoption changes, tests, and experiments
authority. Let me just clarify, of the four issues on the slide, two of them are NRC identified issues and the latter two are to be compatible with ST-1. The adoption of changes and tests, what this allows is for the reactors and for the spent fuel certificate holders. They are allowed to make certain changes to the design or do certain experiments without prior NRC approval. This became problematic specifically for the duel purpose cap that are both for storage for spent fuel and also an approved transportation. So, the issue was to look at Part 71 to see if we would allow this type of change authority for spent fuel transportation packages, not only for the duel purpose cap, but also for the central transportation packages.

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

The third issue is the radionuclide exemption values. Currently the exemption value and the requirements is 2,000
picocuries per gram and it is not isotope specific. New IAEA standards has radionuclide specific values for event materials.

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

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

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

Switching gears a little bit, we also have a rule making with relation to Part 34. This is one that has been in response to a petition for rule making from the Amersham Corporation. It was noticed that as we received comments -- there were several workshops held on it. We did have several representatives working with us on developing the rule making
plan. Unfortunately, it has slipped somewhat in the schedule and we are trying resurrect this to get this back out again and back out on the street. Specifically the petitioner requested that we remove all references to associated equipment from the NRC regulations. Because only the registration devices that are required in 30-32 and 32-310.

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

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

In terms of how we are proposing to handle that, the
next slide, for Category A, it would need to be either registered or licensed. The current 34-20 would continue to apply. And, all the other equipment in the Part 34 Category A would remain essentially unchanged. For the Category B equipment, it wouldn't require registration or licensing, but it would require certification by the manufacturer licensee that the equipment meets the performance criteria.

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

The last rule making that I quickly wanted to cover is one that address new dosimetry technology. On the next slide, the current regulation, Part 20, there is a requirement that personal dosimeters that are processed to determine dose must be processed by an accredited NVLAP processor. However, in Part 34, 36, and 39 there are very specific requirements that specify the use of film badges and TLD's for NVLAP processing.
The problem that arose with that is that there are some new technological advances. In specific the optically stimulated thermoluminescent dosimeter that also requires processing to determine dose. The problem was that some of the licensees wanted to use this, but were limited by the current requirements to use either film badges or TLD's. Also there is the possibility of other dosimetry technology coming in the future.

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

On the next slide, the proposed compatibilities, there is no change in this from what the existing requirements are. So, category C for personal monitoring. Category D, for the ones in Part 36 and Part 39. As I said, that is not a change from the current compatibility requirements.
Where we are is -- because this was determined to be a non-controversial rule making we have gone by a direct final rule process. It was signed by EO last week. So the Direct Final Rule and the Proposal will be published in the Federal Register for, probably by the end of this week or next week. When we do a Direct Final Rule there is a proposal that is published for a thirty day comment period. If no significant and adverse comments are received then the Direct Final Rule will be affective seventy-five days after publication. If we do have what is determined to be significant and adverse comments then we will withdraw the Direct Final Rule and go to a normal -- whatever process is appropriate.

So, that is a quick rundown of four of the rule makings that we have ongoing. I know that -- if I can just take one minute more, earlier I think that Ed had asked about some of the guidance documents. The Part 20 guidance document will be published in the draft next month. Our numbers are now final. We are discussing by the end of the year publishing the final Volume 12. Bankruptcy should be published next month as will the -- the general licenses guidance document will be published once we publish the Final Rule. The Final Rule is still with L & B for approval.
CHIP CAMERON: Thanks for that overview, Trish. Four very different topics. Who wants to start us off with either a question or a comment on these area? We will go to Kirk first.

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

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

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

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

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

PATRICIA HOLAHAN: Yes. That will be part of the
individual plan that we are looking at.

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

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

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

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

PATRICIA HOLAHAN: Yes.

DAVID WALTER: Thank you very much.

CHIP CAMERON: Okay. Cheryl?

CHERYL ROGERS: Cheryl Rogers, Nebraska. This is on
the transportation and we did not make comments. I don't know if we missed our opportunity or not. I was curious about the radionuclide exemption values. You know, that seems like a lot of work to go risk informed on a nuclide basis. What kind of comments are you getting on that?

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

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

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

PATRICIA HOLAHAN: Not at this point in time. We did recognize that there is a need for the DOLAP, but we could not go a Direct Final Rule, if we were going through DOLAP, because there was an expectation that it would get comments on that.
So, we are going to be developing a rule making plan to address
the DOLAP issue.

CHIP CAMERON: Anything else on this rule making?

Trish, thank you for doing that and covering that for us.

(Recess.)

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

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

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

I have three main messages today. The first is that
NRC doesn't have jurisdiction under current law to regulate
either on-site clean up of FUSRAP materials or off-site
disposals of FUSRAP materials. The second is that if Congress wants us to regulate the FUSRAP program we are ready to assist them in lending legislation to help make that happen. The final is that whether if you agree with what the Corps has done, particularly with radioactive materials in hazardous waste facilities or not, they have at least added to the conversation, advanced the conversation on more risk informed disposal of low activity waste. So, I will be talking some about that.

Next slide. Here are the topics that I am going to talk about first, a little bit of background on the FUSRAP program. Next. Interest in NRC regulation FUSRAP, that is really an understatement. We have had lots of letters and so forth from different folks arguing that we should be regulating the FUSRAP program. Next. I am going to go over briefly the Director's Decision that was issued in March of 1999, concerning our lack of jurisdiction over on-site clean ups of FUSRAP sites. Next. I will give you our current view on regulation of off-site disposal of mill tailings in the FUSRAP program. Then, I am going to jump off sort of a level and compare low activity waste in general, not just mill tailings from the FUSRAP program, but also unimportant quantities of
source material, like 75 percent source material, low end of low level waste. Finally, I am going to talk about some related issues, even more probably, regarding risk informed disposals of low activity materials.

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

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

Next slide. That is a map that I took off the Army Corps web site. What that map doesn't show and is the most controversial issue right now, I think, is the four disposal
sites where the Army Corps has been sending waste. One is down in Texas. They have sent a lot out to Utah. Some have also gone, one train load went to California. And then there has been some that has been sent to a hazardous waste site up in Idaho, near Boise.

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

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

Next slide. With respect to on-site clean ups, we issued a Director's Decision that was actually signed by Dr. Paperiello, who was the director at that time. In it we addressed the issue of NRC's regulation of on-site clean up.
He stated that we lacked the authority for on-site clean ups. That the Corps clean ups are being conducted pursuant CERCLA, which waived permit requirements for on-site activities. We also pointed out that Congress gave NRC no money and no personnel for an oversight goal when the transfer was made back in late 1997. We said, as I said earlier, that if Congress believes that NRC should regulate the on-site clean ups, we stand ready to assist Congress in amending legislation to that ends.

Next slide. With respect to off-site disposal of FUSRAP mill tailing, as I mentioned earlier, the Corps practice has been to use RCRA hazardous facilities, in a few cases, for disposal of mill tailings and low activity waste. Earlier this year, back in February or March, we received two petitions requesting that we regulate off-site disposal of mill tailings from FUSRAP sites, particularly the material already in RCRA hazardous waste facilities. They were submitted by EnviroCare of Utah and the Snake River Alliance, which is an environmental group out in Idaho. Those petitions have been combined into one. They both ask for the same thing and they were both submitted at the same time. We are working on that Director's Decision right now. That Director's Decision will be issued
soon. It will have a definitive agency position on where we stand with respect to regulation of off-site disposal. The views that I am giving today, our views today, are what we had to say at the July 25th hearing, Senate Hearing, before the Environment and Public Works Committee. That was also given by Dr. Paperiello. Dr. Paperiello was there, along with a number of other folks.

Here are our views that we presented, NRC views.

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

Now, at the hearing, I am going to talk about this chart. At the hearing there were basically two categories of testimony. First there was testimony that dealt with the legal issues, which addressed what UMTRCA says, what the Atomic Energy Act says, and how the law should be interpreted about
whether NRC has authority over these mill tailings. The other
category of testimony at the hearing though was of more
interest to me, because I am not an attorney, and that is
having to do with the risk posed by disposal of low activity
waste and different kinds of waste disposal facilities, mainly
mill tailings and RCRA hazardous waste sites.

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

There is a couple things to point out on this chart.
We could talk about this chart for a long time, but first,
there is a lot of overlap at the low end, that is mill
tailings, soil, low level waste overlaps mill tailings. Not
only that, but one other thing that is not shown in this chart is that in many of those cases where there is an overlap of statistic radioactivity the radionuclide are the same, uranium, thorium, and radium, not in all cases, but in many cases.

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

The other -- let me bring this back to the Army Corps for a minute. On of the things that the Army Corps has done that has caused a lot of controversy is taken some of the uranium mill tailings or 11e(2) by product material and disposed of it in the same matter that TENORM is disposed of, that is in RCRA hazardous waste sites. We can argue about what the appropriate number is for that, whether it is 2,000 picocuries per gram or -- but that is one of the issues that they forced. They have sort of broken down some of the walls
that have been put up by the regulations and laws, not
everybody has liked that.

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

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

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

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

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

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

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

Let me just reflect on the thing. I am not a lawyer and honestly much of what we did was determined by our office of general council, not by the technical people. That is not bad, I am just saying. My reflection, because I read the law quite often in preparation for this, is that I think that the law was defective. I think that Congress split the world in 1978 into two pieces. They said, okay, everybody that is inactive, anybody that doesn't have a license, DOE, you fix it. Congress envisioned the material being stabilized and being place, which is what we are doing on title one sites. Title two says the NRC, for anybody that you have under a license, you are going to take care of and you are responsible for. That is the reason why we are not responsible for FUSRAP sites. Congress split the world that way. I don't think that in 1978
Congress ever envisioned what occurred in the year 2000 or 1999. That is not unusual. That is how we got where we are. So, you know, it's -- it's -- you know, we can't very well tell Congress this. You can imply it, but you don't outright say, you screwed up when you wrote the law.

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

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

EDWARD BAILEY: That is a big if.

CARL PAPERIELLO: I am agreeing with what you said
earlier today. This is the reason why we are trying to address the <.05 percent. We are going to bubble gum for our licensees, for the specific licensees, we are going to bubble gum. We are not going to let them transfer material <.05 percent without us knowing what in Gods name they are doing. But it does create a hystereses, because if somebody has material that they never had to have a license they are all right, but once you have a license you are in trouble. I will admit that is what we are doing. We are bubble gumming it until we can solve the problem. To solve the problem we are going to have to somehow put all of this material in the same box. You just can't get a solution if you turn around and say, well, if it is uranium that resulted from digging up cooper ore and processing it for cooper, and you never got above .05 percent by weight uranium, you can throw it wherever you want. But, if you turned around and you dug up uranium or if you dug up the same ore even and processed it for uranium, it now becomes mill tailing. If you have dug up the ore and processed it for something else, but you got uranium above .05 percent it now becomes low level radioactive waste, which can happen. We have licensees that are dumb enough to tell us that they have done something like that. You have got to put this all in the
The issue of us and FUSRAP deals with a legal issue. It deals with something that -- our attorney said you don't have it. If I look at the law, I think that the law is just flawed. Congress didn't envision this situation. They thought that the world could be just cut in half in 1978 and they were wrong.

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

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

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

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

EDWARD BAILEY: I am not saying that all of the sites are unsuitable. I am not saying that they are unsuitable of some of these kinds of waste. In fact, one of the utilities in
California came to us to dispose of some slightly contaminated oils out of a reactor. We agreed that that was an acceptable way, an alternate method of disposal. That was acceptable. We have done this on several other occasions for other disposal of both AEA material and non-AEA material. What has not been done is these sites have not been evaluated on a site wide basis to except any particular value of material going in to them, as a low level waste site would have to be.

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

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

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

EDWARD BAILEY: But it is not licensed material.

JAMES KENNEDY: It is not licensed material -- in the
case of FUSRAP it is not licensed material.

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

CHIP CAMERON: Carl, use this.

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

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

CARL PAPERIELLO: 11e materials -- that is why -- I understand that. I had a case years ago with a long argument about what was there was source material or 11e(2) material. In fact, the licensee used both. At that time I was just an inspection section chief. I didn't appreciate why all the lawyers were arguing over whether or not it was source material
or 1le(2). Now I understand it is because of -- you know, the
different thing. The position of the agency was as mill
tailing, FUSRAP material, mill tailing, we don't have
jurisdiction over it.

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

CARL PAPERIELLO: Well, DOE owns it.

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

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

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

JAMES KENNEDY: Well, I was trying to keep it simply
first off. Both of you have brought up valid issues. One
thing that you are talking about is low-level waste. I was
talking about mill tailing. That is another issue. You are
talking about alternate feed. That is an issue. The court has
-- what they have done is that they have taken some contaminated material, mill tailings, sent it to the International Uranium Corporation, that has a uranium mill out in Utah, and processed it for the residual uranium, which is not very much. What they do is they extract the uranium, they distill it, and then they dispose of all the mill tailings. So, as Bill will quickly point out, it is a way to get rid of -- not only to extract uranium, which isn't a whole lot, but also to get rid of the tailings from the FUSRAP program.

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

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

AUBREY GODWIN: There is another little problem that is floating around in all this mess. Typically there is an analysis performed by some laboratory, so I asked the question
of the Corps of Engineers, since they took a grand total of twenty-six samples to determine if this material was below the limit -- on all eighty-four train car loads -- you know, just how good were these laboratories? They came back and said they are all certified. They were certified for water. None of them are certified for solids. They quoted a whole bunch of water procedures that they had used to analyze the material with. I on questioning the Corps of Engineers -- you know, I pointed out that they had water certification and did they adjust their levels for solids -- that is a rather important correction factor that you might add -- they talked about radium 228. I was interested in which method they used and how did they count that. Did they use an ingrowth method? Did they allow the ingrowth to complete itself or did they calculate alphas? With alphas, again the thickness of the sample is a major consideration on your accounting.

The Corps of Engineers thought that was so important -- I wrote them in December. They wrote me back that they had not worried about it until I reminded them that I needed an answer to my letter. So, you can tell that they are really on top of figuring out if the laboratories were right. They are going to ask the laboratories to provide some of this data. My
guess is that they will be somewhat close to right, but maybe not as good as you would like. It is important to look at the laboratory data and the quality control work that the laboratory does when you start looking at these environmental samples, particularly when you are using radium, uranium, and thorium series for a decision.

CHIP CAMERON: Let's go to --

EDWARD BAILEY: Can I ask one more question?

CHIP CAMERON: Yeah. Sure.

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

AUBREY GODWIN: In terms of the Southwest Compact --

EDWARD BAILEY: I know the problem --

AUBREY GODWIN: -- copied the federal law, so 11e(2) get exemption from it. However, should your investigation reveal that this is not 11e(2) then the Corps of Engineers and the federal government is in violation of federal law. You could probably proceed that way.
CHIP CAMERON:  All right.  Let's go to Ruth McBirnie from Texas.

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

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

CHIP CAMERON: Thank you, Ruth. Kirk?

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

In Aubrey's wisdom, before he left -- we have RCRA site, prohibits disposal material without a background. Think about that. It means you can't take dirt there from anywhere
in the state. It comes in by the barge load in Mobile.

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

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

JAMES KENNEDY: No.

CHIP CAMERON: Anybody else out here?

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

So, they did their work plans to start work at the
site. The work plan tells the -- well, the contractor wrote
the work plan and it says they will segregate everything that
the excavate into clean and contaminated piles. Anything below 600 picocuries per gram uranium is clean, anything above is contaminated and is going to be shipped off-site. They are demolishing several buildings on the site. Some of which were built on contaminated soil. So, they aren't contaminated. They have been surveyed. We have been out there and surveyed them too. But they started looking around for local landfills where they could dispose of this clean material.

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

EDWARD BAILEY: Can I ask Barbara a question? If I remember correctly, 600 picocuries of uranium exceeds .05 percent by weight.
BARBARA YOUNGBURG: Yes. It does.

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

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

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

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

BARBARA YOUNGBURG: No.

CHIP CAMERON: All right.

STEVE COLLINS: Steve Collins, Illinois. I would like for all of you just to think about the waste that was just described from New York, if it is not federally regulated or regulated by NRC, is it below your exempt concentrations or quantities in your rules that require people to get a license if it is above certain amounts. I would tell you that it is above those amounts. So, as soon as Corps of Engineers get through cleaning up the site and walks away, they have to get a license from New York to possess that material left.
CHIP CAMERON: Good question. Anybody else? I think that we all heard enough issues raised for the NRC to ponder. We just thank Jim for the presentation. Cheryl, I am just going to turn this over to you.

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

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

I have my CRCPD hat on right now, as the Chair of Part U, which is the group that is suppose to do the parallel rule making with the NRC. My main task is to look around and make sure that I know what all the various states that are affected, the seven states, might have views on this. Also to make sure that we have adequate state representation on the rule making group. My understanding is that NRC has not made
it to the step of asking for representation, but we think that
they will be going to the CRCPD because they have the priority
rule making group and potentially to the OAS.

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

The other big issue is that since it -- the
regulation of ground water, that line does not cut down whether
you are an Agreement State or a Non-Agreement State. You may
want to go talk to your people who regulate ground water.

Alice Rogers from Texas has been busy about informing me what
relying on the EPA regulation might mean and where some wholes
in that might be.

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

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

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

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

CHIP CAMERON: Thank you, Trish. Anyone else?

(Whereupon, the meeting was concluded.)