

ORIGINAL

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

**Title: MEETING WITH ORGANIZATION OF
AGREEMENT STATES AND CONFERENCE OF
RADIATION CONTROL PROGRAM DIRECTORS
PUBLIC MEETING**

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1 UNITED STATES OF AMERICA
2 NUCLEAR REGULATORY COMMISSION
3 OFFICE OF THE SECRETARY

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5 MEETING WITH
6 ORGANIZATION OF AGREEMENT STATES AND CONFERENCE OF
7 RADIATION CONTROL PROGRAM DIRECTORS

8 ***

9 PUBLIC MEETING

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12 Nuclear Regulatory Commission
13 One White Flint North
14 Rockville, Maryland
15 Wednesday, October 20, 1999
16

17 The Commission met in open session, pursuant to
18 notice, at 9:27 a.m., Greta J. Dicus, Chairman, presiding.
19

20 COMMISSIONERS PRESENT:

21 GRETA J. DICUS, Chairman of the Commission
22 EDWARD MCGAFFIGAN, JR., Commissioner
23 JEFFREY S. MERRIFIELD, Commissioner
24
25

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1 STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE

2 ANNETTE L. VIETTI-COOK, Secretary of the
3 Commission

4 STEPHEN G. BURNS, Deputy General Counsel

5 STANLEY R. MARSHALL, OAS Chair.

6 ROBERT M. HALLISEY, CRCPD Chair-Elect.

7 EDGAR D. BAILEY, OAS Chair-Elect

8 RICHARD A. RATLIFF, PE, LMP, OAS Secretary

9 ROLAND G. FLETCHER, OAS Past Chair

10 DAVID K. WALTER, Chair, SR-6 Committee

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P R O C E E D I N G S

[9:27 a.m.]

CHAIRMAN DICUS: Again, good morning, ladies and gentlemen.

On behalf of my fellow Commissioners, I would like to welcome representatives from the Organization of Agreement States and the Conference of Radiation Control Program Directors to discuss topics of particular interest to our regulatory programs.

I would like to recognize that this briefing is part of an ongoing constructive dialogue on a continuing exchange of information between the states and the NRC concerning areas of mutual interest.

Today, we will hear from the OAS, Organization of Agreement States, and the CRCPD, Conference of Radiation Control Program Directors, regarding several issues, including the OAS resolution in support of NRC's budget, the DOE pilot program as it relates to the states, NRC's allegation protocols, a petition for rule-making on the topic of source material, 10 CFR Part 40, continuing off-run source initiatives, release levels for solid materials, and the Part 35 medical rule-making proposed draft final rule.

I would ask that, before you begin each of your presentations, please introduce yourselves, provide your affiliation, either the OAS or the CRCPD, and identify the

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1 state that you are from, and we may stop your presentation
2 from time to time to ask questions, however we will try to
3 let you get through your presentation with minimal
4 interruption and save our general questions till the end of
5 each of your presentations.

6 Do any of my fellow Commissioners have any opening
7 remarks they wish to express?

8 COMMISSIONER MERRIFIELD: Madam Chairman, I'd like
9 to add my appreciation for the representatives to come in
10 today. I think the relations between the NRC, the agreement
11 states, and the CRCPD are important. I look forward to
12 having an opportunity for a good dialogue today.

13 In a clarification, I take it that Madam
14 Chairman's intention is for us, at the end of each of the
15 presentations, to have an opportunity to ask questions on
16 the areas in that presentation?

17 CHAIRMAN DICUS: That's my intent, if everyone is
18 willing to do that, because each one is addressing a
19 particular subject. So, rather than hold the questions to
20 the end, I think at the end of each subject, it would be
21 appropriate to address the issues.

22 COMMISSIONER MERRIFIELD: I think that's fair.

23 CHAIRMAN DICUS: All right.

24 Well, if there are no further questions or
25 comments, then, Mr. Marshall, will you please proceed with

1 the briefing?

2 MR. MARSHALL: Thank you.

3 My name is Stan Marshall, from the State of
4 Nevada, and I'm pleased to be here as Chairman of the
5 Organization of Agreement States.

6 I'd like to quickly introduce Ed Bailey,
7 Chair-Elect for the Organization, Secretary Richard Ratliff.
8 David Walter from the State of Alabama is also here. We
9 understand Roland Fletcher is en route to the meeting, and
10 also Bob Hallisey as Chairman for the Conference of
11 Radiation Control Program Directors from the State of
12 Massachusetts.

13 The purpose of the OAS briefing today is to
14 provide an update to the Commission about OAS concerns and
15 issues in support of the state-Federal relationship in a
16 longstanding national radioactive material program.

17 Briefing topics today will include Department of
18 Energy regulation and external regulation -- the external
19 regulation pilot program status, by Ed Bailey; source
20 material exemptions, by Richard Ratliff, State of Texas;
21 comparisons of Part 35 and Part G, David Walter from
22 Alabama; and NRC allegation protocols, Roland Fletcher;
23 lastly, my closing remarks of the Organization of Agreement
24 State resolution to support the NRC proposed budget.

25 I'd like to turn this over to begin the

1 presentations.

2 MR. BAILEY: My name is Ed Bailey, and as Stan
3 mentioned, I am with the State of California Radiologic
4 Health Branch and here representing the Organization of
5 Agreement States.

6 Today I'd like to make a short presentation on the
7 external regulation project of DOE facilities.

8 I believe you have copies of the slides. Simply
9 note the facilities that have been looked at in pilot
10 projects: Lawrence Berkeley National Lab, Oak Ridge
11 National Lab, Radio-Chemical Engineering Development Center,
12 and Savannah River Site for Receiving Off-Site Fuel.

13 California is particularly interested in the
14 external regulation of DOE because we have seven DOE sites
15 in California. Some of those are fairly unique in that two
16 of those sites are actually on State of California land;
17 three of them, the employees at the labs are State of
18 California employees, not private contractors, not DOE
19 employees.

20 When we get into the models that were presented in
21 the pilot studies, that becomes important, because Federal
22 OSHA does not cover state employees, so that OSHA would not
23 be a viable regulator for the people at Lawrence Berkeley
24 National Lab, Lawrence Livermore National Lab, as it turns
25 out, Los Alamos National Lab, because they're also employees

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1 of the State of California, and the smaller lab, the
2 Laboratory for Energy-Related Health Research at the
3 University of California at Davis.

4 The reason we are interested in this, in
5 regulating DOE, is that a rem is a rem is a rem, and it
6 doesn't matter where it comes from, whether it's from AEA
7 materials, whether it's from accelerator-produced
8 radioactive material, whether it's naturally-occurring, or
9 whether it's from machines, and we feel that there should be
10 consistent regulation of all these sources of ionizing
11 radiation, not only at our licensees' facilities but at
12 Federal facilities.

13 The next part of my presentation, I'm going to
14 concentrate primarily on Lawrence Livermore -- I mean
15 Lawrence Berkeley National Lab, because that's where we did
16 the pilot project.

17 CHAIRMAN DICUS: Before you go further, I'd like
18 to acknowledge that Commissioner Diaz is on the bridge, and
19 it is a two-way communication, that he can hear you and we
20 should be able to hear him. I'd like for you to be aware of
21 that.

22 MR. BAILEY: Okay.

23 CHAIRMAN DICUS: Please continue.

24 MR. BAILEY: All right.

25 The Berkeley Lab was founded in 1931, is the

1 oldest of the national labs. It, of course, is named for
2 Earnest Orlando Lawrence, the inventor of the cyclotron.

3 It's an unusual lab, because nine Nobel prizes
4 have been awarded to researchers at that particular lab.
5 Also, when we look at all the trans-uranic elements, almost
6 all of them were discovered at Lawrence Berkeley National
7 Lab -- americium, californium, berkelium.

8 They've recently discovered two more elements
9 there, I think 116 and 118.

10 So, it's been a focus of primary physics research
11 for a long time.

12 As I mentioned earlier, it is managed and operated
13 by the University of California. The work at Lawrence
14 Berkeley National Lab is basically unclassified research in
15 basic sciences.

16 Presently employee over 3,000 people, sits in the
17 Berkeley Hills across the bay from San Francisco, totally
18 surrounded by the University of California at Berkeley, and
19 as I mentioned earlier, it has little or no weapons-related
20 work.

21 University of California has nine university
22 campuses and three national lab campuses. The national lab
23 directors are on the same level, have the same status as the
24 chancellor of each of the U.C. campuses. So, it's truly
25 integrated into the U.C. system.

1 Lawrence Berkeley Lab is a rather unique facility
2 in that it has, as I've said, very little weapons-related
3 material, and for the most part, it works with materials
4 that are not normally regulated by the NRC.

5 I've given a list here of the primary sources of
6 radiation that exist there: the advance light source; the
7 Bevatron, which is not in production now; PET accelerator;
8 heavy ion accelerator.

9 The one facility that would be regulated normally
10 by NRC if it were a private business is the National Tritium
11 Labeling Facility, which literally sits in a building not
12 much larger than this room we're meeting in today, has an
13 88-inch Cyclotron there.

14 The next slide shows sort of the history of the
15 Department of Energy and its self-regulating programs,
16 starting in 1946 with the Atomic Energy Act and going to
17 1977, where DOE was created as a cabinet-level agency.

18 The external regulation of DOE is already
19 occurring. The Clean Air Act Amendments extended NESHAPS to
20 DOE sites, and California is now in the process of signing
21 an agreement with EPA to assume regulatory authority under
22 NESHAPS.

23 So, we will be into the national labs. We will be
24 going and seeing anything that we would see regulating the
25 radioactive materials or other radiation sources there.

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1 Also, the Federal Facilities Compliance Act places
2 DOE sites under RCRA. We are involved in -- or a signer to
3 a Federal Facilities Agreement for the Lear facility at the
4 University of California, Davis, which is cleanup.

5 There are also existing NRC and agreement state
6 oversights at other DOE facilities, and there's a list of
7 them there.

8 I would mention just in passing that the fusion
9 facility at General Atomics in San Diego -- I don't know
10 whether they messed up, but they registered all of their
11 x-ray machines with the State of California, and we
12 regularly inspect those facilities.

13 The drivers for external regulation -- this is
14 from the Ahearne Committee -- were safety, credibility, and
15 stability, and I think we will see that those can be
16 afforded.

17 We have been involved at LBNL for quite some time.
18 There's a list of different projects we've been involved
19 with as the State of California at Lawrence Berkeley Lab.

20 The external regulation pilot, phase one -- that's
21 when we met with NRC and did the original pilot.

22 After Congress said, hey, we want more involvement
23 by OSHA, we went back, and one of the big problems with
24 having OSHA involved at all was, if you're not familiar,
25 OSHA is still on the 12-rem-per-year quarterly dose-based

1 system.

2 Their regulations are terribly out of date, and
3 so, it was really interesting to see them go in there and
4 try to apply their regulations to a national lab. It just
5 didn't work.

6 In fact, after the second day, the people from my
7 team that were there called and said, please, may we come
8 home, because we're looking at ladders, we're looking at
9 electrical cords, we're not doing anything in radiation.
10 So, I let them come home.

11 The external regulation process -- the next slide
12 gives sort of a brief oversight of what has happened,
13 including the phase two pilot study.

14 A few of these slides, including the next one,
15 were given to me by DOE.

16 It doesn't show up well, but you can look at it in
17 your packet. This was presented by one of the people from
18 DOE at a meeting I was at recently.

19 The diagram on the left represents the DOE
20 structure for regulating and controlling radiation
21 protection, environmental protection, and waste management
22 under the present system.

23 This person, who is the radiation safety officer
24 at one of the national labs, says, under external
25 regulation, which this particular lab very much favors, all

1 of the sudden all of these three things that we normally
2 think of as being under some sort of radiation safety head
3 come together under a radiation safety committee regulated
4 by an external regulator.

5 The next slide shows some of the jurisdictional
6 issues. The top shows NRC and OSHA, OSHA covering NARM,
7 radiation-producing machines -- and this is at the present
8 time -- whereas the states have a continuing spectrum of
9 regulation throughout.

10 A few quotations that have gone along with it:

11 The external regulation of DOE -- essentially all
12 aspects of safety at DOE's nuclear facilities and sites
13 should be regulated externally.

14 "Mr. Chairman, the Department is ready to move
15 forward now to work with you and others to develop a path
16 forward to externally regulate single purpose Energy
17 Research laboratories," and I think that's important.

18 The weapons program is sometimes held up as a red
19 herring.

20 None of these external projects involved the
21 weapons program, it was always the energy program, although
22 we could get into a discussion of the weapons program,
23 because we also regulate facilities, just as you do, which
24 are involved in weapons production -- namely, some of the
25 aircraft companies, shipbuilding yards, and so forth.

1 So, if clearances are needed, we and you have
2 those clearances; it's not a matter of national security,
3 really.

4 The next slide are statements that were put into
5 the draft final report out of LBNL, and I want to read these
6 two.

7 The first one is "LBNL agrees with the DOE Team
8 preference that LBNL should be regulated by the same
9 regulators as private industry and academia. LBNL believes
10 that there would be a smooth and seamless transition to
11 external regulation if the regulator were the State of
12 California."

13 The next slide, "LBNL considers that the benefits
14 of external regulation are strongly dependent on the
15 licensing model. LBNL believes that the only license model
16 that represents a clean break from DOE's self-regulation is
17 the model in which the University of California-LBNL is
18 licensed directly by the NRC or the State."

19 The main issues from our standpoint are who would
20 be the regulator, would it be the NRC, would it be OSHA,
21 would it be California Radiologic Health, would it be
22 California OSHA?

23 Next issues are who would be the licensee, would
24 it be the U.S. Department of Energy, University of
25 California, or the lab itself?

1 I might mention that each of the University of
2 California campuses holds a separate license to do their
3 operations. So, this would be just like adding another
4 license to their pile of licenses.

5 NUREG-1708 just recently was published, and there
6 is one huge disappointment in that document to the states,
7 and that's the statement which follows.

8 "With respect to state regulation of DOE
9 facilities, sovereign immunity should not be waived and the
10 states should not regulate DOE facilities."

11 This finding in the NUREG seems to have some
12 contradictions.

13 I do not believe that that was the conclusion of
14 the LBNL site team from NRC. This was not the conclusion of
15 the DOE Oakland operations. This was not the conclusion of
16 LBNL, and this was not the conclusion of the State of
17 California.

18 The question, then, is whose conclusion was it?

19 In a humorous vein -- I hope you'll take it this
20 way -- as we were going through the phase one or phase two
21 of the external regulation projects, one of the people from
22 the lab said to me, "I don't want to replace one regulator
23 in Washington with another regulator in Washington," and I
24 think that sort of sums up how some of the labs feel in that
25 they would like to be treated as just any other commercial

1 establishment or academic establishment in the state.

2 In closing, the Organization of Agreement States
3 recommends that the NRC aggressively seek regulatory
4 authority over DOE and its contractor facilities and,
5 secondly, that NRC include the regulation of DOE
6 contractor-operated facilities in the agreement state
7 program, and I hope it goes without saying that the
8 Organization of Agreement States continues to encourage NRC
9 to become the sole regulator of all sources of radiation,
10 whether they be AEA materials, NARM, or machine-produced.

11 I thank you. I'd be happy to take any questions
12 or comments.

13 CHAIRMAN DICUS: Okay. Thank you. Appreciate
14 that.

15 Commissioner McGaffigan.

16 COMMISSIONER MCGAFFIGAN: The answer to your
17 question is, I guess, us.

18 [Laughter.]

19 COMMISSIONER MCGAFFIGAN: And I want to explore
20 that with you.

21 The big issue that you didn't come back to is
22 who's the licensee, and one of your diagrams shows that it
23 was a relatively clean diagram, whether it was the agreement
24 state or NRC, and it is the strongly held view of DOE --
25 well, they don't want anything, but if there was going to be

1 something, it had been their view all along that they would
2 be the licensee, in which case you get the smorgasbord box
3 rather than the clean diagram.

4 So, that's an important issue. We're, I think, in
5 agree on that, that the licensee needs to be -- and I guess
6 you didn't come down as to what the university or the lab --
7 it probably doesn't matter that much between those two, but
8 it is not DOE, and that's your recommendation, right?

9 MR. BAILEY: Yes, that certainly would be -- my
10 recommendation is that these laboratories, which to the best
11 of my knowledge are almost exclusively run by a contractor
12 rather than by DOE -- that the contractor be the licensee,
13 that the contractor being held responsible for compliance
14 with regulations, just as you see with the Department of
15 Defense where they have essentially captive laboratories or
16 captive manufacturing plants, and they don't exclude those
17 from regulation.

18 COMMISSIONER MCGAFFIGAN: You just mentioned the
19 Department of Defense, and that leads to the next issue.
20 The VA and the DOD medical centers in your state and around
21 the nation are regulated by us, and we have not -- I mean
22 that's a longstanding approach, and it has some real
23 benefits, you know, for the VA in terms of dealing with a
24 single regulator, namely us, that has, you know, whatever
25 rules we have applying Part 35 -- applying to their

1 facility, and that was, I think, the main thing that
2 motivated us and the Commission and, I think, the senior
3 staff.

4 I don't know what the team that was involved in
5 the program review -- but that's what was motivating us to
6 think in terms of this other model, that we would -- and
7 obviously, if you do this other model, then we have to have
8 the ability to deal with the accelerators, because a rem is
9 a rem is a rem, we agree with that.

10 But there is this other model, which is widely
11 used for other Federal licensees, and why doesn't that model
12 -- why can't that work in this case, and why can't that be a
13 real advantage for DOE in terms -- and its licensees in
14 terms of having a single regulator across the country? U.C.
15 should not face New Mexico rules in New Mexico and
16 California rules in California. They could face NRC rules
17 in both places.

18 MR. BAILEY: I'd like to address that.

19 The two examples you mentioned, DOD and the VA,
20 again to the best of my knowledge, in both cases those
21 facilities are operated by VA or DOD employees, not by
22 contractor employees. In other words, the VA does not go
23 out to UCLA, for instance, and say come across the street
24 and run VA-Wadsworth. It just doesn't happen, so that you
25 are directly regulating a Federal agency, and we think

1 that's proper.

2 COMMISSIONER McGAFFIGAN: But are oftentimes -- I
3 don't know the deal in California, but in New Mexico, the
4 big VA medical center in Albuquerque has all sorts of --
5 it's right in a whole hospital complex, I'm sure they tend
6 to be, and there's all sorts of work between the -- joint
7 work between the VA medical center and the large hospitals,
8 with one being regulated by us and the others being related
9 by the State of New Mexico, and it seems to work. You know,
10 somehow, when things get to be joint between the two, we
11 somehow make it work.

12 MR. BAILEY: Well I think there are numerous
13 examples -- almost every university reactor ends up having a
14 line painted on the floor that says here's NRC jurisdiction
15 and here's state jurisdiction.

16 We could look at the fusion facility, General
17 Atomics. We've got a working agreement now. That's a
18 facility -- that's an NRC licensee, a State of California
19 licensee, and a DOE facility, just as E-Tech -- used to be
20 Rocketdyne.

21 All three entities operate there, and you have
22 licenses, we have licenses, and DOE has their little niche
23 carved out.

24 We really don't see where you're talking about a
25 contractor operating something, that there needs to be this

1 issue of sovereign immunity involved. Any one of those
2 contractors could lose that contract at any time.

3 In the case of the facilities we have in
4 California -- and I'm sure it applies to other places --
5 those facilities are actually on State of California land,
6 some of them. The employees are State of California
7 employees.

8 We don't see why they need to be restricted to a
9 Federal license if one occurs, and you mentioned that you do
10 regulate DOD. We're involved in base closures in
11 California, quite a large number of them. The major
12 problems that we're finding at DOD base closure is not AEA
13 material.

14 It's two categories of material: radium from dial
15 operations and nuclear weapons debris which was washed off
16 of aircraft and so forth. And I don't believe you regulate
17 either one of those.

18 So, we go in and try to work on those sites. We
19 go in with EPA teams and so forth.

20 We find that people are a little amazed that we
21 don't have authority as they do under their EPA agreement to
22 set a standard and make that standard stick, say that's a
23 regulation, and I think that's an important aspect of a
24 nationwide, comprehensive, radiation protection program, is
25 that we do have authority to regulate all sources of

1 regulation -- most states have that in their provisions --
2 and that any derived authority that we have through the
3 Atomic Energy Act, through NRC, covers all the sources that
4 you can cover.

5 COMMISSIONER MCGAFFIGAN: I won't pursue this much
6 longer. Unfortunately, as you well know, the political
7 climate in Washington, given Secretary Richardson's
8 opposition, the prospects for this legislation passing in
9 this Congress are not high.

10 I think we're in agreement more than we
11 disagreement, namely that there would be a real benefit to
12 external regulation, that the licensee needs to be the
13 regulated party, because if DOE or both are the licensee,
14 then you'll get the worst of all worlds.

15 So, there's a lot that we agree on.
16 Unfortunately, it's not going to happen anytime soon.

17 MR. BAILEY: We recognize that, too, I'm afraid.

18 COMMISSIONER MERRIFIELD: I would like to explore
19 some of the issues that Commissioner McGaffigan has gone
20 over in some greater detail, starting with your
21 recommendations. You've got two, and I would like to deal
22 with them separately to the extent Commissioner McGaffigan
23 hasn't.

24 First is that the NRC aggressively seek regulatory
25 authority over DOE and its contractor facilities.

1 In your slides, you quote Energy Secretary Bill
2 Richardson, in a letter that he sent to Representative Ron
3 Packard on February 29th of this year, and in it, you quote
4 him as saying "Many of the potential benefits that we
5 expected to see from external regulation have not been
6 demonstrated and appear to be outweighed by associated costs
7 and difficulties raised in the pilot projects," unquote.

8 I think we, as an agency, have been relatively
9 robust in our defense of the activities that we undertook in
10 the course of this pilot project.

11 We disagree fervently with those very
12 characterizations of Secretary Richardson.

13 We believe, and certainly I believe, that -- well,
14 I should say I believe. I, perhaps, shouldn't speak for the
15 Commission on this, but I certainly believe that the
16 activities undertaken by our staff were, in fact, a
17 value-added benefit, were cost-effective, and led to
18 increased and enhanced safety for the individuals who work
19 at these DOE facilities.

20 The report that we have put out relative to those
21 pilot projects, we believe, demonstrates that the pilots
22 were a success.

23 Now, I believe that -- as does -- as Commissioner
24 McGaffigan has pointed out -- that we have a good role to
25 play in external regulation of DOE facilities, and indeed, I

1 believe that the workers at those facilities deserve to have
2 an external regulator to ensure that they have the
3 appropriate levels of health and safety protection as they
4 go about their jobs.

5 Certainly, the individuals who live around those
6 plants, the stakeholders and the states, also deserve
7 assurances that those facilities are managed in an
8 appropriate fashion, and I think, in my own respect, I think
9 external regulation could be an important enhancement of
10 that program.

11 My question is -- you know, we have been very
12 active in making our views known on Capitol Hill. I know
13 we've testified before at least four House and Senate
14 committees during the course of 1999 and alluded to this in
15 our testimony.

16 To what extent have the views of the Organization
17 of Agreement States been carried to Congress, and to what
18 extent have you met, either individually or collectively,
19 with members of your various state delegations to provide
20 them the assurances that this is, indeed, the right
21 direction to go?

22 MR. BAILEY: I think you've hit an Achilles heel
23 there.

24 Fortunately or unfortunately, I think you will
25 find that most of the agreement state programs are not

1 encouraged to directly contact their congressman by their
2 administrations in the state, and often, all of those
3 contacts go through someone far above us in government.

4 It is certainly a weakness, in my opinion, of the
5 agreement state program in that we don't have that
6 flexibility.

7 I think the direct answer to your question is that
8 very few people have actually contacted their congressional
9 delegation.

10 I will say that I was talking to one of our
11 senators' offices on Monday on another issue, and it came up
12 that I was going to be in Washington and we were going to be
13 before the Commission, and the staffer asked, well, what are
14 the topics, and she said would you mind giving me a call?

15 Well, I can respond in that way, when I get a
16 direct request from a U.S. senator, I can call them back and
17 say, well, we met with the NRC Commissioners and it was a
18 very fine meeting and we brought up the issues that we
19 discussed and I think that they agree with us on some
20 things, but you know, I don't know, and if you've got any
21 magic words for me to say to them, I'd be happy to take
22 them.

23 CHAIRMAN DICUS: If I could follow up on your
24 question, and then I'll come back to you if we can, but you
25 mentioned -- and I understand the problem, because I've been

1 in the same situation, but you mentioned that you try to
2 elevate these issues to the senior management at the
3 department level that can go, presumably, to the delegation
4 of the state.

5 To what extent do you have information or data
6 that shows, when that is done, something did happen to it,
7 or do we not know -- do you not know, when you've tried to
8 elevate these issues, that they have, in fact, been carried
9 forward for you?

10 MR. BAILEY: I would say it is mixed. Sometimes
11 we get some feedback, yes, that there has been a letter
12 sent.

13 Normally what will happen in our process, at
14 least, is we will prepare a letter for whomever's signature,
15 whether it be the department head, the agency head, the
16 governor's office, or whatever, and quite often, the
17 feedback we will get will simply be a signed copy of that
18 letter or things go into limbo and you have people call up
19 and see where is it, where is it, where is it?

20 COMMISSIONER MCGAFFIGAN: When I was a former
21 staffer -- I spent 14 years on the Hill, and I had wide
22 contacts in New Mexico, and I told anybody in your situation
23 that they should presume that I called them.

24 [Laughter.]

25 COMMISSIONER MERRIFIELD: I had the same standing

1 observation with my home state of New Hampshire.

2 Perhaps you may want to volunteer that, if asked,
3 you do have an opinion on it, and that may bring some of
4 that forth.

5 On the first item, I'd just close with a notion.
6 When we testified before the House Science Committee, which
7 is more supportive, I believe, of external regulation, we
8 were there with DOE and with OSHA testifying. There was not
9 a state view there.

10 I think it would have helped to further flesh out
11 that opinion, and to the extent you can work with
12 individuals in organizations and in other states to perhaps
13 increase that, I think it would be helpful.

14 MR. BAILEY: Could I just add one thing to that?

15 We've expressed -- or I've expressed what I
16 believe the states feel about external regulation, that we
17 should be involved in it.

18 I think, even if we can't be involved in it, we
19 still very strongly support external regulation of DOE and
20 would support that NRC preferably would be the organization
21 to do that.

22 COMMISSIONER MERRIFIELD: Just briefly, I want to
23 get to the second point, because I know the Chairman wants
24 to move on, and that is that the NRC include in the
25 regulation DOE contractor-operated facilities in the

1 agreement state program, your disappointment. I guess
2 there's two levels of issue here.

3 One is, under the Atomic Energy Act, under Section
4 274, basically we can only give away those authorities for
5 which we have. So, we can't very well give the authority to
6 you which we don't have.

7 So, the first thing we need to do is get the
8 authority and then consider perhaps the appropriateness of
9 delegating that to the individual agreement states.

10 The second issue in that is, though, as you well
11 know, the waiver of Federal sovereign immunity as it relates
12 to DOE and DOD facilities is a very sensitive and relatively
13 contentious issue up on Capitol Hill.

14 I used to be the lead Senate staffer on Superfund
15 issues, where we had to grapple with that in the sense of
16 our committee. There was great disagreement, and it crossed
17 party lines, it crossed a variety of spectra.

18 This is one, I think, we, too, as an independent
19 agency, have to trudge very carefully given the fact that
20 there is that level of disunity of a common position of
21 Congress.

22 So, while you have a huge disappointment, I think
23 it would be not in the best interests of this agency to
24 necessarily be in the forefront of waiving Federal sovereign
25 immunity, since there doesn't seem to be a great deal of

1 agreement among that, or consensus, I should say, in
2 Congress.

3 So, I sort of leave that.

4 COMMISSIONER MCGAFFIGAN: There is one last
5 thought I have on this subject, again to try to keep us
6 focused on the main thing, if it ever is going to happen,
7 which is to try to get external regulation with the licensee
8 being the person who is the -- you know, the contractor
9 being the licensee, and that's that you mentioned earlier
10 these other models and you mentioned some in the materials
11 space.

12 We have similar models in reactor space where
13 something is worked out with the state. We regulate the
14 gaseous diffusion plants, but the states obviously can come
15 in under an MOU and do certain things.

16 With the State of Illinois, at Zion, we just
17 approved an amendment to an MOU that will allow them to be
18 involved in the decommissioning -- not decommissioning --
19 watching that facility over an extended period of time while
20 it's in safe-store, and so, there are things that -- if we
21 could get the main thing done, as Commissioner Merrifield
22 suggests, there are things short of dealing with sovereign
23 immunity that would give you a role, and I think we could
24 work those things out.

25 CHAIRMAN DICUS: Mr. Marshall, do you want to

1 continue?

2 MR. MARSHALL: I'd like to move next to Rich
3 Ratliff with the topic "Source Material Exemptions."

4 MR. RATLIFF: Good morning, Commissioners.

5 This is one of the topics, I think, that impacts
6 many of the states, and I want to go through some of the
7 initiating events of what we're seeing on source material
8 exemptions.

9 The first slide, please.

10 You have the bullet where it says "Shipment of
11 waste containing source material to unlicensed facilities,"
12 and I want to clarify that.

13 What we have done for years -- I've been in 28
14 years now working on these rules, working with the NRC,
15 through the State of Texas -- I'm with the Texas Department
16 of Health Bureau of Radiation Control, and we always looked
17 at 10 CFR 40 and would ask the question of staff, when it's
18 exempt, does that mean it's exempt for disposal, and we
19 always got the answer no.

20 So, when material from FUSRAP sites went to
21 California, we felt that -- that kind of brought the issue
22 to a head. It went to a landfill, really not a licensed
23 site, and then, as the Commission, you've reviewed the
24 policy and have confirmed that, yes, if it's exempt,
25 concentrations exempt by the 10 CFR 40, it's totally exempt.

1 COMMISSIONER DIAZ: Madam Chairman?

2 CHAIRMAN DICUS: Commissioner Diaz?

3 COMMISSIONER DIAZ: Can you hear me now?

4 CHAIRMAN DICUS: Yes, I can hear you now.

5 COMMISSIONER DIAZ: The reason I was so quiet is
6 because you couldn't hear me before. It's not that I did
7 not have questions.

8 CHAIRMAN DICUS: Okay. Did you have any questions
9 with regard to the DOE oversight?

10 Commissioner Diaz, we're not being able to hear
11 you very well, you're breaking up. So, we'll have to
12 re-look at what the problem is so that we can you on the
13 bridge, and I think that's the feedback that we're getting,
14 as well.

15 Why don't you continue?

16 MR. RATLIFF: The fact that the NRC clarified that
17 especially the source material that's less than .05 percent
18 by weight was exempt really brought a new regulatory area
19 that the states had to look at, because as you know, the
20 formally utilized sites were determined not to be under NRC
21 jurisdiction, and now the material really was exempt from
22 other sites, and so, we've really looked at this a lot, and
23 when we get down to the point of looking at exempt
24 concentrations versus release for unrestricted use and some
25 of the comments I'll have at the end are some of the

1 suggestions we have, because when we look at the different
2 levels of uranium and other products that really aren't
3 addressed that come in from the exempt concentration or
4 exempt levels, if it's exempt and it goes to a sandbox at a
5 day-care center, I have a lot more concerns than I do if it
6 goes to a hazardous waste or a regular landfill, and so, I
7 think that there's some tweaking that really needs to be
8 done when this rule is reviewed.

9 The Colorado program then found a company that was
10 not under the exempt part, but they were a general licensee,
11 and under the general license in 10 CFR 40.22(b), the
12 facility was exempt from a lot of things, including the
13 worker protection, contamination control, and so, they ended
14 up with a facility that would not be released under the
15 state's criteria nor the NRC criteria, but yet, because they
16 were exempt, they really were able to do this operation and
17 really cause radiation areas that were much higher, so we
18 get back to the same thing, a rem is a rem is a rem, really
19 didn't work here.

20 Then, in specific, the next slide, on 10 CFR
21 13(a), this is one that -- NRC, I think, started to really
22 look at this in 1992, the 57 FR 48.749. You all proposed to
23 totally re-look at the 10 CFR 40. You know, it's been since
24 the Atomic Energy Commission, I think, created in 1946, and
25 this was set up in 1947 but not based on any radiation

1 safety criteria but based on the strategic use of the
2 materials, and now that you have real specific
3 decommissioning standards, as agreement states we're
4 adopting these standards.

5 When we look at the radiation concentrations and
6 the ensuing radiation levels that people could be exposed
7 to, they're not consistent from the standards to what the
8 exemptions are in the rule.

9 When you look at the exemption, it's less .05
10 percent by weight, and you go to the next slide, for
11 uranium, just natural uranium, you're looking at 330
12 pico-curies per gram, for thorium, 116, versus what you and
13 what we require as agreement states, cleanup for uranium
14 sites of 30.

15 There's a wide difference there.

16 The thing that we really look at in the states is
17 the fact that you do have the daughter products in any of
18 these, and the radium tends to be one of the more hazardous
19 materials.

20 In fact, work that I did on the Conference of
21 Radiation Control, working on low-level waste, using NRC's
22 models, radium was equal to or greater hazard than
23 plutonium, because it's a long half-life, it's a
24 bone-seeker, it's a alpha-beta-gamma emitter, you have radon
25 gas produced.

1 So, radium tends to be one of the materials that
2 can really cause multiple real hazards to people.

3 So, what we're recommending is that 10 CFR 40, I
4 think, is going to be reviewed, but it's been a long time
5 since this started, and it really needs to be reviewed with
6 your current dose methodologies, your current biological
7 data, and to really go through and look at what is safe,
8 because you really, I don't think, want to have exemptions
9 like you have now, with the source material less than .05
10 percent by weight is exempt, because it's exempt and it
11 could go to sandbox in a day-care center.

12 I don't think that will happen, but it's possible,
13 whereas controlled disposal really would be what I would
14 suggest when we get into the amendment, because you could
15 have a two-stage exemption, exemptions that really are
16 exempt, totally exempt.

17 For instance, the smoke detectors with americium
18 sources -- they're exempt, you put them in the landfill,
19 there's no hazard.

20 Even if they end up somewhere, they're just not a
21 hazard, whereas those concentrations of uranium and thorium
22 really are not appropriate to be released to put in
23 someone's backyard as fill dirt or whatever.

24 So, I think there's a two-pronged approach that
25 could be used as stuff that's truly exempt and stuff that's

1 exempt from being disposed of as radioactive waste but that
2 could go to equivalent disposal.

3 Then that whole part gets to be one of the parts
4 that -- you can see I have pulled a lot of my hair out over
5 the years about it, because after the Juarez incident back
6 in the '80s, most of our scrap-yards and our landfills have
7 radiation detectors, and so, they detect multiple things.

8 I would say more than half of it is naturally
9 occurring radioactive material, a lot of patient diapers
10 from medical treatments, but aircraft engine parts come in,
11 and it gets real confusing with the way the rule is set now,
12 because if it's a complete engine, it's not been worked on,
13 it doesn't have any milling or grinding, it can go into the
14 landfill as an exemption, but if it's a part that's less
15 radiation, it can't go in there, and so, this whole part
16 confuses the people who have the aircraft engines, it
17 confuses the regulators, and in general, everybody, and I
18 think, when you do the reviews to this section, it really
19 needs to look at something that will be useful, given the
20 circumstances today, that you have a lot of material
21 recycled, either at the steel mills or material disposed of
22 at the scrap-yards or you do have detectors, so that you
23 really look at the radiation safety as the bottom, that if
24 it's safe it can go there, if not it should not be disposed
25 of in that manner.

1 Then my final slide here is, looking at the whole
2 issue that we deal with, and I think Ed's touched on it and
3 others will, is NORM, the naturally occurring radioactive
4 materials.

5 We have many of the same isotopes, you have the
6 same problem, and it's really not an NRC problem, it's the
7 Congress' definition of what you have regulatory authority
8 over.

9 A number of years ago, the states had worked with
10 NRC to really have control over NORM, and there were studies
11 that were done, but I think the final word came down that
12 really, no, it was a states issue and NRC didn't have
13 resources.

14 But I think to have -- what we've always talked
15 about is a uniform regulatory program across the United
16 States, which we feel the agreement states have, that NRC
17 really has to regulate these other materials, the NORM, the
18 accelerator-produced materials, and I think it's a big leap
19 to get to the machine-produced, the x-rays and accelerators,
20 but the ideal situation would be that, but just regulating
21 radioactive materials would really, really help.

22 The FUSRAP issue -- just to touch on it, you know,
23 it's something that was forgotten, now it's come up, it's
24 shifted around, but as states, we're dealing with it daily.

25 We spend a lot of resources on it, but we feel

1 that, with the exemption, if it's for disposal only, we have
2 disposal sites that we feel comfortable with that can go
3 there.

4 The ones that we are looking at in Texas are both
5 hazardous waste sites, so even if it did become a RCRA issue
6 in the future, they're already in hazardous waste sites, but
7 I think clarification on that whole rule to make sure that
8 those things can go there without any problem, because we
9 devote a lot of resource to that, and I think, in the
10 future, as you make changes to this rule, we would really be
11 willing to come to the table, devote our resources to
12 develop a rule that's workable for all of us.

13 CHAIRMAN DICUS: Thank you. I appreciate your
14 comments on that, and I know that the Part 40 rule-making is
15 lagging a bit. In fact, it's probably been put on hold
16 because of competing priorities that we have and the
17 resource issue that you mentioned.

18 We recognize, for several of these issues, there
19 are a lot of concerns with both technical issues as well as
20 jurisdictional issues, and we have the staff working on some
21 ideas on how we're going to deal with some of these, and I
22 think we expect a paper to us next month on some of those
23 issues.

24 FUSRAP is clearly our most frustrating issue, to
25 me, I think to all of us, and we look at it just from the

1 legal point of view that we have to deal with and then
2 looking at it from a scientific point of view, the two don't
3 -- they pass in the night and they don't quite meet, but
4 that's just part of the fun that we have in our various
5 programs and dealing with some of the issues that we must
6 deal with.

7 Commissioner Merrifield, did you have any comments
8 you wanted to make?

9 COMMISSIONER MERRIFIELD: The first one is sort of
10 a clarifying question. You mentioned the notion of these
11 materials -- it was determined they need to be disposed of,
12 could go to equivalent disposal facilities. Did you mean
13 RCRA sub-title C facilities?

14 MR. RATLIFF: If it has hazardous materials, then
15 I think it could go to a hazardous waste site. If it was
16 just contaminated dirt with no hazardous constituent, it
17 could go to just a regular permitted landfill.

18 So, I think, you know, it really depends on the
19 other constituent, whether it has a hazardous constituent,
20 but I think, at that exempt level, I have no problem, from
21 the health and safety risk, that it goes to those sites.

22 I think it's better -- that way, at least, it's
23 put into a facility that's monitored, secured, and you don't
24 have it appear in different places in the environment.

25 COMMISSIONER MERRIFIELD: Okay. So, you're

1 comfortable with subtitle D facilities.

2 MR. RATLIFF: Correct.

3 COMMISSIONER MERRIFIELD: For materials that have
4 hazardous components, subtitle C, and for that which is not
5 exempt, it would go to Enviro-Care or one of the other
6 facilities permitted to take low-level waste.

7 MR. RATLIFF: Yes.

8 COMMISSIONER MERRIFIELD: All right.

9 You talked a lot about the need for consistency in
10 a regulatory approach. Although it wasn't part of your
11 presentation, I do want to explore one issue.

12 Currently underway at the agency is an effort we
13 have to seek stakeholder input on how or if we should move
14 forward on a clearance rule, and I was wondering, given the
15 issue of consistency, is there a position among your group
16 on that issue that you'd like to share with us, and is that
17 consistent among you all?

18 MR. RATLIFF: I think the answer is we've
19 discussed it, and the majority, I think, agree. We need a
20 floor that, below this level, it can be handled not as
21 radioactive material.

22 Without that, you're continually having to go into
23 different modeling, different approaches from state to
24 state.

25 I think it also helps the people that we both

1 regulate if they know that this is -- anything above this is
2 going to be disposed of as radioactive waste or radioactive
3 material.

4 It gives them the up-front foresight to know how
5 they have to conduct their operations and help them conduct
6 them in a better way. The exemptions like this -- I think
7 you run into so much opposition.

8 What we had, though, in Texas was successful. We
9 were petitioned for rule-making to take radioactive
10 materials with a half-life less than 300 days to go to a
11 landfill, and we had certain concentrations.

12 It was not only supported by our board of health
13 and our boards and the regulated community, but the Sierra
14 Club supported this rule-making, because it really saved
15 money for the universities, for materials that could go to a
16 landfill under controlled situations and not have to go as
17 low-level waste and therefore leave them money they needed
18 for doing other educational issues.

19 So, I think there's a lot of different things out
20 there that we can work on to make this issue work, and I
21 really think that the whole clearance regulatory issue is an
22 important one to all of us.

23 COMMISSIONER MERRIFIELD: Just by of clarifying,
24 you mentioned that a majority of members were supportive of
25 this. I wouldn't want to have you point out which states

1 weren't, but is there some attempt to come to a consensus
2 view that could be represented as a view of OAS?

3 MR. RATLIFF: Well, we haven't voted on it, is the
4 thing. We've discussed it a lot, and I think that's what we
5 need to do.

6 I think that's an issue that's definitely one that
7 we'll have to address and that Ed, as Chairman next year --
8 it will be a challenge to really get everybody on-board, but
9 there are a few people that still don't think that you need
10 to have a level like that, but most of us who have worked
11 with us and seen the realities agree, you really do need a
12 clearance rule, a below regulatory concern, whatever you
13 want to call it, something that really establishes the lower
14 limit that really causes no health concerns to the public.

15 MR. MARSHALL: I would suggest there's probably
16 not a significant opposing opinion, that many states without
17 resources or the circumstances to need to address it will
18 probably be in favor, but as Richard says, we've not voted
19 with a formal -- for a formal record on it.

20 MR. BAILEY: I was at the San Francisco public
21 meeting, and I think there are a couple of things that
22 struck me at that meeting.

23 One is that somehow we got it over into recycle,
24 and that raised concerns among environmentalists, consumer
25 groups, and so forth.

1 In listening to representatives from the
2 individual power plants, from the steel industry, and so
3 forth, they were hoping the rule wasn't going to be used as
4 a recycling rule; rather, that it was going to be sold as a
5 disposal rule, and I think if it were repackaged and
6 presented in that fashion, rather than, as it got turned
7 around to, a recycling issue, that it would be a much easier
8 sell.

9 I didn't see any of those groups, other than some
10 of their organizations, saying, hey, we want this, we want
11 this rule so we can recycle more of that stuff. The steel
12 people didn't want it. The power plants said I don't want
13 me steel going and being recycled.

14 So those were sort of my takes on that particular
15 meeting, and I did have to add at that meeting, since I was
16 there in California, that both members of the legislative
17 and executive branches of California government really have
18 expressed concern about this rule and whether or not it
19 would be an item of compatibility, strict compatibility, and
20 if it weren't, then would we have shopping around? Could I
21 take my stuff to Nevada or Texas and get it recycled if I
22 couldn't in California?

23 So, there are all these kinds of issues.

24 COMMISSIONER MERRIFIELD: This reminds me,
25 whenever I used to have discussions with the state, I would

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1 always refer to the state of Aurora, so you never had to
2 refer to any particular state.

3 So, let me just get your last point, so it's clear
4 to me, at least.

5 What you're saying is you think the idea of our
6 having a baseline standard so that there isn't shopping by
7 some of these folks is a positive thing. That was the
8 impression.

9 MR. BAILEY: Yes, I do, and we did -- I think,
10 during that meeting, did suggest that you have a table
11 similar to what you do for water and air, rather than having
12 all this dose modeling, which anybody that's worth their
13 salt as a dose-modeler can change it by at least one order
14 of magnitude in the process. So, give us a table, you
15 measure it, if it's below it you throw it away or dispose of
16 it however it should be.

17 CHAIRMAN DICUS: Okay.

18 Do we have Commissioner Diaz on-line?

19 COMMISSIONER DIAZ: I am on-line.

20 CHAIRMAN DICUS: Can we turn up the volume,
21 because we can barely hear you.

22 COMMISSIONER DIAZ: Can you hear me now?

23 CHAIRMAN DICUS: Barely.

24 COMMISSIONER DIAZ: I guess this is not working.
25 So, I'll just listen and be quiet.

1 CHAIRMAN DICUS: I apologize, Commissioner Diaz.
2 I think our technology is a little behind the times right
3 here, so we need to keep working on that, but at least you
4 can hear us, so that part is good, and I'm sure, if you have
5 any particular questions, if you'd like to submit them in
6 writing, I think we can probably get them address.

7 Commissioner McGaffigan.

8 COMMISSIONER MCGAFFIGAN: I will get off the
9 clearance for the moment and get back to the Part 40 issues
10 that you have raised with us.

11 The first comment I would make is that the Staff
12 has not been consistent over the years with regard to exempt
13 materials and whether they could be disposed of. We went
14 and looked at the history of that last year.

15 The second point I would make is that in the case
16 of the Metcoa material that ended up at WCS, the state
17 regulator in Texas for RCRA had previously allowed some
18 FUSRAP material from another state which they had declared
19 exempt NORM, almost identical stuff, to go to WCS. That was
20 a factor and it was not going to a school sandlot. It was
21 going to a hazardous waste facility. It was all those sorts
22 of things that weighed in our mind in making that decision.

23 I agree that we need to look at Part 40. I think
24 one of the issues -- I hope it is not forever on hold. We
25 have three papers before us at the moment that need to be

1 voted on once we get some additional information and
2 additional things need to be looked at.

3 One of the problems we face in all honesty in this
4 area is we have got a very small number of licensees and
5 under the fee legislation they get weighed down with
6 everything. At the moment they get weighed down with a lot
7 of adjudicatory matters which hopefully rules would help
8 straighten out so that there would be less adjudication, but
9 this may be an area where some day somebody in the Congress
10 who really wants us to legislate in this area is going to
11 have to give us some money off the fee base to revitalize
12 Part 40 and get it done and get the resources for it,
13 because we will bankrupt the few remaining people who are
14 trying be prepared to mine uranium if we make this too large
15 a process, and yet it needs to be done.

16 The issue I would like to explore is NORM, because
17 you guys have been saying, both of you, a rem is a rem is a
18 rem, and one of the perplexing things for me still learning
19 this business is the way that NORM gets handled -- you know,
20 the CRCPD had some draft rules on NORM and you got the usual
21 letter from EPA saying it was inconsistent with Superfund
22 principles, blah-blah-blah -- that we get, that DOE gets
23 that anybody who tries to make rational regulations gets,
24 but what you were trying to do there was consistent with
25 your current practices, as I understand it, with regard to

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1 NORM.

2 Could you tell me a little bit -- Mr. Bailey
3 should feel free to talk -- you know, one of the perplexing
4 things is the famous Buttonwillow case. That facility for
5 better or worse is regulated and presumed safe by I guess a
6 different state of California regulator to receive NORM
7 materials from the nearby oil fields, the slag and whatever,
8 up to 2,000 picocuries per gram, as I understood it, and
9 that is what the Corps has been saying and yet stuff that is
10 far less contaminated coming in from New York the state has
11 a problem with and how often are these RCRA facilities
12 allowed to take fairly significantly contaminated materials
13 from oil fields or whatever?

14 MR. RATLIFF: In Texas, where we have a lot of oil
15 drilling and reworking of wells, we have real specific
16 rules, and the 2,000 picocurie per gram is a Department of
17 Transportation rule for their purposes. If it is below that
18 it wasn't regulated for transportation purposes.

19 I think somehow EPA got this transferred to some
20 of the states' hazardous waste groups and they put this in
21 permits and that is not an appropriate number. In Texas we
22 set up our numbers based on two things for a oil and gas
23 related scale that has NORM, but we went with the limit for
24 uranium mill tailings for radium, which is 5 picocuries per
25 gram unless they could show that the radon emanation was

1 less than the 20 picocuries per square meter per second,
2 which is the real controlling factor EPA had on looking at
3 the dose, and if it is less than that they can go to 30, so
4 radium ends up being the controlling factor, then other
5 isotopes you have in NORM the uraniums, the thoriums, other
6 daughter products. We have gone to the .05 percent by
7 weight exemption and extracted that and just came across the
8 board for 150 picocuries per gram.

9 It has worked well for oil and gas, but the unique
10 thing with oil and gas though in Texas is that it is
11 regulated by us and our Railroad Commission of Texas and
12 they are allowed to take -- there is a license that we have
13 with two companies and they permit these companies where
14 they put it back where it came from.

15 The have deep injection wells and so you don't end
16 up with a disposal problem for oil and gas NORM. Other NORM
17 is a different situation. There really is no disposal site
18 to handle that NORM. I think it has to be based on risk and
19 that is what we have done in our rules, and we have looked
20 at what equivalent rules do we have for uranium industry and
21 for other areas.

22 CHAIRMAN DICUS: Yes.

23 COMMISSIONER MERRIFIELD: Can I just interrupt
24 because this is a very good piece I want to ask a question
25 to clarify. You said the EPA adopted the DOT rules relative

1 to the 2,000 picocuries per gram --

2 MR. RATLIFF: I don't know if they adopted it. I
3 think they presented it that it was a number out there, and
4 I am not sure how the states got it but it seems that there
5 are multiple state hazardous waste regulatory agencies in
6 states that have come up with that magic number and really
7 they are using it inappropriately.

8 COMMISSIONER MERRIFIELD: But that number
9 apparently went through EPA, do you believe? I am just
10 guessing because they are EPA delegated programs.

11 COMMISSIONER MCGAFFIGAN: And I think this is a
12 discussion that I think some day we need to have in much
13 greater depth, but the other place --

14 CHAIRMAN DICUS: So are you suggesting we have a
15 NORM briefing?

16 COMMISSIONER MCGAFFIGAN: Well, some day we need
17 to have it, although that is not our area.

18 CHAIRMAN DICUS: It might be some day though.

19 COMMISSIONER MCGAFFIGAN: A rem is a rem is a rem.

20 COMMISSIONER MERRIFIELD: I was going to also
21 suggest that there is some possibility at least, although I
22 wouldn't want to unfairly characterize our brethren at the
23 EPA that we may be suggesting levels that are more
24 protective of health and safety than they are.

25 [Laughter.]

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1 COMMISSIONER McGAFFIGAN: Well, certainly our
2 Agreement State colleagues are.

3 MR. BAILEY: I think they would disavow any
4 knowledge of that number.

5 COMMISSIONER MERRIFIELD: That is why we don't
6 want to make an unfair characterization.

7 COMMISSIONER McGAFFIGAN: But just to stay on this
8 subject, I mean again something that was motivating us when
9 we were thinking about what the right thing to do is here,
10 and Mr. Paperiello is sitting there behind you, but coal
11 ash, which is probably the single largest amount of
12 technologically enhanced NORM we have out there, as I
13 understand it EPA encourages the recycler of coal ash in
14 concrete for building materials, et cetera.

15 You mentioned your state legislators are concerned
16 about things. Well, some of that coal ash can be 500 parts
17 per million uranium and thorium, right? -- or higher. It
18 can be fairly hot and if it were controlled by us it would
19 be in this mix. I don't know what the effect of recycling
20 the coal ash in building materials and concrete is but if it
21 is fairly hot coal ash it is trivial compared to all the
22 granite on Capitol Hill probably but there's some dose that
23 probably would be higher than any dose you would get from
24 any recycled nickel coming out of Mike Mobley's contractor
25 in Tennessee by many orders of magnitude.

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1 MR. RATLIFF: I think the reason sometimes it gets
2 blessed is because it is natural. It has been here. It is
3 extracted and what we see with the coal ash is that it can
4 be high. Typically it is lower but it is still being put
5 into building materials and if I remember right, there is
6 still a requirement that federal new buildings use this for
7 recycling purposes.

8 The studies we have done have looked at the radon
9 emanation, which is because radon would be the greatest
10 problem --

11 COMMISSIONER McGAFFIGAN: Right.

12 MR. RATLIFF: -- and there is just not a radon
13 problem, but yet it is still material going there for
14 inappropriate use and we concur with that.

15 COMMISSIONER McGAFFIGAN: I don't know whether it
16 is inappropriate or appropriate. It is just the practices,
17 the actual practices that we have going on across the
18 nation, and your viewgraphs were to the point that the
19 practices don't add up to a coherent whole, the practices
20 don't add up to a coherent whole and it is not just our
21 fault and it is not your fault.

22 CHAIRMAN DICUS: It is a combination.

23 COMMISSIONER McGAFFIGAN: It is EPA has to take
24 some responsibility as well. Why don't I leave it at that.

25 CHAIRMAN DICUS: All right. Mr. Marshall is

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1 ready. We can proceed to the next topic, and I am kind of
2 looking at the watch. We still have a lot of material to
3 cover, so try to move us along.

4 MR. MARSHALL: I am watching it as well and I will
5 just ask David and Roland to bear that in mind as we
6 still --

7 CHAIRMAN DICUS: Thank you.

8 MR. MARSHALL: -- have Bob -- David Walter from
9 Alabama on comparisons of Part 35 and Part G.

10 MR. WALTER: And you might say I am here as
11 Agreement State but I am also here as the CRCPD since
12 virtually everything that I am going to talk about has to do
13 with the Conference's SR-6 committee.

14 I would like to take a few minutes to inform you
15 about areas of the revised Part 35 for the Agreement States
16 and the Conference's use of radioactive materials or the
17 SR-6 committee have some differences of opinion, but I also
18 want to give you my opinion on how the parallel rulemaking
19 processes work for Part 35.

20 Let me start with the second slide with the duties
21 of the authorized user. At the public hearing conducted at
22 the '98 Organization of Agreement States Meeting a number of
23 states commented that the specific duties of the authorized
24 users should be detailed in the rules. Well, currently the
25 definition of an authorized user includes reference to their

1 required training and experience. The only time that a
2 specific duty is spelled out for an authorized user is in
3 35.40 where it says that the authorized user must prepare a
4 written directive.

5 If you look at 35.27 it says the licensee shall
6 require a supervised individual to follow the instructions
7 of a supervising authorized user, but there is no reference
8 to the duties of that supervising authorized user and 35.27
9 further refers you to Rule 35.11, but when you look at 35.11
10 it states that an individual may perform license duties
11 under the supervision of an authorized user as provided in
12 35.27, and that appears to be a Catch-22.

13 Our committee believes the rules should be a
14 little bit more specific regarding the duties of all the
15 authorized users. It is our intent to offer rule text that
16 specifies the radiation safety related duties of the
17 authorized user based on the radiation risk of the study.

18 These will be broken into three specific
19 requirements that may sound very familiar to many of you --
20 selecting the patient, prescribing the dose or dosage, and
21 interpreting the results of the study. The reason it may
22 sound familiar is because this text is similar to that that
23 was used in the mid-1980s Reg Guide 10.8.

24 Now there will be those out there who say it is
25 the practice of medicine and we have to stay out of it, and

1 I say to them that that is true. It is the practice of
2 medicine. But it is also dealing with radiation safety of
3 the patient and that is our job, and you simply just can't
4 separate those two. Next slide.

5 Next I want to discuss the submission of written
6 procedures. Throughout the new Part 35 there are
7 requirements to develop and implement written procedures.
8 However, there is no requirement that the licensee submit
9 these procedures for review by the Commission Staff. Rather
10 the intent is to review these written procedures only when a
11 problem is found during an inspection that should have been
12 addressed by one of these required procedures.

13 Well, the SR-6 committee intends to have Part G
14 recommend the submission of these written procedures for
15 review by the state agency. The reason is, simply stated, we
16 would rather determine the adequacy of a written procedure
17 before a problem occurs. If you wait until after a problem
18 occurs you may find that the written procedures were totally
19 inadequate, were never even written or that nobody even knew
20 they existed and if that is the case, that means each person
21 is left on their own in handling any given situation and
22 quite likely they are going to handle it in a different way,
23 and I don't believe that this is in the best radiation
24 safety interest of the patients or occupational workers.

25 Additionally, we also believe that the review and

1 discussion of a written procedure opens a line of
2 communication between the agency and the licensee and can
3 build a rapport or at least start building a rapport between
4 them and it can increase the confidence of both parties in
5 the resultant radiation safety program. Next slide.

6 Now let me discuss patient release criteria. Rule
7 35.75, or the patient release rule subject, is a very
8 difficult one for us states. On the one hand you have a
9 possible small increase in exposure to the general public
10 with a tradeoff of lower medical costs and better patient
11 morale, but on the other hand you have muddied the radiation
12 safety aspects of unsealed source therapies by placing
13 radiation safety into the hands of a minimally trained
14 patient and their family and you may have led to increased
15 costs to state agencies who have no choice but to respond to
16 landfill alarms and deal with resultant waste.

17 There are some points I would like to discuss
18 here.

19 First, if a member of the public can receive 5
20 millirems of exposure from a released patient, what is the
21 limiting factor for this exposure? Can this same member of
22 the public -- for instance, an LPN working at a nursing
23 home -- be exposed to numerous released patients resulting
24 in exposures much greater than 500 millirems in a year? If
25 so, then what is the point of having a 100 millirem per year

1 limit for the general public?

2 On this point, why not offer the same types of
3 exemptions to all other different types of licensees, not
4 just medical? Well, once it is decided that such exposures
5 are acceptable, then your heart of the matter is the
6 training that is given to these patients and their families.
7 Is it adequate and effective? If it is and the patient
8 really understands why and follows through on how to
9 maintain these exposures to others' ALARA and how to
10 minimize the waste problem, then this rule should work. If
11 not, we end up with unnecessary doses to the public and
12 increase landfill alarms.

13 Judging by the increases in landfill alarms over
14 the last few years, it appears that at least some of the
15 licensees are not providing adequate ALARA training as
16 required. Next slide.

17 The revised Part G will offer as an option to the
18 states verbiage that will allow the release of patients but
19 will try to assure that the ultimate responsibility for
20 radiation safety remains with the licensee. Additional text
21 will be included that requires the authorized user to
22 personally approve the release of the patient based on their
23 professional opinion that the individuals are adequately
24 trained and fully understand how to maintain exposures ALARA
25 and minimize the release of radioactivity. Next slide,

1 please.

2 Now let's turn to authorized user training and
3 experience. In the revised Part 35, there has been an
4 increase in the required total number of hours of training
5 from 800 to 700 hours for uses covered under 35.390. SR-6
6 applauds this increase in training hours because the new
7 Part 35 is supposed to be a more risk-based rule and we
8 believe that the therapeutic use of unsealed radioactive
9 material is about as high a risk as you are going to get in
10 these rules.

11 However, we disagree with the decision to maintain
12 the training and experience for oral I-131 as specified in
13 35.392 and .394 to only 80 didactic hours and three
14 supervised cases.

15 When you compare to other therapies those
16 involving I-131 have proven to be the most likely to have
17 misadministrations, and of all the current unsealed source
18 therapies, oral I-131 poses the greatest radiation risk to
19 ancillary personnel and to the general public. For these
20 reasons the new Part G will recommend not have lesser
21 training requirements for those authorized users who wish to
22 use only oral I-131 for therapy. The committee will
23 recommend that they be required to have the same 700 hours
24 of training and experience as anyone else who wishes to use
25 unsealed therapeutic radiopharmaceuticals. Next slide.

1 One of the things that SR-6 wanted included in the
2 revised Part 35 was a set of minimum training and experience
3 criteria for technologists. I mean they are the ones who
4 actually handle the isotopes and dose the patients 99
5 percent of the time but there are no minimum training and
6 experience requirements in the rules. Unfortunately we were
7 unable to get such criteria included in the new rule, so our
8 committee is going to try to come up with a set of
9 recommended minimum radiation safety -- and I stress
10 radiation safety -- training and experience criteria for
11 nuclear medicine and therapy technologists.

12 The committee has already gathered minimum
13 training and experience requirement information from many of
14 the states that already require licensure or registration
15 for technologists and will use that information in drafting
16 our rule text and although this text that we draft will not
17 be as restrictive as many of these current state
18 requirements, there are a number of states out there that
19 have no current requirements, so this could be a good
20 starting point for them. Next slide.

21 Now I want to discuss probably the most
22 contentious rule in this draft Part 35, to me at least, and
23 that is 35.3047. As anyone on your staff who was at the
24 working group meetings can tell you, I don't agree with this
25 reporting rule at all. Regardless of its intent, I view

1 this rule as a de facto approval to allow embryo fetuses and
2 nursing children to receive 50 times more exposure than the
3 rest of the general public and 10 times more exposure than
4 the allowable limits from a released patient.

5 Because of the obvious contrary health physics
6 implications the SR-6 committee has decided that the revised
7 Part G will not recommend the inclusion of such a reporting
8 requirement. We will instead allow our Part 20 equivalent
9 exposure limits and reporting requirements to take
10 precedence. Next slide.

11 Now a few statements about the parallel rulemaking
12 process during this Part 35 rewrite. I believe the process
13 has worked very well and has been quite helpful to the
14 states, but for the process to work its best the states
15 should be represented on the rule writing teams. Now the
16 Part 35 working group included Marsha Howard from Ohio as
17 well as myself, and Tom Hill from the state of Georgia
18 represented the Agreement States on the steering group.
19 This seemed to work quite well, and my being on the SR-6
20 committee helped a great deal.

21 For any major rule revisions or new rule writing I
22 strongly urge that a member of the Conference SR committee
23 that is affected by the change be included on the NRC
24 working group. In addition, the Agreement States should
25 have a representative on the steering group, because having

1 these state representatives on these working and steering
2 groups has provided for a better line of communication to
3 the Agreement States. The representatives can relate
4 specific areas of concern to the states and let them comment
5 and give suggestions about the rule, and give those back to
6 those individuals who can relate them to the working groups
7 in person.

8 I was also able to give regular updates to my SR
9 committee members and this allowed them to understand the
10 direction the NRC rule was taking and tried to start
11 formulating ideas for suggested state regulations text.

12 Our committee met in February of this year and I
13 think we were all very pleasantly surprised at the amount of
14 work that we got down in the amount of time that we had, and
15 I attribute much of this to the members being informed of
16 what the NRC drafts were so that we didn't have to bring
17 them all back up to date before or during the meeting.

18 In closing, I believe the Agreement States
19 actually do agree with the majority of the new Part 35,
20 however I urge the Commission to consider the statements I
21 have made about the small number of problem areas and
22 consider appropriate actions. Thank you.

23 CHAIRMAN DICUS: Thank you very much. And let
24 me -- I did mention that since we are having trouble with
25 being able to hear, Commissioner Diaz suggested that if he

1 had written questions to submit that you would be responsive
2 to answering them. And he has indicated that he will have
3 some written questions to submit. He'll have those to us in
4 a couple of days, and I'll channel them either to Mr.
5 Hallisey or Mr. Marshall, depending on what topic they
6 happen to be on. So we will take care of that in due time.

7 I've got a couple of questions I'd like to pose to
8 you on the Part 35, and I think you're aware tomorrow we
9 will have a briefing on Part 35 from the staff and ACMUI
10 involved as well.

11 It's my understanding that there is general
12 agreement with the NRC's medical policy statement with
13 regard to the fact that NRC should not delve into the
14 practice of medicine. Is that a fair statement?

15 MR. WALTER: As much as possible; that's correct.

16 CHAIRMAN DICUS: Okay. And I think then we have
17 some concerns from the NRC because you're wanting to require
18 such prescriptive requirements of authorized users, their
19 duties require selection of the patient, prescription of the
20 dose, et cetera and so forth. Do you see that as delving
21 into the practice of medicine? Because I think the NRC's
22 position maybe is that we're getting into that arena.

23 MR. WALTER: There is no specific cutoff point
24 that you can say that everything to the right of this is
25 going to be medical, and everything to the left of this is

1 strictly radiation safety. The fact of the matter is that
2 we require anyone who uses radioactive material or oversees
3 the use of radioactive material to have a good understanding
4 of radiation safety and the use of these materials. And for
5 that reason I don't believe that to the point that -- the
6 extent that we've gone we're not telling them what they have
7 to do as far as medical is concerned unless it has to do
8 specifically with radiation-safety-related matters. To that
9 extent no, I do not believe that we're having a problem with
10 that.

11 CHAIRMAN DICUS: Okay. I think we may have a
12 slight difference of opinion there, but we understand where
13 you're coming from, we understand that concern.

14 Let me bring up one more thing, then I'd like to
15 have the other Commissioners -- and this has to do with the
16 training and experience requirements on your slide on that,
17 on 35.392 and 35.394.

18 The NMED data base, which Agreement States do
19 provide information on with regard to misadministration
20 data, et cetera, frankly in our opinion does not appear to
21 support the SR-6 concerns that, and I'm quoting what you
22 said, iodine misadministrations pose the greatest biological
23 radiation risk to the patient, I think is a quote taken from
24 some comments that have been made.

25 Where is the SR-6 Committee -- what are you basing

1 that comment on, what sort of scientific data, since the
2 NMED data does not appear to support that?

3 MR. WALTER: Let me get a little clarification
4 exactly what you mean. Are you speaking specifically about
5 the effects on the patient or the effects on ancillary
6 personnel and the public?

7 CHAIRMAN DICUS: I was talking about the questions
8 related to the effects on the patient, but I would expand it
9 to the ancillary personnel as well as the public.

10 MR. WALTER: Okay. It only takes 30 microcuries
11 of iodine to deliver a 50-rad dose to the thyroid. We're
12 dealing with millicurie quantities that if you're only a
13 millicurie off, you're looking at a substantial difference
14 in dose.

15 Now from a patient's standpoint, that is not the
16 most important thing. The fact of the matter is using oral
17 iodine you're flooding the body so that the entire body --
18 it's a whole-body exposure rather than a specific area of
19 the body that would be exposed if you were using beam
20 therapy or a sealed-source device -- the vast majority of
21 the dose is going to go to any thyroidal activity or tissue
22 that is still active with then a great deal of it going to
23 the kidneys and bladder.

24 But in looking at this, we looked at the
25 misadministration data, and looking at that specifically

1 there is no doubt that the misadministration -- the number
2 of misadministrations that occur, and we're not 100 percent
3 certain on this last part that I'm about to say, but we do
4 know that the number of misadministrations that occur in
5 therapy are much higher in iodine than they are with
6 virtually any other kind of radioactive material, whether it
7 be sealed or unsealed-source medical use.

8 The question was whether or not the percentage of
9 iodine therapies that became misadministration was actually
10 higher. There are a huge number of iodine therapies that
11 are given in comparison to every other type of therapy.
12 It's one of the highest, if not the highest, at this point
13 in time. It's more than -- I would say probably twice as
14 high than any of the next ones after that.

15 But we're basing that on the biological aspects of
16 the radioactive material. You have a much larger area of
17 the body receiving a large dose for the patient. But when
18 you get out to the -- as I said in here, it's the ancillary
19 personnel and the general public. The general public, yes,
20 the general public can be exposed to the individual as a
21 point source, but to a greater extent they're exposed to an
22 individual's contamination that they didn't even know that
23 there was a patient around there.

24 CHAIRMAN DICUS: I don't want to take up too much
25 more time, so I just wanted to pursue it a little bit, and

1 it had to do really, because you're working around to the
2 patient-release criterion in some ways, and a little bit
3 concerned about that, because, you know, a variety of things
4 to into the decision on patient-release criteria, including
5 the well-being of the patient, psychologically, et cetera,
6 there are a lot of other things that have to come into that.

7 Granted, it is something of a problem, but I think
8 also you were working around in your comments the fact that
9 then State radiation control programs, for that matter the
10 NRC, may find itself responding to alarms that are set off
11 at waste facilities, et cetera, and therefore they need some
12 ability to recoup from these kinds of expenses. And point
13 out that nothing in any of the proposed rules prevents that.

14 Now, I think what you're trying to go to, well if
15 you have a tighter grip on the release criteria and maybe
16 don't allow these patients to be released, then you won't
17 have as many of these alarms going off. But --

18 MR. WALTER: No, what I actually --

19 CHAIRMAN DICUS: I'm not sure where you're going.

20 MR. WALTER: When I was saying that, what I
21 actually mean is that when a patient is released, the
22 licensee is generally not held accountable for their
23 exposure to other individuals because the data that was --
24 the equations that were worked on show that it's unlikely
25 that that individual will expose any other person to more

1 than 500 millirem. That's all they have to do. If that
2 patient then goes to a restaurant within the next two hours
3 or less and becomes sick to their stomach, if they don't
4 notify the licensee that something has happened, the
5 licensee will not know anything about it and will not take
6 any responsibility for it, even if they were going to.

7 CHAIRMAN DICUS: Well, I've actually been under
8 the impression that they are given some instructions before
9 they leave the hospital on certain things they should be
10 doing. Are you saying that's not the case?

11 MR. WALTER: They are -- the only part that
12 requires written instructions is if it's greater than 100
13 millirem. Okay? If there is a possibility of an exposure
14 greater than 100 millirem, yes, there is something that is
15 in there that states that.

16 But having worked with a number of these patients,
17 if you have your choice of being cooped in a room for the
18 next two to three days, in a hospital room with no ability
19 to get outside or having the ability to say I'm going to go
20 home and I'm not going to go anywhere, and being able to be
21 released, there is a no-brainer. They are going to say
22 whatever they think is necessary to get -- to go home.

23 The written instructions notwithstanding, that
24 doesn't necessarily mean, knowing the patients, they may --
25 there are going to be some of them that are going to be very

1 conscientious and are going to definitely call immediately
2 and say something about it. But I'd also believe that there
3 are a number of them out there who -- their training is
4 not -- when I say adequate, I mean it's not actually clear
5 in their mind that this is an important thing that they need
6 to make sure that they're doing.

7 CHAIRMAN DICUS: I think I understand what you're
8 saying, but I'm not sure there's a rule that really fixes
9 that. But --

10 MR. WALTER: There isn't right now in the
11 current draft --

12 CHAIRMAN DICUS: Well, I'm not sure that --

13 MR. WALTER: And there may not be a possibility of
14 that.

15 CHAIRMAN DICUS: Right.

16 MR. WALTER: We're not -- at this point in time
17 I'm not really attacking 35-75 on its release -- allowing
18 the release of an individual who can receive 500 millirems,
19 but -- because personally I didn't see a problem with the
20 500-millirem public dose from pre-1993. But if a person --
21 and most of these patients will come in, if it's thyroid, if
22 they've had a thyroidectomy, they very often will come in
23 two to three times a year, which allows their family members
24 and anyone else to receive up to 1,500 millirems in a year.
25 Is that your intent? Is that the intent of this rule, to

1 allow much larger doses per year than the 500 millirem?
2 That's just the point I'm making for that.

3 The other is that you have to consider nursing
4 home facilities and other places where a lot of these -- a
5 lot of these patients and their families are in support
6 groups. So they may be exposed to not just the one person
7 in their family, but to numerous other patients. So now
8 we're looking at occupational exposure rates, possibilities
9 of occupational exposure rates.

10 CHAIRMAN DICUS: All right. We need to move on.
11 Commissioner McGaffigan.

12 COMMISSIONER MCGAFFIGAN: Well, you've talked
13 through the patient release. I just come back to the T&E
14 for endocrinologists. Our data, as Chairman Dicus
15 indicates, is that endocrinologists in the practice of the
16 use of sodium iodide have not had problems. There have
17 been -- there's two data points in the data base, and
18 neither were serious for the patient.

19 And so the question -- if you go to 700 hours, the
20 endocrinologists have also testified to us that you will
21 disrupt the practice of medicine, because they will not be
22 able to build that into their educational programs, and you
23 basically will be denying an option for patients. We could
24 not, based on the data we have, deny that option to
25 patients. That's the choice we made. I hope you guys have

1 a vigorous debate, and I think you will, because the
2 endocrinologists will bring it to you when the SR-6 findings
3 go to the broader community of the CRCPD.

4 The technologist T&E will -- that's not an issue I
5 was up to. On the embryo-fetus, when you say you're going
6 to propose to your colleagues that you use the Part 20
7 reporting, is that 100 millirems per year?

8 MR. WALTER: For an embryo-fetus, it would be 500
9 millirems in the full term. For a nursing infant, it would
10 be 100 millirems or a released patient criteria of 500
11 millirems. Yes. So I could see where 500 millirems would
12 be applicable to either of those.

13 COMMISSIONER McGAFFIGAN: As you know, the doctors
14 tend to think of the mother and child as a unit that they're
15 treating, and so again you're going to -- I mean, this is
16 going to be one of these issues that come up against
17 practice-of-medicine considerations, and we're going to have
18 to -- we're going to have to hear tomorrow's testimony from
19 ACMUI and the staff and make a judgment. But the staff
20 paper justifies the 5,000-millirem reporting requirement on
21 the grounds that -- I guess ACMUI has told the staff that
22 there are no deterministic effects and stochastic effects
23 are less than 1 percent. I mean, that's the line in the
24 paper.

25 So it's a judgment. It's a judgment as to how

1 much we treat medicine as a different -- because there is a
2 clear benefit being provided by medicine -- as a different
3 thing from dealing with reactors or fuel-cycle facilities.
4 It's -- I appreciate your raising the issue, but I know the
5 doctors will have a very different view.

6 MR. WALTER: I think originally that this was
7 brought forth because of the belief that there was no doubt
8 that you would have to have a pregnancy test done before
9 every study. But if you go and you look at the actual
10 information about the dose that would be expected under
11 normal dosing procedures for diagnostic uses of
12 radiopharmaceuticals, you're not going to find a huge number
13 of those tests that are going to expose that embryo-fetus to
14 greater than 500 millirem unless you are saying I don't want
15 a bone scan of 20 millicuries, I want one of 60.

16 COMMISSIONER McGAFFIGAN: Um-hum.

17 MR. WALTER: And that determination is something
18 that needs to be made by the physician anyway. And I am not
19 saying to any physician that they cannot dose this patient
20 if their medical decision, and I'm saying that this is their
21 practice of medicine, they can make that decision to give
22 higher doses based on the fact that this is what is going to
23 best for my patient. There's no doubt that that's what they
24 can do. They can give a 500-millicurie dose of technetium
25 to do an ingrown toenail for all I care, as long as they say

1 it's the best thing for their patient.

2 CHAIRMAN DICUS: Commissioner Merrifield. Moving
3 on from the ingrown toenail.

4 COMMISSIONER MERRIFIELD: I would weigh in, along
5 with Commissioner McGaffigan, in terms of the concerns
6 relative to iodine-131, but I don't want to belabor that any
7 more.

8 Just a short word on misadministration and doctor
9 notification of the NRC. This is probably the single most
10 third-wire issue for doctors, and the number of vehement
11 letters that we get from members of the medical community
12 relative to the fact they don't believe the NRC should be in
13 the business of worrying about this is certainly noteworthy.

14 Similarly noteworthy in terms of the review that I
15 have done since I've been here is the lack -- surprising to
16 a certain degree to me -- the lack of patient involvement in
17 the concerns about those notifications. I mean, we've been
18 talking about relaxing our standards for notification for
19 misadministration, and there has been no -- I would have
20 expected more comment from the stakeholder community outside
21 of you all about that kind of change, and to my knowledge we
22 just haven't gotten a lot of that. So I sort of throw that
23 out there. I'd be interested to see what comments you get
24 when you release your report. I'd second Commissioner
25 McGaffigan on that one. Thank you.

1 MR. WALTER: I do want to point out that
2 regardless of what we put in SR-6, the rationale will
3 specify that there is a less restrictive option to maintain
4 compatibility for the State. And so that will be included
5 as a possibility, and if the State so chooses, they can go
6 that route, but that does not mean that that will be the
7 recommendations of our committee.

8 CHAIRMAN DICUS: Okay. Stan.

9 MR. MARSHALL: I am glad to introduce, a bit late
10 but not lost, Roland Fletcher. Roland is from the state of
11 Maryland and is Past Chairman for OAS. He is here to talk
12 about allegation investigation protocols.

13 MR. FLETCHER: Chairman Dicus, Commissioners, good
14 morning.

15 As you may see from my topic, this is something of
16 a follow up of an area that I have been looking at for the
17 past couple of years. In fact, at the Commission briefing
18 last year I talked about information-sharing and at that
19 time Chairman Jackson recommended that I go and talk with
20 some of the specific offices including the Office of
21 Investigations, which I did, so I am approaching this topic
22 today from a more generic perspective. I am not focusing in
23 on specific things although they fit into my information,
24 but what I want to talk about is what we see as areas of
25 concern and some of the recommendations that I think might

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1 help to ease those areas.

2 One of particular concern is Management Directive
3 8-8, which is going to be highlighted on a few instances as
4 perhaps the source of a problem and the location of a
5 possible solution.

6 What we are talking about are instances where
7 investigations may be conducted in Agreement States and on
8 several occasions that I am aware of throughout the country
9 the Agreement State program management, the state senior
10 management themselves are essentially either not informed,
11 not made aware, and for various reasons of course but
12 oftentimes we found that there are other options.

13 As I look through Management Directive 8-8 in
14 reference to the first area, the failure to recognize or
15 acknowledge Agreement State authority, in the glossary there
16 is no definition of an Agreement State. In the procedures
17 there is no information that could be given to an
18 investigator as to how an investigation should be conducted
19 in an Agreement State.

20 As a result, what we are finding is that in some
21 instances investigators are not taking the Agreement States
22 seriously, either because they are unaware of the
23 jurisdiction of the Agreement State over licensees within
24 that state or for other reasons that I don't want to touch
25 upon, but we find that their relationship in conducting the

1 investigation is often inappropriate to successful results.

2 We also find that there have been instances where
3 there is an extreme reluctance to share information. I am
4 well aware that there are instances where information,
5 integrity of information must be preserved but oftentimes the
6 Agreement State once again deals with many of the licensees
7 on a regular basis and can perhaps provide information that
8 the investigator is not even aware of.

9 There have been instances where information has
10 been shared with either the Headquarters or the region and
11 the investigator from one or the other is not aware of that
12 information. I find that a little difficult to understand.
13 So what happens is there is a reinvestigation of
14 investigations that have already been conducted and that
15 leads to some problems with the Agreement States.

16 There is oftentimes staffs who in many instances, as
17 I said before, are very familiar with certain licensees and
18 they have information from cradle-to-grave about certain
19 licensees. It may be an instance dealing with reciprocity,
20 it may be an instance just dealing with some concern, but
21 some contact or at least -- well, some contact or
22 communication with a member of the Agreement State staff
23 might be beneficial for those conducting the Agreement
24 State.

25 The last is I guess a perception, a feeling that

1 is shared once again by many Agreement State individuals,
2 and that is that oftentimes personnel are made to feel as
3 though they do not have the expertise, they do not have the
4 competence, they do not have the relevant information that
5 an investigator should bother to seek. This is very far
6 from the truth and I think it does not aid in continuing to
7 build and strengthen our partnership as far as handling
8 these types of investigations.

9 I have some recommendations that hopefully we can
10 jointly pursue and that is perhaps when information that
11 requires an investigation is revealed either through an
12 allegation or other information an analysis is done as to
13 whether or not this information should be precluded from an
14 Agreement State. I am not sure that this should be done by
15 an investigator. I think there has to be some contact with
16 the Agreement State personnel at that headquarters, either
17 at the region or at the headquarters level to make a
18 rational determination as to whether or not this
19 investigation might be aided by contact with the Agreement
20 State.

21 There needs to be, I believe, more information,
22 perhaps even a paragraph or procedure, outlined in the
23 Management Directive giving guidelines on appropriate
24 contacts and appropriate procedures to be followed when
25 pursuing an Agreement State licensee within an Agreement

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1 State. I haven't seen anything in here. I have been over
2 it a couple of times. There is a reference to referring
3 allegations to Agreement States but there is nothing that I
4 have been able to uncover that says this is how you
5 coordinate with an Agreement State.

6 Whenever there's instances such as reciprocities
7 some states have indicated that they find out the day after
8 that an investigation has taken place in their state. There
9 needs to be some precoordination and I think in the best
10 interest of partnership perhaps there needs to be some joint
11 communication with the licensee. Unless there is some real
12 reason to preclude it, I think this would be very helpful.

13 I believe that once an allegation has been
14 referred to Agreement State and that it is completed, if
15 there is no follow-up on such a thing there needs to be a
16 real good reason why and there needs to be communication
17 between the region and the headquarters when such a thing
18 happens and there have been instances throughout the country
19 where that has not occurred.

20 When final reports of Agreement States for
21 allegations are prepared once again, and I am not making
22 light of the need for confidentiality, but I do find and
23 states have indicated that there have been instances where
24 they have been blindsided on information within their own
25 state and this does not bode well with the states and their

1 state government oversight.

2 I believe I have already mentioned about the
3 reciprocal investigative information exchange process. What
4 we in Agreement States normally do is whenever we have a
5 violation that occurs under reciprocity we will communicate
6 with that licensee but any follow-up will normally take
7 place within our state under the reciprocity agreement. We
8 will not normally pursue that licensee into an NRC state and
9 if that should be necessary, we should feel it's necessary,
10 then we communicate with the NRC. We only ask that the same
11 process be afforded to states if such is deemed appropriate.

12 As in other instances, and I know that we in
13 Agreement States are always pressed to find the time and the
14 energy and the individuals to do so, but I believe this is
15 another instance where we get to know each other better when
16 we demonstrate that we are doing the same thing, we have the
17 same mission, we have the same intent and we want the same
18 results, so some type of a joint system I believe would be
19 preferred.

20 These are the things that I wanted to present as
21 far as concerns and recommendations and I will entertain
22 questions.

23 CHAIRMAN DICUS: Thank you for your comments.
24 This is a somewhat complicated issue. It may not lend
25 itself easily to resolution, but whatever appropriate

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1 methods are available for us to discuss these issues, we
2 certainly I think would have an open mind to doing it.

3 I think one of the things we have to keep in mind
4 is whenever there is a situation where there is sensitive
5 material or the need to protect sensitive information, an
6 alleger, whatever, some states do not have that ability to
7 protect that information. That is one of the complications
8 that we must deal with when we deal with this sort of issue.

9 Commissioner Merrifield?

10 COMMISSIONER MERRIFIELD: There are a couple of
11 things that got raised that I would like to comment on.

12 I think one of the things that bothered me in your
13 presentation was the area of concern, your statement that
14 there's a tendency to treat Agreement State personnel as
15 co-conspirators in wrongdoing investigations.

16 I would say two things relative to that. First, I
17 think we have a Office of Investigations we feel pretty
18 confident in. We think they do a pretty darn good job
19 around here. Now that is not to say that there may not be
20 an individual investigator who may not have the appropriate
21 attitude relative to state personnel.

22 We as an agency obviously have provided for --
23 have given the responsibilities to the Agreement State to
24 run these programs. With that comes a respect of this
25 agency for this program and that should run up and down

1 throughout our agency, and so it does bother me that at
2 least your impression is that we have investigators that are
3 treating you, our colleagues, in some disrespectful manner,
4 and that is certainly something I think we can go ahead and
5 take that as a lesson learned and look at.

6 We are professionals. We should treat it as a
7 professional relationship and it would be unfortunate for
8 you to feel that you were treated in a disrespectful manner.

9 That having been said, the issue of our sharing
10 this information, as Chairman Dicus has mentioned, is very
11 sensitive. I am aware since I have been a Commissioner of
12 one investigation that was underway in which I wasn't even
13 able to share with my staff activities relative to an
14 investigation, so that the need for tight control over this
15 is very important.

16 The preferences in the federal whistleblower
17 statutes are to protect alleged confidentiality -- when in
18 doubt protect that alleged, and so we have to act with great
19 care in terms of making sure that we meet those goals of
20 federal law.

21 Now that is not to say that there may not be some
22 way in which we can explore a manner in which we can provide
23 some greater information. I don't know. We certainly
24 haven't tasked the Staff to do that. That may be something
25 worth a discussion between yourselves and members of our

1 Staff to see if there is a way of having better
2 communication and better interaction so that we are treating
3 you in a fair and professional manner.

4 MR. FLETCHER: And I am very, very sensitive and I
5 think I mentioned to the need for confidentiality and the
6 sensitivity of information. States also, many states -- I
7 am sure it is not all -- but many states also, I mean we
8 conduct investigations and we have the same kind of protocol
9 and all I am saying is that in those instances where those
10 things don't apply there needs to be more sharing of
11 information.

12 COMMISSIONER MERRIFIELD: Well, maybe what we are
13 doing here is applying a one-size-fits-all method of dealing
14 with these issues here at our agency, and maybe we need to
15 explore some way of being more flexible on more of a case by
16 case basis. That is something to at least consider.

17 CHAIRMAN DICUS: I think that is one of the things
18 we mentioned, that whatever way is appropriate and proper
19 that we can address some of these issues I think we would be
20 willing to do so. Commissioner McGaffigan?

21 COMMISSIONER MCGAFFIGAN: I don't really have a
22 question, but I do see, as Commissioners do, the monthly OI
23 report, and I can't recall very many cases -- I mean the
24 vast majority of the cases are reactor sites, et cetera,
25 that are open OI. There aren't too many, on an annual

1 basis, that I can recall off the top of my head --
2 investigations in an Agreement State or something that is in
3 your jurisdiction. I think it is a sensitive matter when it
4 comes up but I don't think the numbers are very large.

5 CHAIRMAN DICUS: No. Mr. Bailey?

6 MR. BAILEY: Alphabetically I'm first.

7 CHAIRMAN DICUS: Well, I saw two hands.

8 MR. BAILEY: We had a problem some time ago in
9 regard to what I am sure was just a formatted letter that
10 came out and said we have got this complaint -- this
11 allegation about the use of an x-ray machine, it is not in
12 our jurisdiction, but oh, by the way, give us a report back
13 in 30 days how you handled it.

14 So we went to Region IV and we said, hey, just
15 look at your letter, and I am happy to report that they did.
16 They looked at it and said, okay, this is in your
17 jurisdiction, it is not in ours and so we are referring the
18 allegation to you.

19 But I understand the frustration on several of
20 these that have been referred to us to investigate. We
21 don't get a name so we don't know who the guy is and what we
22 do, what we have done, is gone to the licensee and then they
23 tell us who the allegor is and then we can investigate them,
24 so when we do get these letters down that do involve
25 Agreement State materials and we don't know who the allegor

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1 was it is very difficult in many cases to follow up, to see
2 if there is in fact any truth, but when you go to the
3 company they are very seldom saying okay, you caught me, I'm
4 guilty. You have got to go to someone else.

5 MR. MARSHALL: That's real similar to what we've
6 had. One that I had in the last year was that we have a
7 report allegation that one of your licensees -- and they
8 gave us the licensee name -- has radiation safety problems.
9 That's it.

10 Where do we start, since we can't talk to the
11 alleged? It really made it hard for -- you know, we've done
12 inspections, we look at this, and I think that's where you
13 run into the problem is we can't really do our job --

14 COMMISSIONER McGAFFIGAN: It isn't us
15 investigating you, it's --

16 MR. MARSHALL: Right.

17 COMMISSIONER McGAFFIGAN: Turning it over --

18 MR. MARSHALL: Turning it over so that we can --
19 where do we start?

20 COMMISSIONER McGAFFIGAN: Have enough information.
21 Okay.

22 CHAIRMAN DICUS: All right. I think we can effect
23 some improvements there.

24 Okay, Mr. Marshall, is there anything else?

25 MR. MARSHALL: I truly appreciate Bob's patience.

1 I'm going to try to take one breath and get through a couple
2 slides very quickly.

3 The last item is the OAS resolution to support
4 NRC-proposed budget. I truly appreciate, on behalf of the
5 States and the executive committee, appreciate the
6 attendance and participation of Chairman Dicus at the recent
7 Agreement State meeting in Austin, Texas. At that meeting
8 we discussed what we understood was the NRC-proposed budget
9 to include some additional funding to address NRC
10 initiatives involving Agreement States. At a business
11 session of the attending States a resolution was proposed,
12 discussed, and passed by those participating in the business
13 meeting.

14 The next slide indicates that the 29 States
15 participating in the discussion voted unanimously to support
16 the resolution, which we sent to Chairman Dicus, as well as
17 to the Senate and the House Finance Committees. In the
18 resolution States were also encouraged wherever possible
19 within constraints of communicating to legislatures to also
20 support such budget. Many States have struggled, and I
21 believe most, I'm proud to say, have been successful to get
22 our own dollars to come to our own OAS meeting. I was
23 pleased that we had as many States, including Ohio and even
24 four other -- I don't mean it derogatorily, but Agreement
25 State wannabes. There were the four additional States

1 looking at the option, and we look forward to continuing the
2 relationship in this national program with maybe your help
3 to --

4 CHAIRMAN DICUS: Okay.

5 MR. MARSHALL: That's all I'm going to say, and
6 defer the balance of time to the Chairman and Bob Hallisy.

7 CHAIRMAN DICUS: Thank you.

8 Go ahead, Bob.

9 MR. HALLISEY: Good morning, Chairman Dicus and
10 Commissioners McGaffigan, Merrifield, and Diaz. My name is
11 Bob Hallisey, and I am the Director of the Radiation Control
12 Program, but I'm here this morning as the current Chairman
13 of the Conference of Radiation Control Program Directors,
14 commonly referred to as CRCPD.

15 I am also the Director of the Massachusetts
16 Radiation Control Program, which on March 21 of 1997 became
17 the 30th Agreement State.

18 In this respect, I want to relate to the
19 Commissioners how proud and pleased we are to have entered
20 into this agreement with the Nuclear Regulatory Commission,
21 and what a tremendous effect this has had on the identity of
22 our program within the State government, our relationship
23 with the medical community, academia, and industry in the
24 Commonwealth of Massachusetts, and the professionalism and
25 great sense of accomplishment of our expanded staff.

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1 Becoming an Agreement State to us was the final
2 step towards a comprehensive radiation control program, and
3 Massachusetts would like to take this opportunity to thank
4 the Commissioners and all of the staff of the NRC, and
5 especially Paul Lohaus and the staff in the Office of State
6 Programs, for all this work in making this happen, and for
7 the continuing excellent relationship we have with all the
8 staff that we have experienced as a new Agreement State, no
9 longer the baby, though, now that Ohio is.

10 Back to CRCPD, which is the primary purpose of my
11 being here. I thank you for this kind invitation, and I
12 would like to tell you a bit about CRCPD and to briefly
13 relay to you some related issues that our organization
14 wishes to call to your attention.

15 Many of our issues have already been addressed by
16 the Organization of Agreement States, because obviously all
17 of the Agreement States are part of the conference.

18 The conference is a nonprofit organization
19 incorporated in the State of Kentucky, with our principal
20 offices there in Frankfort, and incidentally our 31st annual
21 meeting was held last May in Louisville, Kentucky, and the
22 Chairman was present at that meeting.

23 The overall purpose of the conference is to
24 provide a common forum for the exchange of information among
25 State and local radiation programs, and also to provide a

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1 mechanism for States to communicate with the Federal
2 Government on radiation issues.

3 Our mission is to promote consistency in
4 addressing and resolving radiation protection issues, to
5 encourage high standards of quality in radiation protection
6 programs, and to provide leadership in radiation safety in
7 education.

8 Our overall goal is to keep the radiation exposure
9 to the patient, the worker, and the general public to the
10 lowest practical level, while not restricting the beneficial
11 uses.

12 Our members are State and local radiation program
13 directors and their staff, staff of radiation-related
14 Federal and international agencies, individuals from the
15 medical profession, academic institutions, and the radiation
16 industry, and some retired radiation protection
17 professionals. We have about 1,000 members.

18 The activities at our organization are divided
19 into five separate councils, depending upon the matter --
20 subject matter of the committee and task force.

21 The five councils are the Healing Arts Council,
22 which deals primarily with X-ray matters; the Environmental
23 Nuclear Council, which deals with radiation environmental
24 matters; the Suggested State Regulation Council, which
25 oversees the various working groups.

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1 [Increase in amplification.]

2 I'm not going to start again, though, I hope.

3 CHAIRMAN DICUS: Your voice carries so well.

4 MR. HALLISEY: I apologize for that.

5 The Suggested State Regulations Council, which
6 oversees the various working groups that develop the
7 SSRCR's, a General Council which oversees all of our liaison
8 activities with various Federal and other organizations, and
9 now a Special Council which oversees the task forces that
10 report directly to the Executive Board, such as our Trading
11 Commission and our Strategic Planning Group.

12 CRCPD, through cooperative agreements, works very
13 closely with numerous Federal agencies, in addition to the
14 known activities that we have with the Nuclear Regulatory
15 Commission.

16 We work very closely with the Food and Drug
17 Administration in the diagnostic X ray area and in the
18 mammography area; with the Environmental Protection Agency
19 in the Office of Radiation and Indoor Air in our
20 decontamination and decommissioning issues; MOSSUM, orphan
21 source, low-level radioactive waste, radon, NORM; with the
22 Department of Energy with our low-level radioactive waste,
23 hazardous waste sites, orphan sources, and norms in
24 transportation of radioactive materials; with FEMA, the
25 Federal Emergency Management Agency, on our offsite reactor

1 emergency planning and response, our potassium iodide
2 protection issue, emergency guides in pathway analysis.

3 Some other Federal agencies that we deal with are
4 Department of Transportation, CDC, Department of
5 Agriculture, the National Institutes of Occupational Safety
6 and Health, and some State -- Department of State on Import
7 and Export Issues.

8 Professional organizations that we work with are
9 numerous and many, and I won't name them all, but they
10 include the Health Physics Society, the American College of
11 Radiology, American College of Medical Physicists, our
12 Association of Safe Drinking Water Administrators, the Joint
13 Commission on Accreditation of Hospitals, the National
14 Governors Association, and the National Council on Radiation
15 Protection and Measurements.

16 I did want to call to your attention some special
17 services of CRCPD that we are especially proud of. One is
18 our accreditation of regional calibration laboratories,
19 traceable back to standards for survey instruments for State
20 use.

21 The second is our program of recognition of
22 licensing States, those that license NORM uses.

23 The third is our issuance of special
24 transportation authorization for shipping of radium.

25 The fourth is we coordinate and broker the Texas

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1 Industrial Radiography Examination to States. And we also
2 coordinate and conduct an annual national conference on
3 radiation protection, which is now involving many other
4 associated agencies and organizations with us.

5 We also conduct comprehensive reviews of State
6 radiation control programs using a team of experts. These
7 reviews are similar to the IMPAIR process, and they're done
8 by request to the State to review the entire State radiation
9 control program, and 12 States so far have been through this
10 process, and we've used in addition to NRC EPA and FDA
11 representatives for their respective program areas.

12 We are especially proud of our numerous
13 publications, which are disseminated widely in the radiation
14 protection community, such as our bimonthly news brief, the
15 directory of personnel responsible for radiological health.
16 This directory lists addresses and telephone numbers for
17 many of the key individuals in the radiation arena. This is
18 a directory of professional personnel and State and local
19 government agencies who administer radiation control
20 activities. And in selected Federal agencies, certain U.S.
21 territories, Canada, and Mexico who have radiation
22 protection responsibilities.

23 I have brought with me copies of the 1999
24 directory for each of you, and I have instructed the CRCPD
25 executive office to see that each of you are sent a copy of

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1 next year's directory when it comes out in January.

2 Hopefully you'll use it to contact any of us for any issue.

3 We also have the publications of our proceedings,
4 our annual national conference in which all of our
5 presentations and papers are presented. We also have a list
6 of State contacts that can be used during radiological
7 emergencies. Our radon bulletin is widely disseminated
8 throughout the country. We also do profiles of State
9 radiation control programs which are available for the
10 numerous programs that have participated that list program
11 staff, budget, salary ranges, job descriptions, et cetera.
12 And we also do various technical reports relating to
13 radiation protection.

14 Lastly I wanted to mention our Web site, which is
15 CRCPD.org. And on the Web site, which we hope you will
16 visit, we have all of our SSRCR's, we have some technical
17 papers and publications, and a method to communicate and ask
18 questions at any time of the conference.

19 Over the years CRCPD has taken positions on many
20 radiation-related issues. The conference has three
21 different forms of positions. First is the position of a
22 task force or a committee. As a matter of fact Dave had
23 mentioned as a committee chair certain positions that his
24 particular committee had on Part 35.

25 The next step up would be an executive board

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1 position where an item is brought to the board and the board
2 votes on it unanimously for that position.

3 And the third step up would be a conference
4 position for all of the members, which is done primarily
5 through resolutions.

6 With these three types of positions in mind, I
7 would like to briefly like to call to your attention two
8 resolutions of the conference relating to current issues.

9 First is a resolution which was first in 1993 in
10 which CRCPD resolved to formally request Congress to amend
11 the Atomic Energy Act to provide for the regulation of the
12 Department of Energy by the NRC. The conference is aware of
13 the continuing discussions on this issue and offers our
14 assistance to the NRC in this area.

15 The second resolution, which was passed in 1998,
16 related to the regulation of 11(e)(2) material and the
17 transfer of FUSRAP to the Army Corps of Engineers.

18 The remainder of my comments are from the
19 executive board and the committees and task forces. We want
20 to convey to the Commissioners our sincere appreciation for
21 NRC's role in the CRCPD orphan source initiative and the
22 importance of NRC's continuing its support to locate, track,
23 provide for the disposition of, and overall management of
24 these orphan sources. This is a very intense interest to
25 the States, CRCPD, as well as internationally. We must not

1 let this initiative be weakened, but rather strengthened.

2 Secondly, with more and more States signing
3 agreements with the NRC, the conference has been thinking
4 about a potential role in providing guidance and rules to
5 States in the future. At some time in the future, probably
6 95 percent or greater of radioactive material licenses will
7 be issued by Agreement States. At such time it may not be
8 economically feasible, as you know, for the NRC to continue
9 its current regulatory program for such a small number of
10 licensees. However, there will still be need for national
11 guidance and regulatory development to assure consistent
12 regulatory control. With our experience in CRCPD conducting
13 comprehensive program reviews, in developing the SSR's, and
14 our licensing State process, we are looking to put together
15 a blue-ribbon panel committee to investigate CRCPD's
16 potential role in this area.

17 Next we support and sympathize with the NRC as you
18 deal with the concept of establishing in regulations release
19 levels for solid materials.

20 We also support the NRC's effort to establish an
21 expanded NMED data base to cover all incidents.

22 We also applaud your efforts to get accountability
23 of GL sources and devices.

24 Lastly, the conference supports the NRC budget
25 request to receive general revenue funds to support the

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1 State and international programs of the Nuclear Regulatory
2 Commission.

3 Again, we thank you for the opportunity to speak
4 before you this morning, and I'd be happy to entertain any
5 comments or questions at this time.

6 CHAIRMAN DICUS: Thank you very much. We do thank
7 you for the support OAS and CRCPD did give us in our budget
8 quest. We weren't quite successful this year but we will
9 keep trying to get where we want to be with regard to
10 getting some things off the fee base so we can continue to
11 support programs that we think are very vital to radiation
12 safety.

13 I only have one question. You mentioned that 12
14 states had undergone a comprehensive review of their
15 programs by CRCPD, by your panel. What was the general
16 findings, the outcomes of that?

17 MR. HALLISEY: Most of the states have a positive
18 outcome from that. They were looking for a review of their
19 program to determine if it was comprehensive enough and also
20 to go back to their hierarchy for support to expand the
21 program in areas in which it was lacking.

22 In the majority of the instances, the process
23 worked. The states were able to get better support from
24 their organizations, increase their budget.

25 CHAIRMAN DICUS: All right. Commissioner

1 McGaffigan.

2 COMMISSIONER McGAFFIGAN: I was just going to ask
3 who is the current CRCPD representative to ISCORS, the
4 Interagency Steering Committee on Radiation Standards? Do
5 you happen to know?

6 MR. HALLISEY: Yes, I believe it is the second
7 Past Chair, Jill Lapodi.

8 COMMISSIONER McGAFFIGAN: Jill Lapodi? Do you
9 personally have any view as to how ISCORS is working? Maybe
10 it would be second-hand from Jill or one of the things we
11 have tried to push is to open more of the meetings. We have
12 had a couple open meetings when they happened to be here,
13 but do you have any views on how the ISCORS process is
14 working?

15 MR. HALLISEY: Well, Commissioner McGaffigan, I am
16 sure that if you know Jill Lapodi, her response would always
17 be on a very positive vein, and I know she is very intense
18 with the ISCORS issue, and she has reported back to the
19 Board that she feels that the process is working and looks
20 forward to continue working with us.

21 COMMISSIONER McGAFFIGAN: Okay. She may be more
22 positive than is appropriate --

23 MR. HALLISEY: That may be --

24 COMMISSIONER McGAFFIGAN: -- in that instance.

25 You mentioned the possibility of some day, if we

1 have very few Agreement States left, ISCORS potentially
2 becoming a body that would develop rules and regulations for
3 the nation.

4 That is something that I know the Chairman
5 mentioned once in a speech. It will require legislation and
6 it may -- that is some years off, but it is a fairly
7 profound change that we are going to need to do some
8 thinking about because it will require legislation almost
9 surely.

10 There will be a lot of people thinking about it
11 and I am not sure. You know, if we can get things off the
12 fee base, then we may be able to maintain that core
13 rulemaking capability here, working with you all in the way
14 that currently we do. If resources are really, really tight
15 and Congress wants this outlet -- but you aren't going to do
16 it for free either, right?

17 [Laughter.]

18 COMMISSIONER MCGAFFIGAN: So I suspect, you know,
19 maybe your choice is whether they give us the resources off
20 the fee base or they give CRCPD the resources off the fee
21 base in order to have this rulemaking capability.

22 MR. HALLISEY: Much of our rulemaking activities
23 have been done by the Conference based upon contributions to
24 the operation of the Conference from various federal
25 agencies.

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1 COMMISSIONER McGAFFIGAN: Right.

2 CHAIRMAN DICUS: Commissioner Merrifield.

3 COMMISSIONER MERRIFIELD: Just a couple of things,
4 because I do want to follow up Commissioner McGaffigan on
5 that.

6 Appreciate the kind words in a number of the areas
7 you spoke about in terms of our budget, in terms of DOE
8 external regulations, support for our trying to get some
9 money for general revenues for state programs -- appreciate
10 all those very kind comments.

11 One of the things you did mention was the issue of
12 orphan sources. I think most people know but it is
13 certainly worth repeating that Chairman Dicus has been a
14 real leader in making this element of the program happen,
15 and I think it should be noted -- her active support based
16 in part on her prior experience with your group, which has
17 led this agency into that effort, and she is to be
18 congratulated for that.

19 On the issue of our lasting materials program, I
20 am as fervent a member on this Commission in terms of being
21 a federalist, in being supportive of Agreement States coming
22 into this program and taking more responsibility for the
23 material areas. That having been said, I think there is a
24 logic in having a national program through the NRC to set
25 the standards. The question is how big should that program

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1 be as we move out into an area where we have an increasingly
2 larger and larger number of Agreement States.

3 I believe that our Materials staff is excellent.
4 I think they do a very good job and I think it would be
5 unfortunate to lose the capability that we have as a
6 national agency to conduct those programs.

7 An effort to have you take some of that, obviously
8 there's some difficult funding issues. There's also the
9 issues of economies of scale, the fact that we have got all
10 those folks here in one agency in one place clearly makes it
11 easier than trying to have 50 states plus the territories
12 try to replicate the same thing and so as you go forward
13 with your blue ribbon panel, I certainly would leave that
14 with you from my personal standpoint.

15 We have a problem right now, and our problem right
16 now is that there are more Agreement States. We have fewer
17 material licensees. We are continuing to place an
18 unfortunate burden on that group for an increasingly larger
19 portion of the Materials program.

20 We need to do those Materials program efforts. I
21 believe our efforts to try to get those efforts off the fee
22 base and into general revenues because they benefit all
23 American people whether they are Agreement States or not is
24 important. As I did before, I would urge you to the extent
25 you can to ratchet up even further your efforts to be in

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1 touch with members of your delegation to let them know the
2 importance of those programs.

3 CHAIRMAN DICUS: And assume they did call you --
4 [Laughter.]

5 COMMISSIONER MCGAFFIGAN: Like McGaffigan and
6 Merrifield.

7 CHAIRMAN DICUS: Anything else?

8 COMMISSIONER MCGAFFIGAN: No.

9 CHAIRMAN DICUS: Did you have anything you wanted
10 to add? Comments?

11 COMMISSIONER MCGAFFIGAN: I think Mr. Marshall had
12 a closing statement.

13 CHAIRMAN DICUS: Okay.

14 MR. MARSHALL: We are pleased for this opportunity
15 again. This has been a very interesting, challenging and
16 enjoyable time as Chairman. I will relinquish gavel on
17 January 1 to Ed Bailey as the new Chair and we look forward
18 to the next Commission briefing.

19 CHAIRMAN DICUS: Thank you -- and I remind you
20 again that you will get some questions in writing from
21 Commissioner Diaz, and as I said before, I will channel
22 those to the proper place to try to get the answers.

23 COMMISSIONER MERRIFIELD: Chairman? Just before
24 you make your closing comments, I would just like to put a
25 plug in, as they did for their website --

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1 [Laughter.]

2 COMMISSIONER MERRIFIELD: NRC.Gov -- in addition,
3 hopefully if we are successful and things work out, perhaps
4 next year when you have your meeting we will do it
5 videostreaming so that your colleagues will also be able to
6 see it on the Internet.

7 CHAIRMAN DICUS: Yes.

8 COMMISSIONER MERRIFIELD: And if --

9 CHAIRMAN DICUS: That is something we are working
10 on.

11 COMMISSIONER MERRIFIELD: In place hopefully in
12 place by the end of the year.

13 CHAIRMAN DICUS: Yes. Yes, that is -- okay.
14 Thank you for bringing that up. I had forgotten about that.
15 We are looking forward to being able to do that.

16 Well, again, on behalf of my fellow Commissioners
17 I want to thank both the Organization of Agreement States
18 and the Conference of Radiation Control Program Directors
19 for another very informative briefing. It is clear from our
20 discussions today that I think we have made a lot of
21 progress in pooling our resources to work together and
22 achieving consensus on many topics of concern to both of all
23 of our regulatory programs.

24 As I noted at the OAS Annual Meeting in Texas in
25 September, states have steadily increased their

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1 opportunities for early involvement in regulations, guidance
2 and other regulatory development activities and now play a
3 much more significant role in helping direct and shape the
4 NRC program. Part of that ongoing involvement includes a
5 new direction, an exchange of ideas for including more
6 performance-based, risk-informed decision-making processes
7 in our routine interactions with all of our stakeholders as
8 well as inclusion of these ideas into revised regulations.

9 Since the public's health and safety is paramount
10 in all of our endeavors we must take it upon ourselves to
11 reach beyond our comfort level with the old way of
12 developing regulatory strategies and instead use our
13 technical competence and insights drawn from past operating
14 history to better focus licensee and regulatory attention on
15 design or operational issues commensurate with their
16 importance to health and safety.

17 A solid materials regulatory program in the United
18 States helps provide reassurance to our stakeholders that we
19 are and we will continue to work together to resolve
20 regulatory issues that are of mutual concern.

21 Again I thank you very much and unless my fellow
22 Commissioners have any further questions or closing
23 comments, this meeting is now adjourned.

24 [Whereupon, at 11:44 a.m., the meeting was
25 concluded.]

CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: MEETING WITH ORGANIZATION OF AGREEMENT
STATES AND CONFERENCE OF RADIATION
CONTROL PROGRAM DIRECTORS
PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Wednesday, October 20, 1999

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Rose Gershon

Reporter: Mike Paulus

76



Organization of Agreement States

Rev 10/12/99

Stan Marshall, Chair

Kathy Allen, Future Chair-Elect

Roland G. Fletcher, Past Chair

Richard Ratliff, Secretary

Edgar Bailey, Immediate Chair-Elect

**ORGANIZATION OF AGREEMENT STATES
NRC COMMISSION BRIEFING**

**REINVENTING NRC ALLEGATION
INVESTIGATIONS IN AGREEMENT
STATES**

Presented by
Roland G. Fletcher – Program Manager
Maryland Radiological Health Program

PAST-CHAIRMAN, ORGANIZATION OF THE AGREEMENT STATES

October 20, 1999

Rev-10/12/99

AREAS OF CONCERN:

- **FAILURE TO RECOGNIZE OR ACKNOWLEDGE AGREEMENT STATE AUTHORITY.**
- **RELUCTANCE TO EXCHANGE INFORMATION PERTINENT TO AN AGREEMENT STATE LICENSEE.**
- **LACK OF COMMUNICATION BETWEEN NRC HEADQUARTERS AND THE REGIONS.**
- **INEFFECTIVE UTILIZATION OF THE EXPERTISE ON AGREEMENT STATE STAFFS.**
- **TENDENCY TO TREAT AGREEMENT STATE PERSONNEL AS CO-CONSPIRATORS IN WRONGDOING INVESTIGATIONS.**

POSSIBLE NEW APPROACHES:

- **IMMEDIATE NOTIFICATION AND DISCUSSION WITH AGREEMENT STATE STAFFS ON ALL INVESTIGATIONS INVOLVING STATE LICENSEES, UNLESS SPECIFIC FACTS PRECLUDE.**
- **ACKNOWLEDGEMENT OF AGREEMENT STATE JURISDICTION.**
- **REQUEST FOR THE OPPORTUNITY TO MEET WITH LICENSEE.**
- **ACCEPTANCE OF COMPLETED AGREEMENT STATE ALLEGATION INVESTIGATION REPORTS UNLESS SPECIFIC NEW INFORMATION PRECLUDES.**
- **SHARING OF FINAL REPORTS OF NRC INVESTIGATIONS OF AGREEMENT STATE LICENSEES.**
- **A RECIPROCAL INVESTIGATIVE INFORMATION EXCHANGE PROCESS IS NEEDED.**
- **INITIATE MORE JOINT INVESTIGATIONS OF ALLEGATIONS "ALA" IMPEP.**

74

Nuclear Regulatory Commission Briefing

Part 35/Part G

Presented by:

David Walter, Chairman

SR-6 Committee



Authorized User Duties

- ⦿ **No duties for the Authorized User are specified in Part 35 unless a written directive is required**
- ⦿ **35.11 and 35.27 refer to each other - Catch 22?**
- ⦿ **Select the patient, prescribe the dose and interpret the results**



Written Procedures

- ⦿ **Assures written procedures have been prepared and can be followed consistently**
- ⦿ **Opens communication with the Agency**
- ⦿ **Increases licensee and Agency confidence in the radiation safety program**



Patient Release Criteria

- ⦿ **Can an individual be exposed to numerous released patients**
- ⦿ **Other types of licensees should be allowed to have the same dose limits**
- ⦿ **ALARA training is critical**



Patient Release Criteria

- ⦿ **Radiation Safety should remain the licensee's responsibility**
- ⦿ **Authorized User must approve the release**



Authorized User T&E

- **The new Part 35 is to be more risk-based**
- **Therapeutic use of unsealed sources is a high risk use**
- **Oral I-131 therapy misadministrations are the most common**
- **Sodium iodide poses the greatest radiation risk to ancillary personal and the public**



Technologist T&E

- **SR-6 will include technologist training and experience requirements**
- **Requirements will be based solely on radiation safety**

Embryo/Fetus - Nursing Infant Dose Reporting

- **35.3047 appears to give approval for an embryo/fetus or nursing infant to receive up to 5000 millirem**
- **Part G will not recommend a parallel rule to 35.3047**



Parallel Rule Making

- **Has worked well for Part 35**
- **SR committee representation on the working group**
- **Agreement State representation on the steering group**
- **Provides better communication to the states**

Organization of Agreement States Briefing to the U.S. Nuclear Regulatory Commission

Stanley R. Marshall, NV - Chairman

Roland G. Fletcher, MD - Past Chairman

Edgar D. Bailey, CA - Chairman Elect

Richard A. Ratliff, TX - Secretary

K. David Walter, AL

Introduction

- **The purpose of this briefing is to provide an update to the Commission about OAS concerns and issues in support of the State/Federal partnership in the long-standing national radioactive material program.**

Briefing Topics

- **DOE Regulation/External Regulation Pilot Program Status - Ed Bailey, CA**
- **Source Material Exemptions - Richard Ratliff, TX**

Briefing Topics (continued)

- **Comparisons of Part 35 and Part G -
David Walter, AL**
- **Reinventing NRC Allegation
Investigations in Agreement States -
Roland Fletcher, MD**
- **OAS Resolution to Support NRC
Proposed Budget - Stan Marshall, NV**

OAS Resolution to Support NRC Proposed Budget

- Discussed during recent OAS executive committee meeting in Austin, Texas**
- Understood that proposed budget intended to secure additional funding for NRC initiatives**
- Resolution proposed, discussed, and passed by attending Ag. States during OAS business meeting**

State Support for the Resolution

- **29 states participated in the discussion.**
- **Unanimous attending state support for the resolution**
- **Resolution copy sent to Chairman Dicus**

OAS Correspondence to Congressional Committees

- **OAS Letters and Resolution
to U.S. Senate and House
Finance Committees**
- **Encouraged states to submit
additional letters in support
of the budget**

Source Material Exemptions

Initiating Events

- Shipment of wastes containing source material to unlicensed sites
- NRC Policy that exemptions includes disposal
- Reevaluation of 10 CFR Part 40 Started in 1992
- Exempt concentrations vs. release for unrestricted use
- Contaminated facilities found by Colorado:

Colorado/OAS Petition for Rulemaking

- Worker protection not required
- Facility contamination control
- Need to restrict the exemption in 10 CFR 40.22(b)

10 CFR 40.13(a) Exemptions

- Needs to be reevaluated to conform to the current standards for protection against radiation
- Exemption in rule since 1947 based on low impact assumption and protection of common defense and security
- Inconsistency with decommissioning standards
- Currently 10 CFR 40.13(a) exempts source material that is less than 0.05% by weight

10 CFR 40.13(a) Exemptions (Continued)

- For uranium this is 339 pCi/g for thorium this is 116 pCi/g
- Uranium mill cleanup criteria = 30 pCi/g uranium, 5/15 pCi/g Ra
- 10 CFR Part 20 revisions in 1991 decreased the values for permissible concentrations in air and water for uranium and thorium
- Reevaluation needs to use latest biological data and dose calculation methodology

Disposal Issues for all Unimportant Quantities of Source Material

- 40.13 (a), (b), (c) need to resolve disposal issues
- Aircraft engine parts containing nickel-thoria alloys 10 CFR 40.13(c)(8)
- Thorium alloys containing tungsten or magnesium under 10 CFR 40.13(c)(d)
- Need consistent rule that can be understood by the general user, dealers, and scrap processors

Is it NORM?

- NRC and EPA need to be consistent in regulatory requirements
- Radiation risk should be the basis for regulation
- FUSRAP - The missed but not forgotten atomic legacy
- States forced to deal with the problem

EXTERNAL REGULATION OF THE DEPARTMENT OF ENERGY FACILITIES

Edgar D. Bailey, PE, CHP
California Radiologic Health Branch

External Regulation Pilot Projects

- Lawrence Berkeley National Laboratory
- Oak Ridge National Laboratory (LBNL)
Radiochemical Engineering Development
Center (ORNL/REDC)
- Savannah River Site Receiving Basin for
Offsite Fuels (SRS/RBOF)

CALIFORNIA DOE SITES

- Lawrence Berkeley National Laboratory
- Lawrence Livermore National Laboratory
- Sandia National Laboratories/California
- Stanford Linear Accelerator
- Laboratory for Energy-Related Health Research
- Energy Technology Engineering Center
- Fusion Research Center

With apologies to Gertrude Stein:

- ***“A rem is a rem is a rem.”***

- *Attributed to Mike Mobley and others.*



Berkeley Lab



- ⇒ Founded in 1931 - oldest national laboratory
- ⇒ Named after Ernest Orlando Lawrence,
inventor of the cyclotron
- ⇒ Nine Nobel prizes
- ⇒ Unclassified research in basic energy, earth,
nuclear, life , & computing sciences
- ⇒ Managed and operated by the University of
California for the U.S. Department of Energy

ERNEST ORLANDO LAWRENCE BERKELEY NATIONAL LABORATORY

- Presently Employs Over 3, 200 People
- Occupies 134 Acres in Berkeley Hills
Surrounded by UC Berkeley
- Elevation 500 to 1,000 Feet
- Little or No Weapons Related Work

University of California



The Regents of the University of California

President of the University
Richard Atkinson

Berkeley	—	San Francisco
Davis	—	San Diego
Irvine	—	Santa Barbara
Los Angeles	—	Santa Cruz
Riverside	—	

Lawrence Berkeley National Laboratory	Lawrence Livermore National Laboratory	Los Alamos National Laboratory
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LAWRENCE BERKELEY NATIONAL LABORATORY

**ERNEST ORLANDO LAWRENCE
BERKELEY NATIONAL LABORATORY**

- Advance Light Source (Synchrotron)
- Bevalac/Bevatron (Not Operating)
- Research Medicine (PET Accelerator)
- Heavy Ion Accelerator (Not Operating)
- National Tritium Labeling Facility
- Hazardous Waste Handling Facility
- 88-inch Cyclotron

**U.S. Department of Energy
A self-regulated safety program**

- 1946 Atomic Energy Act established the AEC**
- 1954 AEA amended to give AEC broad powers for peaceful purposes**
- 1962 Kentucky was the first AEC Agreement State**
- 1974 Energy Reorganization Act of 1974 split AEC into ERDA and created US NRC on January 1, 1975**
- 1977 DOE created as cabinet level agency replacing ERDA**

External Regulation of DOE

1990 Clean Act Amendments extended
NESHAPS (air emission stds.) to DOE sites

1992 Federal Facilities Compliance Act placed DOE
sites under RCRA (hazardous waste disposal)

Existing NRC/Agreement State oversight:

Gaseous Diffusion Plants - Paducah KY, Portsmouth OH
Spent Fuel Storage - Ft. St. Vrain CO
Offsite lab, Battelle PNNL - Richland WA

1994-9 Legislation introduced in the House to place DOE
national labs under US NRC and OSHA

Drivers for External Regulation

Safety	Uniform standards consistent with industry
Credibility	Remove conflict of interest of self regulation; open to external scrutiny
Stability	Predictable, resistant to political change

Ahearn Committee, 1995
Report of Advisory Committee on External Regulation of DOE Nuclear Safety

**ERNEST ORLANDO LAWRENCE
BERKELEY NATIONAL LABORATORY**

- Work Smart Standards Program
- Copper Release Study/Concurrence
- DOE AIP Program
- Tritium Issues Work Group
- External Regulation Pilot (Phase I)
- Eucalyptus Release Study/Concurrence
- External Regulation Pilot (Phase II)

EXTERNAL REGULATION

- 1995 Legislation Introduced in Congress
- Secretary O'Leary Convenes Advisory Committee on External Regulation
- 12/95 ACER Recommendations Published
- Secretary O'Leary Appoints Working Group on External Regulation
- 12/96 WGER Report Published

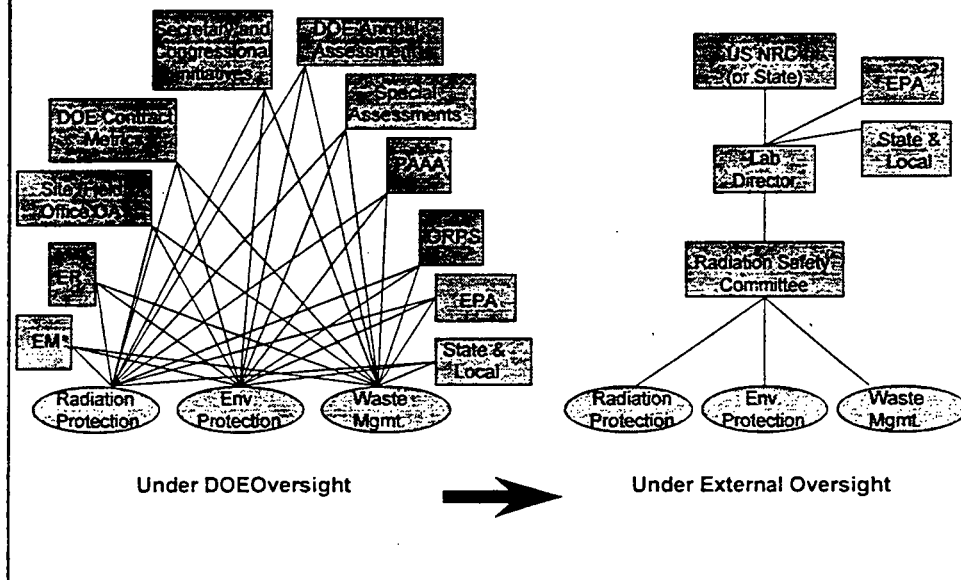
External Regulation cont.

- 9/97 DOE/NRC/RHB Begin Work on Pilot Study
- LBNL Volunteered and Was Selected as First Pilot Project
- 11/97 DOE/NRC Sign MOU for Pilot Project
- Draft Report on Pilot Study Issued

External Regulation cont.

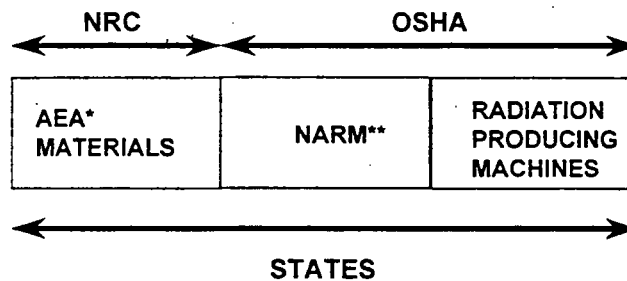
- Congress Instructs Increased Involvement
- Phase II of Pilot Study

More Effective Radiation Safety Management



Jurisdictional issues

Federal Facilities



Non-Federal Facilities

* AEA: Atomic Energy Act
 **NARM: Naturally occurring and Accelerator-produced Radioactive Material

External Regulation of DOE

In the news ...

- **“Essentially all aspects of safety at DOE's nuclear facilities and sites should be externally regulated.”**

Advisory Committee on External Regulation of Department of Energy Nuclear Safety, Dr. John F. Ahern, 12-95

- **“The Department of Energy (DOE) will submit legislation to transfer oversight of nuclear safety to the Nuclear Regulatory Commission, Secretary of Energy Hazel R. O'Leary announced today.”** DOE press release, 12-20-96

External Regulation of DOE

In the news ...

- **“Mr. Chairman, the Department is ready to move forward now to work with you and others to develop a path forward to externally regulate single purpose Energy Research laboratories.”** Acting Secretary Betsy Moler before the House Science Committee, 5/21/98
- **“many of the potential benefits that we expected to see from external regulation have not been demonstrated, and appear to be outweighed by associated costs and difficulties raised in the pilot projects.”** Energy Secretary Bill Richardson, letter to Rep. Ron Packard, 2/19/99

“LBNL VIEWS...”

- “LBNL agrees with the DOE Team preference that LBNL should be regulated by the same regulators as private industry and academia. LBNL believes that there would be a smooth and seamless transition to external regulation if the regulator was the State of California.”

“LBNL VIEWS...”

- “LBNL considers that the benefits of external regulation are strongly dependent on the licensing model. LBNL believes that the only license model that represents a clean break from DOE’s self-regulation is the model in which UC-LBNL is licensed directly by the NRC or the State.”

ISSUES

- REGULATOR(S):
 - NUCLEAR REGULATORY COMMISSION
 - OCCUPATIONAL HEALTH & SAFETY ADMIN.
 - CAL RADIOLOGIC HEALTH BRANCH
 - CAL OHSA

ISSUES cont.

- WHO WOULD BE THE LICENSEE?
 - U. S. Department of Energy
 - The University of California
 - Lawrence Berkeley National Laboratory

NUREG-1708

ONE HUGE
DISAPPOINTMENT!

“WITH RESPECT TO STATE
REGULATION OF DOE FACILITIES,
SOVEREIGN IMMUNITY SHOULD NOT
BE WAIVED AND THE STATES SHOULD
NOT REGULATE DOE FACILITIES.”

CONTRADICTIONS

- This was not the conclusion of the LBNL site team from NRC.
- This was not the conclusion of the DOE Oakland Operations.
- This was not the conclusion of LBNL.
- This was not the conclusion of the State of California.

Whose conclusion was it?

“I DON’T WANT TO REPLACE
ONE REGULATOR IN
WASHINGTON WITH
ANOTHER REGULATOR IN
WASHINGTON.”

OAS RECOMMENDS:

- That the NRC aggressively seek regulatory authority over DOE and its contractor facilities.
- That the NRC include the regulation of DOE contractor-operated facilities in the Agreement State program.