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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

1992 ALL AGREEMENT STATES MEETING

Sheraton Baltimore North Hotel
Ballroom C
903 Dulaney Valley Road
Towson, Maryland 21204

Tuesday, October 27, 1992

The above-entitled meeting commenced, pursuant to
notice, at 8:00 a.m.

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1 ATTENDANCE:

2
3 CARL KAMMERER, NRC/OSP
4 VANDY MILLER, NRC/OSP
5 LLOYD BOLLING, NRC/OSP
6 STUART LEVIN, PENNSYLVANIA
7 TERRY STRONG, WASHINGTON
8 ROLAND FLETCHER, MARYLAND
9 STAN MARSHALL, NEVADA
10 DONNA ROSS, NEW YORK
11 ROBERT DODA, NRC/RSAO REGION IV
12 AUBREY GODWIN, ARIZONA
13 JAMES LYNCH, NRC/RSAO REGION III
14 JOEL LUBENAU, NRC/COMMISSIONER DEPLANQUE'S OFFICE
15 HAROLD BORCHERT, NEBRASKA
16 CARL TRUMP, MARYLAND
17 RAY PARIS, OREGON
18 ROBIN HADEN, NORTH CAROLINA
19 ALAN JACOBSON, MARYLAND
20 TOM FERGUSON, MARYLAND
21 RICHARD RATLIFF, TEXAS
22 WILLIAM MORRIS, US NAVY/NAVSEADET RASO
23 C.D. RAO, TEXAS
24 MICHAEL HENRY, LOUISIANA
25 BOB KULIKOWSKI, NEW YORK

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1 ATTENDANCE [continued]:

2

3

BOB QUILLIN, COLORADO

4

CYNTHIA JONES, NRC/NMSS

5

MARIA LOPEZ-LOTIN, NRC/OSP

6

CHARLES FLYNN, MARYLAND

7

PAUL PERZYNSKI, MARYLAND

8

KATHLEEN SCHNEIDER, NRC/OSP

9

FRANK KASPER, MARYLAND

10

DON FLATER, IOWA

11

EDDIE FUENTE, MISSISSIPPI

12

BILL FLOYD, NEW MEXICO

13

TERRY FRAZEE, WASHINGTON

14

BILL KEMP, OKLAHOMA

15

VICKI JEFFS, KENTUCKY

16

JACK HORNOR, NRC/RSO REGION V

17

WILLIAM WRIGHT, ARIZONA

18

RUTH McBURNEY, TEXAS

19

WAYNE KERR, ILLINOIS

20

VIRGIL AUTRY, SOUTH CAROLINA

21

SHELLY ROBINSON, RHODE ISLAND

22

LARRY ANDERSON, UTAH

23

RICK KELLEY, ARIZONA

24

THOMAS HILL, GEORGIA

25

CHARLES WEST, TENNESSEE

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1 ATTENDANCE [continued]:

2
3 DIANE TEFFT, NEW HAMPSHIRE
4 BOB HALLISEY, MASSACHUSETTS
5 BOB NELSON, MARYLAND
6 DANA MOUNT, NORTH DAKOTA
7 ED BAILEY, CALIFORNIA
8 CLOUGH TOPPAN, MAINE
9 JOHN McGRATH, NRC/RSO REGION I
10 DAVID CASE, US AIR FORCE/OSG
11 GEORGE KASYK, NEW YORK
12 KATHY ALLEN, ILLINOIS
13 PAUL MERGES, NEW YORK
14 KIRK WHATLEY, ALABAMA
15 CHARLES TEDFORD, ALASKA
16 CARDELIA MAUPIN, NRC/OSP
17 NATHANIEL OWRUTSKY, MARYLAND
18 CAROL HARRIS, NRC/OSP
19 GRETA DICUS, ARIZONA
20 RAY MANLEY, MARYLAND
21 STEVE COLLINS, ILLINOIS
22 HALL BOHLINGER, LOUISIANA
23 DENNIS SOLLENBERGER, NRC/OSP
24 JAMES MYERS, NRC/OSP
25 DAVID ZALOUDEK, LOUISIANA

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1 ATTENDANCE [continued]:

2

3

MARY CLARK, FLORIDA

4

RICHARD WOODRUFF, NRC/RSAO REGION II

5

BILL BONTA, MARYLAND

6

RICHARD BLANTON, NRC/OSP

7

RITA ALDRICH, NEW YORK

8

JIM LIEBERMAN, NRC/OE

9

JOHN GLENN, NRC/NMSS

10

LARRY CAMPER, NRC/NMSS

11

JOHN COOK, NRC/NMSS

12

WILLIAM BRACH, NRC/NMSS

13

EDWARD O'DONNELL, NRC/RES

14

WILLIAM LAHS, NRC/NMSS

15

MEG LUSARDI, NRC/NMSS

16

MYRON POLLYCOBE, NRC/NMSS

17

GERALD W. ALLEN, KANSAS

18

KEN LAMBERG, NRC/REGION III

19

20

21

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TABLE OF CONTENTS

1		
2	WELCOME AND INTRODUCTION	127
3	COMPLIANCE AND ENFORCEMENT PANEL	127
4	OPEN ENFORCEMENT CONFERENCE	128
5	AGREEMENT STATE PERSPECTIVE ON ENFORCEMENT	138
6	RECIPROCITY	150
7	ALARMING RATE METERS-EXPERIENCE AND PROBLEMS	167
8	ALLEGATIONS	177
9	REGULATIONS PANEL	190
10	RADIOGRAPHER CERTIFICATION	191
11	MEDICAL QM RULE	197
12	PART 20 PROVISIONS-STATUS OF SSR PART D	223
13	STATE EXPERIENCE IN ADOPTING PART 20	246
14	DEALING WITH AN UNDECLARED PREGNANT WORKER	160
15	MATERIALS REGULATION	272
16	GENERAL LICENSE TRACKING SYSTEM	274
17	TRANSPORTATION	289
18	LOW LEVEL WASTE MANAGEMENT PANEL	301
19	EXTENDED STORAGE OF LOW LEVEL RADIOACTIVE WASTE	304
20	ANION RETENTION IN SOIL	315
21	GTCC WASTES AND DOE	324
22	DEC/DOH WORKING RELATIONSHIP IN THE REVIEW	
23	OF LICENSE APPLICATION	335
24	TRENCH COVERS - BIOENGINEERING	355
25		

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P R O C E E D I N G S

[8:00 a.m.]

WELCOME AND INTRODUCTION

MR. MILLER: Good morning. The second general session of the All Agreement States meeting will now come to order. We have our standing panel here this morning and the Chair of this panel needs no introduction.

Aubrey Godwin is the former Radiation Program Director for the great State of Alabama and he recently moved from the great State of Alabama to the great State of Arizona. He was the first one to come up yesterday and state that he thinks the next meeting should be in his state, and, from what he said to us, it looks like we might be going to the west again. Of course, we'll know that later, however.

Now, this morning, before he comes, I want to also mention his important role in the CRCPD. He is the new Chairman there. He's had his first big meeting, got off to a good start. So he has ran to get here this morning to head this general session on compliance and enforcement.

Aubrey?

COMPLIANCE AND ENFORCEMENT PANEL

MR. GODWIN: Thank you, Vandy. One of the things

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1 that I've been asked about is who is my photographer. He's
2 a real good man and he really knows how to work these
3 pictures up, takes out most of the gray hair, and I really
4 like him. Suffice it to say that some years ago that
5 picture was made, but I still like it. I mean, if the
6 politicians can do it, why can't I? I just don't understand
7 why not.

8 MR. FUENTE: When are you going to be on TV
9 commercials?

10 MR. GODWIN: Well, I have to do a little cosmetic
11 work there, I guess. Our first speaker this morning is
12 James Lieberman, Director of the Office of Enforcement of
13 the Nuclear Regulatory Commission. He will be talking about
14 the Open Enforcement Conference Program that they're now
15 trying out with the Nuclear Regulatory Commission.

16 Jim?

17

18

OPEN ENFORCEMENT CONFERENCE

19

20 MR. LIEBERMAN: Thank you, Aubrey.

21 [Slide.]

22 MR. LIEBERMAN: I appreciate the opportunity to be
23 here today to discuss the Commission's trial program on open
24 enforcement conferences. The NRC is moving towards a more
25 open environment. We want the public to know what we do and

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1 how we do it.

2 In that regard, meetings between licensees or
3 applicants with the staff on licensing matters have long
4 been open. However, while inspection findings and resulting
5 enforcement actions have been publicly available, the
6 enforcement conference by the Commission's enforcement
7 policy is not normally open to public observation.

8 Thus, some may have the impression that there's a
9 cloud of suspicion over NRC's dealings with licensees at the
10 stage between the inspection and the enforcement action.
11 Some may believe that these conferences are where sanctions
12 are negotiated and deals are cut.

13 These conferences are not negotiating sessions,
14 but, rather, meetings which demonstrate a healthy arms-
15 length relationship between the regulators and regulated.
16 These are not meetings where licensees frequently desire to
17 return. In the staff's view, these meetings are one of the
18 most effective parts of the regulatory process.

19 These conferences are where management of
20 licensees and the staff sit face-to-face and discuss
21 potential violations of significance, their root causes, and
22 the need for lasting corrective actions.

23 Opening these meetings may serve to increase the
24 credibility of the regulatory process which will benefit
25 both the NRC and the regulated industry. However, at the

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1 same time, there's a concern that opening meetings may
2 result in licensees being more formal, defensive, and less
3 candid, thereby adversely affecting the effectiveness of
4 this important regulatory tool.

5 Therefore, the Commission has embarked on a two-
6 year trial program to examine the advantages and
7 disadvantages of opening enforcement conferences. It is
8 expected that these conferences would normally be held in
9 the regional offices, as with current practice.

10 [Slide.]

11 MR. LIEBERMAN: During this trial period, we will
12 monitor the impact of opening conferences and consider the
13 four factors noted in the slide. As part of the monitoring
14 process, there will be comment sheets available at each
15 conference for observers to provide comments to us.

16 The first factor that we'll be looking at during
17 this monitoring process is whether the fact that the
18 conference was open impacted NRC's ability to conduct a
19 meaningful conference and implement the NRC's enforcement
20 program.

21 Here we are looking at whether the conferences are
22 more difficult to schedule, resulting in delay of the
23 process, or whether open conferences are disruptive of the
24 purposes of the conferences.

25 The second factor and probably the most important

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1 factor is whether the open conference impacted the
2 licensee's participation in the conference. Here we are
3 looking at whether the licensee will be reluctant to address
4 root causes, management failures, admit violations and
5 describe corrective actions. Will licensees decline to
6 answer questions, seeking to respond in writing and not
7 volunteer information?

8 In essence, will licensees turn this into a more
9 formal meeting conducted by lawyers and only answering
10 questions asked?

11 The third factor is whether the NRC expended a
12 significant amount of resources in making the conference
13 public. Here we are looking at the issue of space and cost
14 and getting more space.

15 The fourth factor is extent of public interest in
16 opening the conference. Here we're looking at whether the
17 public and media attended the conference. Some licensees
18 have already commented on the concept of open conferences,
19 highlighting the potential for increased formality, stifling
20 candor and free flow of information.

21 Time will tell whether these concerns are valid.
22 We recognize that opening conferences may require that the
23 staff be more persistent and demanding in our questions.
24 We'll do our utmost to assure the conferences will continue
25 to be an effective part of the regulatory process.

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1 I have had the expectation that licensees will
2 also continue to participate in conferences as they have in
3 the past, being generally candid, frank and volunteering
4 information. I would note that we have had eight open
5 conferences to date under the policy shown in the next
6 slide.

7 [Slide.]

8 MR. LIEBERMAN: Prior to the policy, we had an
9 open conference of Sequoyah Fields. In my view, the fact
10 that these conferences were open and with members of the
11 public and media present did not impact the formality or
12 candor of the conferences.

13 However, we had not had a conference with large
14 public attendance. The maximum attendance to date has been
15 15 members of the public.

16 [Slide.]

17 MR. LIEBERMAN: Turning now to the next slide, our
18 selection criteria. Our goal is to open up 25 percent of
19 the conferences, with conferences conducted in each regional
20 office with a variety of types of licensees for a two-year
21 trial period. To avoid the appearance of bias that a
22 licensee is being singled out to have an open conference, my
23 office will select every fourth conference involving one of
24 three categories of licensees.

25 These are operating reactors, hospitals and other

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1 licensees. This should be a somewhat random selection. In
2 addition, conferences involving issues associated with
3 ongoing adjudication with intervention will also be open.

4 [Slide.]

5 MR. LIEBERMAN: There are six exceptions from the
6 policy of open conferences. These relate primarily to
7 ongoing actions against individuals, discussions of
8 safeguards, proprietary or privacy information, or
9 administrative convenience, such as having a telephone
10 enforcement conference.

11 Note this flexibility to close a conference for
12 good cause with the approval of the Executive Director for
13 Operations. However, at this point, it's not clear to me
14 what basis we will use to close a meeting for other than the
15 listed exceptions. If we want to open an otherwise closed
16 meeting, we will need to consult with the Commission and get
17 their approval.

18 [Slide.]

19 MR. LIEBERMAN: As noted in the next slide,
20 licensees will be notified in advance that the conference
21 will be open for public observation. We tend to normally
22 provide at least ten working days notice to the public for
23 open meetings.

24 There's an 800 number, 800-952-9674, that people
25 may call in on to determine what meetings are open. TV

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1 cameras and tape recordings will be allowed. The NRC will
2 tape conferences if others tape the conferences.

3 Observers will be reminded, both orally during the
4 conference and in writing by handouts, as noted in the
5 slide.

6 [Slide.]

7 MR. LIEBERMAN: That the conference is open for
8 public observation, not participation. Second, the apparent
9 violations discussed at the conference are subject to
10 further review and maybe subject to change. Three, the
11 occurrence of the conference does not mean the NRC has
12 decided that a violation has occurred or that enforcement
13 action will, in fact, be taken. Four, the statements and
14 views of the staff or silence in response to a licensee's
15 position should not be taken as an NRC position or
16 acceptance of the licensee's views.

17 Let me close the subject of opening enforcement
18 conferences by noting it is an opportunity for the public to
19 gain a better understanding of our regulatory process and
20 should increase the credibility of both NRC and licensees by
21 demonstrating that we are all interested in identifying
22 issues and taking advantage of lessons learned from mistakes
23 by developing lasting corrective actions.

24 Before I sit down, I would like to bring to your
25 attention another enforcement issue that's not on the

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1 agenda. This is the issue of discrimination of individuals
2 for raising safety issues.

3 You may be aware that Section 210 of the Energy
4 Reorganization Act has had a prohibition against such
5 discrimination by Commission licensees and contractors of
6 Commission licensees for some time. That section also
7 established a complaint process for whistleblowers which
8 provides for investigations by the United States Department
9 of Labor and a forum at the Department of Labor to have
10 complaints adjudicated.

11 Just this past Saturday, President Bush signed
12 into law the Energy Policy Act of 1992, which included a
13 number of amendments to Section 210. One of them may be
14 important to you. The amendment in issue redefined the term
15 "employer" to include an agreement state licensee, as well
16 as a Commission licensee. This may mean that employees of
17 your licensees can complain now to the United States
18 Department of Labor if your licensees discriminate.

19 In addition, Section 210 has been renumbered to
20 Section 211. I have some copies of the amendments here if
21 you desire to get a copy. Obviously these changes will need
22 to be studied to determine their scope and impact.

23 Thank you.

24 MR. GODWIN: Do we have any quick questions?

25 MR. MERGES: Paul Merges from New York. Do you

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1 discuss fines at these open conferences and the level of
2 fines and do your attorneys negotiate fines like ours do?

3 MR. LIEBERMAN: No. We do not negotiate fines.
4 At the enforcement conference, we present -- usually the
5 inspector or the section chief involved presents the factual
6 findings, describes the apparent violations. We ask the
7 licensee to either agree or disagree with those facts and
8 violations, explain why if they disagree.

9 We focus on corrective action. We focus on safety
10 significance. But we don't focus on severity levels because
11 under our enforcement policy, we have five severity levels.
12 We don't discuss that, nor do we discuss potential
13 sanctions, other than saying we will consider the
14 information presented in the conference in determining
15 enforcement action.

16 MR. MERGES: Thank you.

17 MR. LIEBERMAN: We then propose the sanction in
18 writing and the licensee can respond in writing, but we
19 never -- never is a strong term -- but almost never sit down
20 with a licensee and discuss are you willing to pay X dollars
21 for this or that.

22 After the conference, we issue the document in
23 writing. If we meet with a licensee, discuss an enforcement
24 action, we do it in a transcribed meeting. The only time we
25 may negotiate a sanction is after we've ordered the payment

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1 of civil penalty or ordered the suspension or whatever and
2 the licensee asks for a hearing. Then in the settlement
3 process or the hearing process, we might negotiate a
4 sanction.

5 MR. MERGES: Thank you.

6 MR. FLETCHER: Roland Fletcher, Maryland. How
7 would you handle a situation where an individual who has
8 been responsible, at least according to the company, for a
9 violation, that individual is terminated, and when the
10 enforcement conference is to be held, the individual wants
11 to be part of that conference to defend himself?

12 MR. LIEBERMAN: Normally, our action is against
13 the company. More recently, we have asked the company to
14 bring employees who have had a significant role in the
15 violation to come to the conference.

16 If the employee's interest is different from the
17 company's interest, we will sometimes have a separate
18 conference with the employee. But if we don't want the
19 employee to come and the licensee doesn't want the employee
20 to come, right now, since most conferences are closed, it
21 would be just between us and the licensee.

22 MR. FLETCHER: Thank you.

23 MR. GODWIN: I see no great rush to the
24 microphones. Next, we have -- I don't think it would be a
25 response, but a discussion of how the agreement states take

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1 their enforcement actions, by Ed Bailey from California, who
2 is the Director of the California program. Ed?

3
4 AGREEMENT STATE PERSPECTIVE
5 ON ENFORCEMENT
6

7 MR. BAILEY: Aubrey, you're the only one with the
8 audacity to put your high school senior picture on the front
9 of the newsletter. What I'm going to propose is that next
10 year we all bring a baby picture and we'll have a contest
11 and the one who guesses the most gets some sort of prize.

12 MR. GODWIN: I'm a trend setter.

13 MR. BAILEY: You are. First of all, I guess my
14 talk is really not going to represent what all the agreement
15 states do, since I didn't take a survey. What I'm going to
16 discuss are some of the ways that I know that agreement
17 states have taken enforcement actions, and perhaps it will
18 be tainted a little bit or perhaps a whole lot by my
19 personal views, primarily that the penalty ought to fit the
20 crime and not simply penalty for penalty's sake.

21 I think that I was probably asked to do this based
22 upon a letter that was composed by members of my staff and
23 sent to Vandy, that I signed. I want to apologize in public
24 to Vandy. We wrote the letter, signed it, mailed it. We
25 were then asked to fax a copy to the regional office, which

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1 we did, and we waited until the next day to fax Vandy one
2 and because of that, I understand it caused a very
3 embarrassing situation at headquarters, and I do apologize
4 to Vandy for that.

5 In the future, if I fax one to anybody, I'll fax
6 one to the addressee.

7 [Slide.]

8 MR. BAILEY: I think first item up there, notice
9 of violation, we're all familiar with. We all issue them.
10 Basically, I think it's a letter saying, here, you did this
11 wrong and let us know what you're going to do to correct it
12 in thirty days. There may be some variations in the number
13 of days and that sort of thing.

14 [Slide.]

15 MR. BAILEY: Then we go to sometimes enforcement
16 conferences and those are where we begin considering them to
17 be escalated enforcement actions. Unlike the NRC, we very
18 definitely, in California, consider them negotiating
19 sessions. Not necessarily negotiations on how much a
20 penalty will be or something, but negotiations on what we
21 can get a licensee to commit to that we may not be able to
22 require them to do.

23 Quite often, those involve the company getting
24 outside health physics support or buying new equipment or so
25 forth. Often, the lawyers are present and, as a rule of

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1 thumb, if the licensee decides to bring in a lawyer, we will
2 have a lawyer at the conference.

3 We hold them either at our headquarters office in
4 Sacramento or at our regional offices throughout the state.

5 [Slide.]

6 MR. BAILEY: You all are awake. I was wondering.
7 It's 5:00 at home. We have instituted recently,
8 particularly in our x-ray program and specifically in the
9 mammography program, what we call immediate corrective
10 action notice. This is a document that we issue to a
11 facility where they agree at the time of the inspection to
12 stop their operation.

13 It's a voluntary cease and desist, if you want to
14 say it that way. We found those very effective,
15 particularly in mammography facilities where the quality of
16 the films are below what are required by our regulations.

17 Basically, the registrant or licensee agrees to
18 stop what they're doing until they get the situation
19 corrected and we say okay, good deal, let us know when you
20 get it corrected and then we will allow you to continue.

21 Above that, we have a cease and desist order. I
22 think probably common among all states, in order to issue a
23 cease and desist order, you must declare an emergency or
24 have an emergency. You can't just say, hey, I don't like
25 what you're doing, stop it, don't do it anymore. Those are

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1 all issued out of our Sacramento office.

2 Similar to that is an impounding order where we
3 actually physically take possession of the radioactive
4 material or impound it in place. We have recently impounded
5 1,500 milligrams of radium and we impounded that in place.
6 We really didn't have anybody that wanted to take it back to
7 their house.

8 So we impounded it in place. We have now got it
9 packaged and shipped to Nevada and we appreciate Beatty
10 taking some of our radium. We worked very rapidly to get
11 that done. It cost the state over \$12,000 and, at that, we
12 got a real bargain because it's normally about \$35 a
13 milligram for radium. We will discuss later on what we're
14 doing in that regard.

15 The next level and one that we don't have in
16 California are administrative penalties. Those are commonly
17 what we see issued by NRC, where, by some magical
18 manipulation of the mind and figures, you come up with a
19 number that you feel that a licensee should pay for their
20 wrongdoing.

21 We had a bill in the legislature this session for
22 administrative penalties and the California Medical
23 Association was successful in killing that bill. The reason
24 they killed it and the arguments that they presented to the
25 legislature were twofold.

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1 One had to do basically with the way the rules and
2 regulations were going with regard to medical uses, and
3 particularly the items related to QA, and also the
4 capriciousness with which administrative penalties, in their
5 opinion, had been administered by other agencies.

6 So they were very convincing to the legislature.
7 Interestingly enough, our Food and Drug people were able to
8 get their administrative penalties through, which were in
9 the same bill. So there was a little bit of a disconnect
10 there on their logic.

11 We do have civil penalties and I think, like most
12 states, you have to go to court to get civil penalties. In
13 California, we can either go through the local court system,
14 using the local DA, city attorney, or use the Attorney
15 General of the state. This is probably the most common way
16 that we get penalties.

17 For example, when we filed charges against USC, we
18 went the civil penalty route. It basically resulted in a
19 \$25,000 fine, plus USC setting up a fellowship in health
20 physics for three years, funded at \$25,000 for each of those
21 years. So that amounted to about \$100,000.

22 Following that, there were more violations there
23 and we went back to court and got another \$65,000 in civil
24 penalties. There were also criminal charges filed against
25 them in which they actually -- this is where it got a little

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1 bit out of hand by the local county attorney -- actually
2 wanted to send professors and others associated with the
3 university to jail. They were very blatant, saying we want
4 them to spend time in jail.

5 In other civil penalty cases, we have been able,
6 through the court system, to accomplish things that we would
7 not have been able to do otherwise. Against ICN, a company
8 located in Orange County, we went the civil penalty route
9 and the judge ordered that the company buy computer
10 equipment and radiation counting equipment for our Orange
11 County offices.

12 Normally, the penalties go into general fund or
13 just the regular court fund, but that was an innovative way
14 for the judge to help out the radiation program and, at the
15 same time, provide some penalty to the company for their
16 wrongdoing. Interestingly enough, the founder, CEO,
17 President of ICN resigned recently to become the Prime
18 Minister of Yugoslavia.

19 It's a very interesting company. It also has had,
20 at one time, and may still have Governor Jerry Brown on its
21 Board of Directors. It's also the single largest waste
22 generator in California. So quite a nice company.

23 Criminal penalties, of course, are something that
24 I think all of us reluctantly take. The criminal penalties,
25 my definition of them is that you can send people to jail.

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1 You make them spend time in jail for criminal penalties, and
2 that separates basically the civil penalties from the
3 criminal penalties.

4 In California, our criminal penalties go up to
5 \$250,000 a day per violation, and that has to do with waste,
6 of course, and if the waste happens to cause bodily injury
7 to an individual. So far we have not used that provision.

8 The next one down is revocation suspension, and
9 here we have to have an Administrative Law Judge, we are
10 represented by the Attorney General's office, and we use
11 these for a variety of things. We presently have one
12 licensee that we're going through the procedure of revoking
13 the license and this is after we have already gotten \$25,000
14 in civil penalties.

15 All of these actions can be taken independently or
16 you can combine all of them together and beat the hell out
17 of them. This particular guy probably will have his license
18 revoked. We also use it -- we certify or license nuclear
19 med techs in California. We presently had -- have had a
20 hearing on the nuclear med tech who used the needle that had
21 been formerly used on an HIV-positive patient to do an
22 injection of a second patient. We have had the revocation
23 hearing on that and that is now pending before the
24 Administrative Law Judge.

25 We have another thing that has been tremendously

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1 effective for us, and that's cost of response. Under
2 California law, cities, counties, state agencies and so
3 forth, if they are called to respond to an emergency or
4 incident or something like that, they may seek to recover
5 their actual costs of conducting those operations.

6 We have found in recent days that this has been a
7 very, very effective way to offset spending a lot of time.
8 We recently had an industrial radiography camera that
9 somehow bounced off the truck. I'm sure you've all had that
10 happen. We spent quite a bit of time looking for the thing,
11 only to have it found by the highway cleaning crew.

12 It so happened that there was a curve in the
13 highway and the road was a little rough there from cars and
14 trucks going around the curve. It was a well-known place
15 for things to fall off. So Cal Trans, the highway
16 department, routinely has crews that go along and pick
17 things up. Well, they picked up this camera with a source
18 in it, took it to their scrap heap, and kept it there for
19 about a week before somebody said, well, you know that funny
20 little symbol on there, I think it means something.

21 Meantime, we've got DOE ready to fly and
22 everything else. The cost of that response, we simply wrote
23 a letter to the company saying here's how much it cost us,
24 would you like to pay. They wrote back and said under what
25 authority are you doing this. We said, well, we can go to

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1 court and get you to pay if you want to. They ended up
2 sending us a check for \$8,700, a very, very effective way to
3 do that.

4 Over in the Bay Area recently we've had a similar
5 thing where an over-zealous perhaps city attorney went into
6 a building and tried to make a big scene about some material
7 that had been left there by a company that moved out. It
8 cost us about \$1,200 to go get the material and dispose of
9 it. That money was recovered as our cost.

10 I mentioned the 1,500 milligrams of radium and it
11 has cost us over \$12,000. A little history. The man who
12 ran the radium service company sold it to a friend of his,
13 who promptly died. The widow was essentially left
14 destitute. It was in a rented building. One of the MDs in
15 the state and another entrepreneur decided they could make
16 money off of it, bought into it briefly, claimed they never
17 did.

18 So we are now suing the original owner, the wife,
19 the building owner, and the doctor and the other person to
20 recover the money for that disposal and we're pretty sure
21 we'll be successful.

22 The other thing that we are doing is we are
23 presently engaging in some undercover operations, and this
24 begins to get really pretty interesting when you try to find
25 wrongdoers by getting into their system. California is a

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1 hot bed of legal activities, so there are several areas that
2 we're looking at that may possibly may be able to bring the
3 people to justice by having some people go undercover.

4 I mentioned earlier the letter and one of the
5 things that has occurred, and I think I sent a copy of the
6 letter to all of you, is that we feel that there has been an
7 inordinate amount of time put in on reciprocity inspections,
8 but only certain reciprocity inspections. And those located
9 closer to the NRC regional offices are perhaps hit harder
10 than other places.

11 I would point out, which was not pointed out in
12 the letter, that none of the violations resulted from an
13 overexposure or from a loss of material. So I and my staff
14 have some difficulty in justifying the civil penalties that
15 were levied in the cases in California. Since they were all
16 against California industrial radiographers, we felt pretty
17 -- well, I won't say picked on -- that all of a sudden
18 California radiographers within a short distance of the
19 regional office were being inspected when they went into
20 Federal facilities under reciprocity, and then there was a
21 lot of time being spent.

22 I'd be happy to answer any questions, if I can.

23 MR. MERGES: I hate to be up all the time. You
24 brought up an issue that I think is very important. You
25 went after -- I'm sorry. Paul Merges from New York, again.

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1 You brought up an issue I think is very important
2 and you said you went after the building owner relative to
3 this radium contamination. We did the same thing in EAD and
4 I really think it's immoral that we're doing it. The legal
5 profession is saying this is legally right to do, but I
6 think we need to remember we are the licensing agencies, we
7 approve a licensee out there, we go out and we inspect these
8 facilities, and many times, for years, we don't find them in
9 non-compliance of anything.

10 A poor building owner rents a place to them,
11 doesn't even know they have radiological sources as part of
12 their process or anything else, and, yet, they get stuck
13 with the liability in the end. I really think it's an
14 immoral act that the state and the Federal Government would
15 go after a building owner that just inadvertantly happened
16 to rent to somebody who was legally licensed to possess
17 material like that.

18 MR. BAILEY: Paul, I basically agree with you. Of
19 course, our lawyers can have a justification for anything
20 and they say that building owner benefitted from that
21 operation. To the side, we have written to the original
22 owner of the radium, who we think perhaps was aware that his
23 friend was near death when he sold the business, and said,
24 you know, we can all avoid a lot of trouble if you'll simply
25 pay for the disposal, because we'll eat him up in lawyers'

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1 fees.

2 It costs a lot of money to be sued by the state or
3 sue the state. Our lawyers are already paid for.

4 MR. MERGES: Okay. But we don't have to live with
5 the lawyer syndrome. They do. When this happened in our
6 case in EAD, I told them right out front, I said you put me
7 up on the stand, I'm going to say this is an immoral act, as
8 far as I'm concerned. They said, well, we're not going to
9 put you on the stand, then. I said, fine, don't put me on
10 the stand because I will say it.

11 I don't think we have to be driven by the legal
12 system totally. We are professionals and we are moral
13 individuals.

14 MR. FLETCHER: Roland Fletcher, Maryland. I
15 didn't want Paul to feel that he was the only one coming up
16 to the mike repeatedly. My question is you didn't mention
17 whether or not you have the option of offering a settlement
18 amount once you establish a civil penalty amount to perhaps
19 keep the lawyers, keep the case out of court.

20 Do you have that option?

21 MR. BAILEY: Yes. Basically, you go with an
22 agreed settlement and that is basically what happened, for
23 instance, in the University of Southern California case. It
24 also happened in the ICN case, where the amounts paid and
25 the things agreed to and so forth were just that,

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1 agreements.

2 MR. FLETCHER: You didn't have to go to court.

3 MR. BAILEY: Well, you go to court and you start
4 talking and then they have one of those delays and then you
5 go outside and really get serious about talking about it,
6 and six months later you come to an agreement or something.

7 MR. FRAZEE: Terry Frazee, State of Washington.
8 The undercover operations, are you using health physicists
9 for that activity? You are?

10 MR. BAILEY: Yes, we are. Thank you.

11 MR. GODWIN: The third presentation, listed as
12 number three, will be a response -- well, maybe -- regarding
13 reciprocity by Jim Lieberman, the Director of the Office of
14 Enforcement, NRC.

15

16

RECIPROCITY

17

18 MR. LIEBERMAN: Let me start by saying I may not
19 be the NRC's expert on reciprocity, but I've become involved
20 in this topic as a result of several enforcement actions.
21 Some of them are the ones that Ed has referred to.

22 Let me start by briefly going over the
23 Commission's reciprocity regulations, found at 10 CFR
24 150.20. This regulation provides that a person who holds a
25 specific license in an agreement state that does not limit

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1 activities to a specific location or installation has a
2 general license to perform the same activity in non-
3 agreement states up to 180 days in a calendar year.

4 There are a number of conditions associated with
5 this general license, two of which I want to highlight.
6 First, Section 20 of Part 150 provides that an agreement
7 state must not only comply with the terms of the specific
8 license issued by the agreement state, but also must comply
9 with certain NRC regulations that are specified in Section
10 20(b) of Part 150. These include Parts 19, 20 and 34.

11 Second, a Form 231 must be submitted to the NRC at
12 least three days in advance of conducting activities,
13 providing certain information concerning the contemplated
14 activity. If three days notice cannot be provided, the
15 Regional Administrator can authorize a shorter notice by the
16 telephone.

17 I should note that a fee of \$600 must be submitted
18 with the 241 form or prior to granting authority by the
19 telephone. The filing of Form 241 is an important
20 regulatory document because it provides NRC with notice that
21 an activity may be occurring that we may need to inspect,
22 or, said another way, without the notice, we can't perform
23 an inspection and ensure the requirements are properly being
24 met and the public being protected.

25 Having that notice may be particularly important

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1 for radiography licensees because of their track record for
2 cutting corners, such as not doing surveys, and surveys is
3 the leading cause for overexposures, as you know. This may
4 be of particular concern if they know we don't know they are
5 in NRC jurisdiction and, thus, won't be inspected.

6 Another reason for not filing a 241 form may be to
7 save the filing fee. Not submitting a fee creates an unfair
8 advantage over NRC licensees, as well as others who submit
9 the Form 241 because they have paid a fee.

10 For these two reasons, during the last major
11 change of the NRC enforcement policy last February, we
12 amended the policy to provide that a failure to submit a 241
13 form may be considered a Severity Level 3 violation. A
14 Severity Level 3 violation is considered for escalated
15 enforcement action normally results in a civil penalty,
16 absent mitigating factors.

17 Responding to Ed's point about the lack of
18 overexposures in some of the cases that he referred to, we
19 don't need an overexposure to have a significant regulatory
20 concern. The fact that someone doesn't do an adequate
21 survey to locate the source, the fact that someone doesn't
22 keep constant control over a source, even though an exposure
23 doesn't occur or a loss of material, that's still of
24 regulatory concern because we're concerned with the
25 potential. We don't want to wait until the incident with

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1 public impact occurs.

2 As an aside, I've noted that many of the agreement
3 states have incorporated aspects of the different versions
4 of the NRC enforcement policy into their enforcement
5 programs. The February version of the policy substantially
6 rewrote it and you might want to consider these revisions
7 for your programs.

8 In any event, as a result of violations of
9 requirements to submit 241 forms being considered for
10 escalated action, more attention has been brought to the
11 issue of reciprocity. There's been a number of cases where
12 the form has not been filed. We find out about these cases
13 either from competitors or from disgruntled or former
14 employees.

15 Some of these failures have resulted in orders.
16 For example, one licensee received an order suspending the
17 general license for an indefinite period. In another case,
18 we required a report from the licensee each week before
19 radiography could be conducted in our jurisdiction. In
20 other cases, we have issued civil penalties and we have
21 issued civil penalties for a number of California licensees.
22 We have also issued civil penalties to licensees of other
23 agreement states.

24 Another frequent violation is the licensee who
25 provides a 241 form and then does not meet NRC requirements.

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1 More specifically, we have had a number of cases where
2 radiography licensees have either not used an alarming rate
3 meter, which is required by 10 CFR 34.33, or not met the
4 requirements for certain types of cameras that are
5 applicable for equipment purchased after January 10, 1992.

6 Both of these are important requirements that may
7 reduce the potential for overexposures. Digressing again
8 from the topic, John Glenn will be discussing alarming rate
9 meters in a moment. But from my perspective, we have not
10 seen an overexposure from any radiographer since this
11 requirement has occurred, with the exception of one
12 radiographer who didn't wear an alarming rate meter.

13 Common stated reasons for licensees operating
14 under reciprocity not meeting our requirements is that they
15 didn't know about them. From my point of view, that's a
16 weak excuse. If I'm going to go fishing in another state, I
17 need a license for that state and I better know what the
18 fishing rules are.

19 If I'm going to drive in another state, I need to
20 know what the rules are. In fact, in submitting a Form 241,
21 the licensee certifies that it has read and understood the
22 requirements. We treat general licensees operating under
23 reciprocity just like our specific licensees. They are
24 subject to enforcement action, including civil penalties and
25 orders if they don't meet our requirements.

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1 Thus, we've issued civil penalties against
2 agreement state licensees not using alarming rate meters.
3 Contrary to the perception of some licensees, our goal is
4 not to maximize the number of civil penalties, but to obtain
5 compliance and improve safety. We have issued information
6 notices and NMSS newsletters to let licensees know of
7 changes to our Part 34 requirements.

8 Some states may pass in information under their
9 licensees, others might not. We've started an effort in
10 some regions and we are extending it to all regions to send
11 a letter out by fax, if possible, to radiographers when they
12 file a 241 form to specifically remind them of alarming rate
13 meter and equipment requirements in the regulations.

14 This should avoid any possible excuse for not
15 knowing what the requirements are. Whether they get that
16 notice or not, we do intend to treat general licensees like
17 our specific licensees. It is their burden, not ours, to
18 know what the requirements are.

19 Another issue that has risen in the area of
20 reciprocity is what must be done to authorize license
21 activities in Federal jurisdiction. There are a number of
22 different types of Federal jurisdiction, such as exclusive
23 jurisdiction, concurrent, partial, or proprietary
24 jurisdiction.

25 Exclusive Federal jurisdiction is when land has

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1 been purchased by the Federal Government and the state has
2 consented to having the Federal Government having exclusive
3 jurisdiction. On such property, a state does not have
4 jurisdiction, notwithstanding the property may be located
5 within an agreement state.

6 Reviewing some licenses from various agreement
7 states, I know that California in its radiography licenses
8 provides that the licensee may perform work at temporary job
9 sites of the licensee in areas not under exclusive Federal
10 jurisdiction throughout the State of California. The
11 licensees of other states I've looked at have been silent on
12 this issue.

13 Part 150 provides for reciprocity in non-agreement
14 states. It does not address reciprocity for work in Federal
15 exclusive jurisdiction within an agreement state. Thus, to
16 be legally correct, only a specific licensee can do work in
17 Federal exclusive jurisdiction. We intend to amend Section
18 150.20 to provide for reciprocity in the future.

19 Meanwhile, we consider filing a Form 241 as a de
20 facto license for work in Federal exclusive jurisdiction.
21 But the real question is how does anyone know whether the
22 property is under Federal exclusive jurisdiction. Our
23 starting point is a memo listing areas issued by Wayne Kerr
24 back in 1978. We recognized that most licensees don't have
25 that memo.

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1 In addition, it's not always a simple task -- I
2 don't know if Wayne still has it. It's not a simple task to
3 find out the type of jurisdiction a piece of Federal
4 property is. Frequently we need to go to the General
5 Counsel's office at the particular agency in Washington to
6 get that information. Thus, we need to consider ways to get
7 the information out to licensees so they'll have sufficient
8 notice.

9 In considering that issue, the question goes as to
10 whether a 241 form was needed for non-governmental license
11 activity on other Federal property in agreement states. The
12 answer to that question is generally no. License activity
13 for other than Federal entities in non-exclusive Federal
14 jurisdiction within an agreement state is generally
15 regulated by the agreement state.

16 However, it is my understanding that some states
17 do not always inspect on Federal property. This may leave a
18 regulatory gap if neither NRC nor the agreement state is
19 inspecting the area. If my understanding is correct, I'm
20 not sure what the solution is to that issue.

21 Our Office of General Counsel has told us we can't
22 establish jurisdiction over Federal property, if we wanted
23 it, by a simple rule change. Clearly, no one wants to
24 renegotiate all the agreements with agreement states to
25 address this issue. Some states might not want to give up

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1 their authority to inspect on Federal property.

2 I bring this issue up only to indicate that this
3 is an area that further attention might be needed to assure
4 that there's not an inspection gap. As we get more ideas on
5 how to handle this issue of oversight on Federal property,
6 I'm sure that Vandy Miller will be contacting you to get
7 your comments.

8 If there are any comments that you might have
9 today, I know we'd be interested in hearing them. That's
10 about all I had to say on reciprocity.

11 MR. TEDFORD: Tedford, Alaska. I think your
12 comments are very encompassing and there are a lot of
13 different perturbations to the problem, if you will.

14 You didn't address agreement state-to-agreement
15 state reciprocity. The bottom line is these people go out
16 and conduct surveys all over the country and the question is
17 how can you come up to assure that they are qualified and
18 that they have a permit to be there, particularly in Alaska.

19 Companies from all over the country come into
20 Alaska. Do they have a permit? Do they have this 241 form?
21 That seems to me to be the answer. Some sort of form that
22 they are authorized to be there.

23 MR. LIEBERMAN: If they're doing work in Alaska
24 and they're an agreement state licensee, they're required to
25 give us notice. Whether they do that or not is another

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1 thing.

2 MR. TEDFORD: That's a good question.

3 MR. LIEBERMAN: But usually we found all over the
4 country, within NRC states, as well, I'm sure, in agreement
5 states, there's enough competitors out there who are looking
6 over the shoulders of their colleagues and they see someone
7 doing something wrong, they let us know.

8 We find an awful lot of violations of the 241
9 issues by competitors. Now, if we find out about it that
10 they purposely did it, that may be a criminal act and we've
11 referred a number of matters to the Department of Justice
12 for purposely not filing a 241. We've also banned agreement
13 state licensees completely from our jurisdiction.

14 MR. TEDFORD: But you asked how to correct his.
15 How you correct it is to have some sort of certificate that
16 they come on-site with that says they are A-okay, because
17 NRC is not going to be up there inspecting every one of
18 these people that come in. The companies should be checking
19 some sort of authorization that they have to come on site,
20 whether it's from an agreement state or whether it's from
21 the NRC, whether it's a Federal facility or whatever it
22 happens to be.

23 This problem goes back even further to the NRC not
24 being aware, if you will, of a lot of activities throughout
25 the country under a different group of licensees, which came

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1 up and actually was discovered up in the northern part of
2 Arizona. The concern became very great, if you will,
3 because these people who were conducting these unauthorized
4 operations with untrained operators, if you will, were also
5 conducting operations and had been conducting operations at
6 reactor sites.

7 So it's a bag of worms and you asked for a way or
8 a solution to correct it. I think the solution is to give
9 these people some sort of authorization that they have to
10 show to the companies or the Federal activities on-site that
11 they are qualified to be there.

12 MR. LIEBERMAN: You mean like the oil refinery or
13 the pipeline company.

14 MR. TEDFORD: That's right, because you cannot
15 come up and inspect them. I can't be up there all the time.
16 They're in there from all over the country.

17 MR. LIEBERMAN: That's a good idea.

18 MR. HILL: Tom Hill from Georgia. I've got a
19 question on filing the 241 form, and memory may be serving
20 me wrong. But if an agreement state licensee in Region II
21 was going to Alaska, as the example here, to do reciprocity
22 work, would they file their 241 form with Region II Regional
23 Office, headquarters or Region V?

24 MR. GLENN: John Glenn. I will answer that
25 question. The way the regulations read, if it is a Region

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1 II licensee who is going to Alaska, which is in our Region
2 V, they would notify the Region II office and the Region II
3 office is responsible then to let Region V know about the
4 activity.

5 MR. HILL: Was that for the agreement state?

6 MR. LIEBERMAN: That's an agreement state within
7 the Region II territory would notify Region II.

8 MR. GLENN: I'm sorry. That was what I meant to
9 say.

10 MR. LIEBERMAN: The issue of how we handle 241s
11 internally, how we inspect them, how frequently we inspect
12 them is an issue of current concern to make sure we have
13 that properly under control.

14 MR. GODWIN: Before we get to our next
15 presentation, I have a couple of questions, too, that sort
16 of plays on this. One of them has to do with how often do
17 you have to file the 241 form? Do you have to file it each
18 time you come in or can you file it once and then are you
19 through paying your \$600?

20 But if you get a 30-day job and you leave for
21 about a week and come back with another 30-day job, do I
22 have to apply again or can I just put down I'm going to be
23 there 180 days and hang in there?

24 MR. GLENN: Because we decided we were going to
25 charge fees for this activity, it required that we issue

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1 additional guidance to the regions in order to assure that
2 the same rules were being applied, they were applied
3 uniformly across the regions and fairly to all licensees.

4 The administrative procedures we have adopted is
5 that within any one calendar year, a formal filing of a 241
6 need only be made once. Now, if that one filing, in fact,
7 includes a description of all the places, locations and
8 times that the licensee -- the agreement state licensee is
9 going to be under NRC jurisdiction, that is all that is
10 required.

11 If that information changes -- in other words,
12 most often, it does change, they get new jobs throughout the
13 year, the regulation provides that the Regional
14 Administrator may waive additional filings of 241 forms.
15 The administrative guidance we have given to the regions is
16 that routinely the Regional Administrator should grant that
17 discretion and essentially what we allow is an updating of
18 the 241 form for the rest of the year.

19 So we are trying to make it so that the fee and
20 the formal filing is done once per calendar year, with
21 information updates at any time that the information
22 describing the activities changes.

23 MR. TRUMP: Excuse me, Aubrey. This is Carl Trump
24 from Maryland. A question to you, John. It seems like the
25 NRC is really starting to tighten up on reciprocity over the

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1 last couple of years than ever before.

2 I know speaking for Maryland and probably other
3 agreement states, as well, we have a little different
4 procedure perhaps than you have in requiring licensing,
5 license in our hands and training procedures, certification
6 of operators not only in radiography, but gauges, as well.
7 Mainly, they're the two.

8 When you say send in a 241 form, that's all you
9 require? Because when we go out and do an inspection, my
10 staff, they always ask the licensees are you -- how far do
11 your travels take you outside the boundaries of Maryland,
12 and they say, yes, of course, Maryland is surrounded,
13 unique, all-NRC territory.

14 Sort of some do and some don't. Some have even
15 called NRC while we're there because they'd have a crew up
16 there in your area somewhere. They kind of sway the truth a
17 little bit and say we've been up there -- we were planning
18 to go up there this weekend or something like that, and a
19 phone call seems to take care of it.

20 But I was just wondering, I don't know the full
21 procedure and I haven't talked with either John McGrath, who
22 is our liaison from Region I, really what is required for
23 Maryland licensees or any agreement licensees to submit
24 material for a license and all you need is a 241 form.

25 MR. GLENN: The formal filing of the 241 is to be

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1 accompanied with four copies of the agreement state license.
2 So we should, in fact, have in our hands both the
3 authorization of the license and the restrictions of the
4 license when that activity is performed.

5 There is a provision that, again, we may waive the
6 paper filing if someone calls us up and says, hey, I just
7 got this emergency call, they want me up there tomorrow
8 morning, I don't have time to get you the copies, that we
9 can waive the filing requirement provided they follow up
10 with that information.

11 We may still show up for an inspection the next
12 day. I think charging fees has, indeed, caused us more
13 attention in this area of reciprocity than in previous
14 years. Mr. Lieberman mentioned one item that is doing it,
15 and that is that NRC licensees are paying very steep fees
16 nowadays for the right to conduct radiography within NRC's
17 jurisdiction. When they determine that agreement state
18 licensees are coming in, want to make sure that they pay at
19 least the \$650 reciprocity fee.

20 So the number of allegations about agreement state
21 licensees operating under NRC jurisdiction without operation
22 has gone up and we've had more inspections, more
23 investigations because of that.

24 Also, I think the tightening up of the procedures
25 for tracking, documenting 241 forms has resulted in the

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1 regions paying more attention to the process and, in fact,
2 they are doing more reciprocity inspections today.

3 MR. GODWIN: Just one further observation before I
4 get to you, Ed. Another group that does a lot of
5 reciprocity work and was very chronic in failing to notify
6 us was the gauge repair companies who go in and work on
7 specific license gauges. Those are required to notify
8 pursuant to the 241 and generally did not.

9 And I don't know how much you all are getting into
10 them and making them start notifying, as well as there is
11 also a general license that allows them to go work on
12 general license gauges, but that one apparently does not
13 require the filing of the 241 and that gets a little tricky
14 for the licensee to keep up.

15 MR. GLENN: I will mention that because of the
16 180-day requirement, at least for NRC, some of this takes
17 care of itself. The very biggest manufacturers and
18 servicers, in fact, decide that what they need to do is get
19 an NRC license, specific license that covers the activity,
20 and then they don't have to do all of this filing.

21 MR. GODWIN: Right.

22 MR. LIEBERMAN: But we've had at least one service
23 company subject to escalated enforcement action in the past
24 few months because of that type issue, too.

25 MR. GODWIN: Ed Bailey from California.

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1 MR. BAILEY: One thing that has occurred, Greg
2 Yuhas out in California has started sending out copies of
3 the regs in response to the reciprocity notices, and I think
4 that's a great idea rather than trying to do it as a shotgun
5 and somebody come in two years later.

6 When I looked at your open enforcement thing, it
7 didn't click right away, but I believe half of them have
8 involved California industrial radiographers. I keep
9 getting the feeling that I'm being picked on.

10 The other thing I would like to suggest that you
11 might want to try is sort of a regional reciprocity within
12 NRC. If somebody comes from Region III NRC to Region V NRC,
13 if they were put in sort of the same priority for inspection
14 that agreement state licensees coming into your regions are,
15 I think you'd see probably very similar results because you
16 don't know where they are either.

17 I think it is correct NRC is going to lose
18 licensees. I've been told secondhand that there are no NRC
19 licensees in California anymore. They've all terminated,
20 for industrial radiography. So I think that's going to
21 occur in a lot of places.

22 MR. GODWIN: We need to move on. The second
23 number three presenter regarding alarming rate meters is a
24 gentleman who is with NMSS in the Medical, Academic and
25 Commercial Use Safety Branch, Dr. John Glenn.

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1 ALARMING RATE METERS
2 EXPERIENCE AND PROBLEMS
3

4 MR. GLENN: Jim Lieberman stole all my good lines,
5 so I really don't know what I'm here to speak about now. I
6 think probably the topic of alarming rate meters is on the
7 bill today because it has been a topic of enforcement action
8 that has involved many agreement state licensees.

9 First, let me just address some of the technical
10 issues and then I think focus mainly upon some of the
11 enforcement and compliance problems associated with it. We
12 don't have a double-lined study to prove that, in fact, the
13 adoption and implementation of a requirement in January of
14 1991 that every radiographer conducting field radiography
15 under our jurisdiction wear an alarming rate meter has, in
16 fact, stopped overexposures.

17 However, as Mr. Lieberman mentioned, in that 14
18 months since that requirement has gone into place, within
19 NRC jurisdiction, there has only been one overexposure, and
20 that one overexposure occurred with a radiographer who did
21 have an alarming rate dosimeter on his person, but who was
22 in the habit of saving batteries by turning the thing off.

23 This was with one of the larger companies in the
24 United States and I think they are personally horrified at
25 this practice, and that gets me into the next area that I

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1 want to address, some problems associated with alarming rate
2 dosimeters.

3 I think early on there were some performance
4 problems, that the meters didn't work quite the way people
5 wanted them to work. I understand some of them drained
6 batteries at a rather rapid rate. So perhaps that's where
7 this individual originally picked up the habit of turning
8 the thing off, except when it was being used.

9 My understanding now is that market forces have,
10 in fact, corrected that problem and that the alarming rate
11 meters that are being marketed today have better
12 characteristics in terms of battery lifetime and in terms of
13 reliability in noisy conditions and under circumstances
14 where they may be exposed to electromagnetic radiation.
15 That was a problem that was identified early on, especially
16 by the Navy, that some of these devices would give false
17 alarms when exposed to microwave radiation.

18 We did put out an information notice on that. My
19 understanding is that the manufacturers have been responsive
20 in most to that and have provided additional electromagnetic
21 shielding to prevent that from occurring.

22 Then I think it appears to us that, in fact, this
23 is a rule that is working. We hope that that's the case.
24 The next problem occurs because of perceptions that perhaps
25 NRC is overdoing the enforcement aspects of it. I guess

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1 this is one particular issue where I'm somewhat to the right
2 of Genghis Kahn and have, from the beginning, felt that it
3 was important with this new rule that we really believe has
4 the potential to eliminate almost all overexposures in field
5 radiography.

6 An upfront decision was made that this would, in
7 fact, be a Severity Level 3 within NRC's jurisdiction. An
8 individual performing radiography after the effective date
9 of the rule would, if found not wearing the alarming rate
10 dosimeter and performing the duties of a radiographer, that
11 that would, in fact, be Severity Level 3, which does not
12 mean that automatically we get into a civil penalty.

13 I guess one thing you do need to take a look at is
14 our full enforcement policy. That gets us into the
15 territory where civil penalties are mandatorily considered,
16 but it's not mandatory that we issue a civil penalty under
17 those circumstances.

18 I will tell you that perhaps my biggest argument
19 with the regions is in this area, that they feel that we
20 have perhaps overdone it. If the survey of the guide tube
21 and the camera is done, they feel that the fact that a
22 redundant safety mechanism, like the alarming rate
23 dosimeter, should not, in and of itself, merit a Severity
24 Level 3.

25 The decision in NMSS and adopted in the

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1 enforcement policy that Mr. Lieberman is in charge of
2 publishing is that, in fact, we are going to treat it that
3 way because we believe there is a need to make a major
4 change in the behavior of radiographers to make sure that
5 these redundant safety systems are used and that the fact
6 that only one of the redundant systems is not used is not an
7 excuse for not having the full safety system.

8 We've had a whole slate of civil penalty actions
9 and Severity Level 3s to be considered early on in the rule
10 after the rule became effective. That seems to have died
11 way. I would say that within NRC jurisdiction, our
12 licensees have the message, they are wearing them. It
13 appears to be something that they've got in the habit of
14 doing routinely.

15 So that means that where we're seeing most of the
16 non-compliance is, in fact, during reciprocity inspections
17 where agreement state licensees are being inspected under
18 NRC jurisdiction.

19 We do take seriously the problem of ignorance of
20 the law. Now, I guess there was the sense that it's unfair
21 to, because someone has deep pockets, to be able to go after
22 them when they had nothing to do with creating the problem.

23 There is some sense that although the law clearly
24 requires that reciprocity licensees understand or are
25 knowledgeable about the NRC regulations, that there is some

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1 duty to give notice, and we take that seriously. We don't
2 think we should take the full burden where we have to go out
3 and individually interview people and make sure that they
4 understand our regulations before we can take actions
5 against them.

6 But as Ed has mentioned, Greg Yuhas in Region V
7 has started a process where he sends out regulations, making
8 special note of some of those regulations that are different
9 right now, which the alarming rate dosimeter is one of
10 those. We, in fact, have encouraged all of the regions to
11 do that and it is in the form of draft guidance right now,
12 where we have included a letter very similar to the one that
13 Greg drafted up, plus some other information that our Region
14 IV office had prepared, and we're asking the regions to use
15 something like that and to let us know any changes that need
16 to be made so that we can get that guidance out to all of
17 our regional offices.

18 We are trying to make sure that as a part of the
19 notification process, licensees are made aware, the
20 agreement state licensees are made aware of these
21 differences between the NRC and agreement state regulations.

22 Most of the problems that we're seeing now,
23 because we have required a redundant safety in terms of the
24 monitoring and the alarming systems. I find myself being
25 called upon by the regions to use the wisdom of Solomon and

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1 determine whether incomplete surveys of the guide tube and
2 the camera were, in fact, adequate to meet the intent of the
3 rule.

4 So I've had to adjust my thinking in micrometer
5 terms as to how much of the full circumference of the camera
6 has to be surveyed before you would have found a source that
7 wasn't fully retracted and how much of the length of the
8 guide tube you have to survey before it's adequate. These
9 have tended to become very heated philosophical discussions
10 with the regions.

11 Again, I tend to fall on the hard-line side of
12 that issue because, again, I think we're all aware of those
13 overexposures that have occurred where you really do have to
14 put the survey instrument very close to the connector in
15 order to be able to detect the fact that the source has not
16 been fully retracted.

17 That pretty much completes what I s planning to
18 say. There are a couple of issues that have come up in the
19 discussion this morning that I would like to make a couple
20 of comments on. One is to maybe -- well, I'll tell you what
21 some of the difficulties we find when we find evidence that
22 people know of a requirement they weren't following.

23 So let's say that there is, in fact, an indication
24 that, say, an agreement state licensee was given notice of
25 the requirement to have an alarming rate dosimeter, and some

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1 of our early enforcement cases involved this.

2 There is a prima facie case there that if we then
3 later inspect them and they're not using those, that that is
4 willful. And certainly within the Nuclear Regulatory
5 Commission, we treat that very seriously. I guess Ed
6 mentioned using administrative actions to get people to
7 voluntarily shut down and this sort of thing. We will, in
8 fact, get those kinds of commitments or what we call a
9 confirmatory action letter that they will stop, cease, not
10 do activities until they do have the alarming rate
11 dosimeters.

12 But now we have the question of if we had told
13 them before, they went ahead, came into our jurisdiction and
14 didn't have the rate meters, how do we know that we can
15 trust them in other issues. We know that they have resolved
16 this issue. They stopped. If they show us the receipt for
17 the alarming rate dosimeters, we know they have corrected
18 the immediate item.

19 So one of the major enforcement issues that we're
20 constantly dealing with is this threshold of concern about
21 licensees who have shown that in some way they can't be
22 trusted. So then how do we trust them in other areas? I
23 don't know how you're handling this in the agreement states.
24 It's a very difficult issue because it may be that the line
25 or the willful non-compliance is an area of relatively

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1 little safety significance, but it still raises the question
2 what would these people do in a situation where it was
3 important to safety.

4 The other thing that I found intriguing was Ed's
5 mention that they're using undercover agents. I have to,
6 again, say that this has been an issue that, within the
7 staff of the Commission, we have had -- been drawn both ways
8 in terms of how far to go.

9 We do encourage our regional inspectors to sort of
10 hang back when they arrive at a radiography field site so
11 that they can observe the activities without the licensee
12 knowing that they're being observed. We feel this gives us
13 a very much better picture of how they behave when they
14 don't know that the regulator is present.

15 However, we would not want to put ourselves in the
16 position of being purely enforcement specialists and out to
17 catch the licensee, no matter what the safety consequences.
18 So we've really put our inspectors in this dilemma. They
19 are to observe in an unobtrusive manner so that their
20 presence is not necessarily known, but they also have a
21 strong instruction that if they believe they see a violation
22 that has safety significance that's about to occur, that
23 they announce themselves immediately and stop the action
24 from happening or at least alert the licensee to the
25 potential for an unsafe and non-compliant act.

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1 So we're putting a heavy load upon the inspector
2 to try to be as hidden as possible, but never to the extent
3 that he would permit an unsafe act to occur.

4 Those are some of the things that we're trying to
5 balance within our enforcement program. We are taking a
6 hard stand in terms of surveys and alarming rate meters.
7 Both have to be done every time radiography is performed.

8 MR. BAILEY: One quick question. I guess this is
9 a response to a response. John, you were talking about
10 trying to decide how much of the camera had to be surveyed,
11 and I think that's one of the things people have been cited
12 for in California.

13 Looking at the descriptions of them, it seems as
14 though they were adequate. They did not go 365 degrees
15 around, but they went 192, which included the front of the
16 camera. Would you care to comment on that?

17 MR. GLENN: All I can say is that we give --
18 actually, we give more consideration than perhaps it would
19 seem due to somebody on the outside to these particular
20 issues. They are not issues that are decided quickly and
21 haphazardly. It will involve discussions with Jim
22 Lieberman's office, my office, and at least divisional
23 management within the region.

24 We really try to analyze what is the potential
25 that, if a source had been sitting in the wrong place, that

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1 it would have been detected. There's going to be
2 disagreements, but that's the honest decision we try to
3 make.

4 MR. LIEBERMAN: That's a real point. A failure to
5 do the required survey is described as an example of a
6 Severity Level 3 violation in the enforcement policy.
7 That's the enforcement policy.

8 We have the discretion to adjust those severity
9 levels as appropriate. The test that we use, as John just
10 said, is was the survey that was done adequate to locate
11 where the source might be. It might not have been the full
12 260 degrees, but if, in the professional judgment of the
13 inspector who is going to have to testify on the witness
14 stand, can he or she testify that a radiographer doing the
15 work that he or she did, locate the source.

16 The answer is if you can't locate the source with
17 a high degree of confidence, then it's a three. If you
18 could, the fact that you didn't do a complete survey, that
19 would be a four. That's a judgment call on the basis of
20 particular facts.

21 MR. GODWIN: Jim, do you have a real short one?

22 MR. MYERS: Very short. John, I've been working
23 with --

24 MR. GODWIN: Jim Myers, NRC.

25 MR. MYERS: I'm sorry. It is Jim Myers from NRC.

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1 John, I've been talking to the Program Management Branch
2 about that policy and guidance directive and, as of last
3 Thursday, they were still clueless as to when this thing
4 would be released from NMSS.

5 Do you have any idea when this is going to be out?
6 Then I'd like to say that very shortly after we get it, we
7 will send it out to the states.

8 MR. GLENN: This is the one that discusses what
9 should go with the 241 form.

10 MR. MYERS: Right. The policy and guidance on
11 reciprocity.

12 MR. GLENN: My belief is that -- maybe I'm wrong,
13 but I think I saw -- yes, okay. The draft copy was sent out
14 on October 15, and I remember concurring in it, and the
15 comments are due back from the regions by November 13. So
16 within a few weeks of those comments being received, it
17 should be issued formally.

18 MR. GODWIN: Our fifth, depending on how you
19 count, presentation this morning will be by Richard Ratliff
20 of the Texas program. He's going to talk about aggravations
21 -- I mean allegations.

22

23

ALLEGATIONS

24

25

MR. RATLIFF: If you looked at this morning's

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1 newspaper with Mr. Perot and all the other people, there's
2 allegations going all over. As you can see between Ed and
3 NRC, they have multiple allegations.

4 When Lloyd first called me and asked me if I would
5 talk about allegations, he said "because y'all have that
6 Texas ranger." I said, "Yeah, we used to." But what had
7 happened back in 1981 when our program expanded, we were
8 able to convince our Commissioner to allow us to have a
9 position that was called the Senior Investigator Examiner,
10 which was someone with no health physics experience, but
11 someone who had been in law enforcement for a number of
12 years.

13 We were lucky to find a retired Texas ranger who
14 came to work for us, and he taught us a lot. One of the
15 things I remember he told us that stuck ever since is it
16 takes one to catch one, and that's probably really true.

17 [Laughter.]

18 MR. RATLIFF: And that's really the way his
19 thinking went. He really tried every way he could to find
20 ways to bend the law. He regretted that the good old days
21 were gone when, as a Texas ranger, wooden chairs were used
22 to get confessions. I explained to him that we really
23 couldn't do that with our licensees.

24 But as it turned out, we found out that probably
25 greater than 95 percent of the allegations could be

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1 completed and investigated without that type of expertise.
2 Most of the allegations --

3 [Laughter.]

4 MR. RATLIFF: In fact, looking at some of the data
5 before I came out here, most of our allegations, more than
6 three-fourths of them, are in the x-ray area. That's
7 primarily because we now require that all of the x-ray
8 technicians be certified. So patients know this, other
9 technicians know this, and we see most often that it's other
10 technicians or other registrants that are the people that
11 call us and say this person is not -- is using an
12 unregistered technician.

13 Just like one of the NRC gentleman said of the
14 licensees also, it's not just the fees in our case because
15 industrial radiographers are now required to take and pass a
16 test and have an ID card, we get many allegations from other
17 certified radiographers when they see a "uncertified"
18 radiographer doing industrial radiography alone.

19 So we found that most of the allegations can be
20 handled by our health physicists and our investigators. But
21 there is that five to ten percent of the cases where you do
22 need the expertise. What really helped us is in a case
23 where it was a combination, where you need health physics
24 and the criminal investigation techniques.

25 One of them was one of our licensees, Gulf

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1 Nuclear, that ruptured an americium source and failed to
2 tell us. When we had an anonymous complaint about this, we
3 sent both the health physicists to look for the americium
4 contamination and our Texas ranger.

5 Probably the best thing that the ranger did was he
6 took the time to take each of the people into a room,
7 without wooden chairs, and talk to them. He was able to
8 really get good written statements that helped us not only
9 prove the allegation and the intent of the licensee, but it
10 went way beyond that.

11 He was able to get people to really talk and it
12 turned out that there had been contaminated soil at the
13 licensee's facility that had allegedly gone to a waste site,
14 but it was used by one of the employees to fill in a low
15 spot on some new property he had bought. So he had a check
16 source of cesium and americium in his front yard.

17 I think that was one of the things we found that
18 has really kept us in the mode of keeping the investigator
19 mentality. When our Commissioner found out how successful
20 it was using the Texas ranger, he decided that that position
21 should be in his office, because he had asked the
22 legislature for two investigators and was turned down.

23 So we lost the position about five years ago.
24 What happened, though, we were able to develop enough
25 contacts in our Incident Investigation Section that we

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1 realized you really have to keep in close contact with 'ur
2 Texas troopers and local police departments.

3 So what we do now is all of our Incident
4 Investigation staff, which we're lucky we have a separate
5 section in our central office that has five people that do
6 incident investigations, they attend the Department of
7 Public Safety's annual training course for new cadets and
8 the additional courses on investigation of allegations.

9 This has helped a lot. I think we do, though,
10 still realize that there comes a time when you really need
11 to go undercover, like Ed's talking about, and the health
12 physicists just are not trained, even after going through
13 the other courses.

14 What we have done recently is gone to our Attorney
15 General's office because they do have investigators who are
16 trained now and because they want to have any irradiation
17 case they can because it makes headlines, they're recall
18 willing to work with us to do investigations.

19 The trap you can get into, though -- that I found
20 out with the investigations is that a good investigator
21 never finishes his job. He likes to keep on the job. We
22 had one case where the investigator, after five years, still
23 said I'm just about there, just give me another six months.

24 So at some time you have to get to a point where
25 you conclude an enforcement action. I really think that

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1 there's really three areas that we're looking at. We have
2 cases where almost all of them could be handled by a health
3 physicist. There are some cases that need to be directly
4 handled by people with criminal training, and a lot of those
5 cases, I think, if it comes to a point where you know you're
6 going to try to go for a criminal prosecution, you really
7 need to involve other law enforcement agencies.

8 Then there are the few cases where you need both,
9 where you need the health physicist to keep investigators
10 out of trouble and vice versa. So I think, as you can see
11 with all the politics going on now, there are a lot of
12 allegations. We get a lot of allegations and probably most
13 of them we can handle pretty rapidly with our inspection
14 staff.

15 We have two different waste sites going in in
16 Texas, one that would take byproduct Type 2 or uranium mill
17 tailings waste and then a proposed site to take low-level
18 waste. We've had probably a dozen allegations already that
19 they've disposed of waste.

20 Well, they don't have a site, a trench or anything
21 and those are pretty easy to investigate. Tougher ones are
22 the ones that say that the NRC radiographer or, in our case,
23 more often, the Louisiana radiographer has come into the
24 state without having a license, and trying to catch them is
25 tough.

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1 Are there any questions? That's basically all I
2 have on this area. I did have one thing about the
3 investigator always told us to keep silent and he says, you
4 know, never let the other people know what's going on. It
5 reminded me this morning of really the definition of
6 silence.

7 After I saw the headlines, it became more
8 important. Silence is when Dan Quayle and Governor Clayton
9 talk about their war stories. I'll leave you with that.

10 MR. GODWIN: Am I to understand that you are
11 recommended a new training course on wooden chairs?

12 [Laughter.]

13 MR. GODWIN: Do we have any questions? I believe
14 somebody from New York had a question and I had to cut him
15 off because we needed to get this last presentation.

16 MR. KASYK: George Kasyk, New York State. I fully
17 agree with the alarming dosimeter. However, there is no way
18 to calibrate them in the field. You have no 500 MR per hour
19 field to calibrate. The only way they are calibrated is in
20 a true radiation field.

21 The ones I have seen have a little button, but
22 that only checks the electronics. Is there any way that
23 this can be remedied or establish some kind of a calibration
24 procedure in the field using possibly the source?

25 MR. GLENN: We can think about it. I guess I

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1 hadn't focused on that. I can certainly see kind of
2 pass/fail things where you would put the meters out by the
3 guide tube as it runs out.

4 MR. KASYK: The meter is useless unless the guide
5 tube works, right?

6 MR. GLENN: Yes.

7 MR. KASYK: And there's no way to set up a 500 MR
8 per hour field in field operations to check it. So the
9 question does it work or doesn't it work is not answered.

10 MR. GLENN: We can certainly look at that. I
11 don't have an immediate answer to a field test.

12 MR. KASYK: Well, it's even difficult at the
13 office, at the installation, to set up a 500 MR an hour
14 field.

15 MR. GLENN: We certainly expect them to have some
16 method of periodically calibrating them, but I guess you're
17 saying you want something where the radiographer can check
18 these things.

19 MR. KASYK: Well, they check the pocket dosimeter.
20 They can check the meter, whether it works. Why shouldn't
21 the alarming dosimeter be checked, which is so -- I consider
22 it quite an important piece of equipment, but it's useless
23 unless it works and you know it works.

24 MR. GLENN: What exactly are you recommending?

25 MR. KASYK: The ANSI standard says that you have

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1 to check the calibration of meters in radiation field. Now,
2 a button that checks the electronics --

3 MR. GLENN: So what you're saying is that the only
4 check is an electronics check.

5 MR. KAYSK: Yes.

6 MR. GLENN: I'll check our regulations. I think
7 that these things have to be checked in a radiation field.

8 MR. KAYSK: It doesn't say that.

9 MR. GLENN: We'll do that.

10 MR. GODWIN: It will be interesting to see how the
11 alarming dosimeters, as they are in the field for great
12 lengths or period of time, how they wear and how the
13 calibrations are retained. There's still a relatively early
14 use cycle on them.

15 Again, to remind everyone, Jim Lieberman did bring
16 a copy of the amended Section 210 and what he has in his
17 handout, and I would suggest you get it, is the old Section
18 210 and then the amending wordage and you see how it
19 changes. I have glanced through it and, yes, they can file
20 a complaint with the Secretary of Labor relative to our
21 activities and things of that nature.

22 So you need to make sure because a complaint that
23 somebody's been discharged because of filing a complaint
24 with you that you might have that right to another
25 investigation.

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1 Do we have anything else? I'm fixing to wrap it
2 up. Vandy, do you want to close this session?

3 MR. MILLER: Yes. I'll be right there.

4 MR. GODWIN: I wish to thank all of our panelists
5 and let's give them a round of applause.

6 [Applause.]

7 MR. GODWIN: Thank you.

8 MR. MILLER: We certainly want to thank Aubrey for
9 chairing this important session here this morning.
10 Actually, there were some important things that were said
11 from this podium today. One of the things that really
12 catches my fancy right off is that with regard to the 241
13 issue, that if it's an agreement state licensee operating in
14 an agreement state and it's not exclusive Federal
15 jurisdiction, you have a responsibility for the inspection,
16 if there is such an inspection that should take place.

17 Now, I know in California that there is a lot of
18 places that are not exclusive jurisdiction and they probably
19 would have to add some people to their staff if they were
20 going to catch and inspect every radiographer under the 241
21 issue.

22 MR. BAILEY: Just as an example, National Forest,
23 there's actually a license issued to one of the California
24 universities to conduct research on releasing radioactive
25 material in our national forest, and I have difficulty with

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1 that being Federal jurisdiction.

2 MR. MILLER: Exclusive Federal jurisdiction.

3 MR. BAILEY: Yes.

4 MR. MILLER: We have made that determination?

5 MR. BAILEY: I don't think it's been done. I
6 think it's just one of those things that somebody looked at
7 the map and it said National Forest Service lands, and so
8 the material that is released there is under NRC license
9 rather than state license. It's an issue that really needs
10 to be addressed.

11 MR. LIEBERMAN: Jim Lieberman. The point may be
12 that it's not Federal exclusive jurisdiction. There are
13 very limited areas of Federal exclusive jurisdiction. So
14 that national park may well be concurrent jurisdiction or
15 whatever, that you and the State of California have the full
16 right to regulate.

17 Someone asked me the other day what happens when a
18 state inspector goes to a military base and they try to do
19 an inspection because it is the state's jurisdiction, and
20 the military guard as an M-16 pointing at him. I said,
21 well, you know, the same thing an NRC inspector would do,
22 you step back and seek help.

23 When we hit these type issues, it may be NRC can
24 provide assistance to speak to the right Federal agency, to
25 make clear to them that this is not an NRC regulated

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1 activity, it is a state regulated activity, and we should
2 provide whatever assistance we can to the states to help the
3 states do their job in these difficult questions where some
4 base commander thinks that they're in charge and not the
5 state.

6 MR. GLENN: John Glenn. I'll just mention to Ed
7 that I think in this particular case, we ought to take a
8 look at that and make sure. I know right now we're trying
9 to investigate who should give a license to someone who
10 wants to release balloons that will have a radioactive
11 device located in them.

12 The Federal agency who wants this done doesn't
13 want to be the licensee and it appears that the launch sites
14 are all in agreement states. So we're investigating just
15 exactly who should be the grantor of this particular
16 license.

17 MR. BAILEY: Ed Bailey. One final word from me
18 and I'm going to shut up for the rest of the meeting.

19 MR. MILLER: Would someone make that a matter of
20 record?

21 MR. BAILEY: The other night, I couldn't sleep, so
22 I read the Atomic Energy Act. Then I pulled out the
23 agreement between the State of California and the NRC or
24 AEC. There is no -- it says we're given jurisdiction in
25 California over source, byproduct and special nuclear

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1 material in quantities not sufficient to form a critical
2 mass.

3 There is no exemption for Federal agencies.
4 There's no exemption for Federal lands. Now, across from
5 the hall from me, I'm seeing people regulating DOD bases and
6 DOE facilities at the state level, and I suddenly don't know
7 if we shouldn't look at the Atomic Energy Act and see if we
8 can't just say if it's in the State of California, you
9 regulate it; if it's in the State of Wyoming, the NRC
10 regulates it.

11 It would certainly clarify things a lot. We are
12 seeing EPA is able to do it and several of the other Federal
13 agencies are, and I think that may be the solution to the
14 whole problem.

15 MR. LIEBERMAN: When you say EPA can do it, you
16 mean EPA can regulate other Federal -- what do you mean?

17 MR. BAILEY: They can delegate it to the states.
18 RCRA, Clean Air Act, all of those.

19 MR. MILLER: You can see we do have some more work
20 to do in this area. As our staffs around the headquarters
21 develop input, we certainly will get the agreement states
22 involved immediately. This is an early involvement.

23 We've already introduced it here, so you can see
24 we need to do our homework further and we certainly will get
25 the agreement states in on that.

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1 Now we are going to take our break and get back
2 hopefully right at 10:00. Thank you ever so much and thank
3 the panel again.

4 [Recess.]

5 MR. MILLER: If we'll get to our seats, we'll get
6 ready to start the second panel for the morning. At this
7 time, we will start the Materials Regulations Panel.
8 Correction, I'm sorry. The Regulations Panel, period. This
9 will be chaired by Terry Frazee, and we all know Terry. He
10 is a Section Chief there in the State of Washington. He's
11 the supervisor of the Radioactive Materials Section.

12 He is also a key panel Committee member of CRCPD,
13 which is the SR-6 Committee. We chose him because if
14 there's anyone out there in these states that know about
15 regulations, it's Terry. So let's call on him at this time
16 to conduct the panel.

17

18

REGULATIONS PANEL

19

20 MR. FRAZEE: Thank you, Vandy. Welcome back from
21 break. Our first speaker for this morning for the
22 Regulations Panel is Dr. John Glenn. Dr. Glenn holds a B.A.
23 in Physics from the College of Worcester and a Ph.D. in
24 Nuclear Physics from the University of Pittsburgh.

25

Prior to coming to work for NRC, he was the

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1 Supervisor of Health Physics and Safety at Mallinckroadf
2 Nuclear. His career with NRC began as an inspector for
3 Region I and he has been the Branch Chief for the Medical,
4 Academic and Commercial Use Safety Branch within the Office
5 of Nuclear Materials Safety and Safeguards for approximately
6 the last three years.

7 This morning Dr. Glenn will speak to us on the
8 status of the radiographer certification. Dr. Glenn?

9

10

RADIOGRAPHER CERTIFICATION

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MR. GLENN: Thank you, Terry. My talk this morning is going to be more aimed at process than content. To put that a little bit in perspective, when I came to headquarters in May of 1989, there had already been quite a bit of activity regarding radiography certification. Some of the states had met with the Commission.

There had been a decision to go ahead with a voluntary certification rule and then reevaluate and determine whether to go ahead with a mandatory rule.

I have to admit I came in thinking that everything was chartered out, it was simply a matter of going through some steps and eventually ending up with a radiography certification rule.

For the first year-and-a-half that I was there,

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1 Glen Sjoblom was sort of the chief NRC person involved with
2 the program. I sort of kept my ear to the ground, tried to
3 know what was going on, but didn't get too heavily involved.
4 Then Glen decided to leave and go to the Department of
5 Energy and I suddenly found myself with some major
6 responsibilities in this area.

7 I began making some trips back and forth between
8 meetings such as this one with the states and meetings with
9 the American Society of Non-Destructive Testing, which is
10 the group that has a program which has been recognized by
11 the NRC for its voluntary certification.

12 I found out that I was talking sort of two
13 different languages with two different groups and that what
14 I thought was a relatively clearcut go-through-the-steps
15 issue really had quite a bit of disagreement in terms of the
16 direction that we should go.

17 The NRC did adopt the voluntary rule and that has
18 been in effect for some time over a year now. The results
19 are clear that although there is a certification program out
20 there, that the testing can be done, only a small fraction
21 of the radiography community is probably going to go through
22 all of the steps required to receive ASNT certification
23 without a mandatory rule.

24 It's something between 200 and 300 people have
25 taken the ASNT exam and been certified by that group so far.

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1 So if there is an advantage to safety to be obtained by
2 having certified radiographers in the field, it is clear
3 that can only be realized if it's a requirement that
4 certification be obtained.

5 It quickly dawned upon me that my running back and
6 forth between the two groups who had suspicions about each
7 other was never going to result in any resolution of the
8 ideas or the disagreements. As a result, a workshop was
9 scheduled last May in Mobile, Alabama. The states were
10 invited, the American Society of Non-Destructive Testing was
11 invited, and members of the public were invited.

12 We sat down for a two-day meeting and I hope that
13 those of you who were there and participated realized the
14 NRC can listen, the NRC can even learn, and based on that
15 listening and learning, we can actually draft a product,
16 which I'm hoping I'll get some feedback from those of you in
17 the audience today, met the expectations of at least most of
18 the participants at the Mobile conference.

19 I think that we resolved some of the major
20 stumbling blocks. I saw Carlton and Vandy sitting at the
21 table this morning and I mentioned to them one thing that
22 I've learned is the importance of vocabulary in some of
23 these disputes. I think in Mobile, the most important
24 hurdle to get over was to decide that the term "third-party
25 certifier" was taboo, should never be used, should be

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1 expunged from not only the dictionary, but from our
2 memories.

3 Those of you who have looked at the draft rule
4 language that we sent out for comment about the end of
5 September, beginning of October, we have done away with
6 that. And in doing away with that, we recognized agreement
7 state programs on parity with NRC programs and did away with
8 this implied lower status that we were going to give
9 agreement states in terms of third-party certification.

10 So the term we have invented is certifying entity,
11 which can be either an organization that the NRC reaches
12 agreement with or an agreement state program that meets the
13 same objectives. So I want to say that from my point of
14 view, the process that we went through in Mobile was very
15 successful. I will be looking forward to getting the
16 comments from the states as to how well we actually
17 implemented that in the rule language.

18 While I'm on that tact, let me just mention that
19 there was a separate workshop that occurred in Atlanta in
20 July having to do with medical issues. Again, I hope that
21 you became convinced, again, that the NRC will listen and
22 that the NRC will learn and that the product we put out
23 will, in fact, in large measure, incorporate those
24 suggestions that we hear and which we discuss and come to
25 agreement on.

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1 So right now my sense is, in terms of this
2 process, it's a way of getting NRC and agreement state staff
3 to discuss the issues at an early enough time and in the
4 right format so that we can come out with proposed rules
5 that have some chance of success. I think we're batting
6 two-for-two and I personally am very much in favor of
7 continuing this process and keeping it going.

8 In terms of how the rule might progress from this
9 point on, once we get the comments back from the regions and
10 the states and other offices within the NRC, Bruce Carrico,
11 who works in my branch, will begin taking those comments,
12 seeing what needs to be done to the rule, developing the
13 commentary that needs to go with the proposed rule, so that
14 it can be published in the early spring, hopefully.

15 First, it has to go up to the Executive Director's
16 office and then the Commission will have to review it and
17 perhaps direct the staff to make some changes in it before
18 it can be published as a proposed rule, hopefully, early
19 this spring. As such, I would not expect this thing to be a
20 final rule until either late 1993 or early 1994.

21 We did leave the Mobile meeting with a few issues
22 that I think we had some resolution in principal, but which
23 we had not really discussed in detail. The suggestion of
24 the group in Mobile was that these be referred to the G-34
25 Committee and, in the next couple of weeks, that Committee

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1 will meet to discuss some of those issues.

2 The outstanding issues have to do with a national
3 registry so that various certifying entities can keep track
4 of what happens with respect to another certifying entity's
5 certification for an individual. So that if John Jones
6 shows up in your state and he has a card and you want to
7 check and make sure that that card is current, has not been
8 withdrawn, you will have an 800 number or something that you
9 can call and, in fact, verify that.

10 The other major issue that we have not fully
11 resolved is how to do the audits of the certifying
12 organizations to assure that the standards of independence,
13 of fairness are being appropriately implemented. Again, G-
14 34 will be taking some look at those issues, as well.

15 But my feeling at this point is that we've made a
16 lot of progress, that we're on track, and I'm hoping that
17 the comments we receive from your review of the proposed
18 rule language will confirm that.

19 That's basically all I wanted to say today.

20 MR. FRAZEE: Thank you, Dr. Glenn. Any questions?

21 [No response.]

22 MR. FRAZEE: Being none, apparently. Our next
23 speaker is Larry Camper. Larry holds B.S. and M.S. degrees
24 in Radiological Health from George Washington University.
25 He also has an M.B.A. from that university.

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1 Larry has worked as a Materials License Reviewer
2 and a Senior Project Manager for NRC. He's also worked for
3 seven years as a consultant in private industry dealing with
4 medical physics and radiation safety issues.

5 Currently, Larry is the Section Leader for the
6 Medical and Academic Section, in Dr. Glenn's branch at NMSS.
7 Larry is going to address the medical QM rule. Larry?

8
9 MEDICAL QM RULE

10
11 MR. CAMPER: Good morning. Thank you, Terry.
12 It's always a pleasure to be here to talk to the agreement
13 states, our partners in regulation, about one of your
14 favorite topics, of course, the quality management rule. I
15 recall some delightful interactions we had on this
16 particular rule.

17 What I want to try to do today is focus not with
18 all the details of the rule itself, but really just talk
19 about primarily a couple of high points in the rule that I
20 do think it's worthwhile to take a moment to revisit, and
21 then primarily talk about the implementation of the rule,
22 what we're doing about it.

23 [Slide.]

24 MR. CAMPER: You might recall this is called the
25 Quality Management and Misadministration Rule.

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1 [Slide.]

2 MR. CAMPER: Its purpose was to provide a high
3 confidence that byproduct material will be administered as
4 directed by an authorized user physician. You might recall
5 that when we were developing this rule, we held two days of
6 workshops with the agreement state representatives in San
7 Mateo, California.

8 One of the things that you felt very strongly
9 about was that we should not say that this was to prevent
10 misadministration. That was too absolute a concept. We
11 totally agreed and we changed it to the wording that you see
12 there. That wording is taken from the actual statements of
13 consideration and the rule itself.

14 [Slide.]

15 MR. CAMPER: The focus of the rule changed
16 dramatically, also. You might recall that, once upon a time
17 in its development, which had about a five-year history, by
18 the way, that it included all of diagnostic nuclear medicine
19 procedures and therapeutic. It was changed dramatically.

20 First of all, it's a performance-based rule.
21 That's somewhat of a paradox within Part 35, although there
22 are other parts of Part 35 that one could argue are
23 performance-based. But certainly the mainstay of it is
24 prescriptive. But this rule is clearly performance-based.

25 I can assure you from having gone with all five

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1 regions myself, along with Ed Kline, we have tried very hard
2 to make it clear to all of our regional offices and to the
3 inspectors in particular that this rule is, in fact, to be
4 inspected differently. We have given them instructions on
5 how to do that and I will talk more about that in a moment
6 or two.

7 The other thing to try to drive home the point
8 that it is performance-based is we are not including
9 submitted QM programs within tie-down conditions in the
10 licenses. So it will be treated differently.

11 Its focus is on very limited diagnostic. The only
12 thing that's captured that's diagnostic is those procedures
13 that involve greater than 30 microcuries of sodium iodide.
14 Nothing else in the diagnostic arena is captured by the
15 quality management rule.

16 In a moment, I will show you also the threshold
17 for diagnostic misadministration, which changed rather
18 dramatically. So a very important point to consider. Very,
19 very limited diagnostic applications. It does capture, of
20 course, all therapeutic uses, which is where we think the
21 important area is and what we should be really looking at
22 under our program where you try to ensure that materials are
23 administered as the authorized user desires it to be
24 administered.

25 We found that the misadministration phenomenon was

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1 the delivery process phenomenon, and that's what we're
2 trying to get at here, get the authorized user more actively
3 involved, particularly for therapeutic procedures. I think
4 most would agree that is a worthwhile objective.

5 Finally, it does include a program review. It's
6 important we think, as in all quality assurance or quality
7 management types of programs, that the licensee revisit
8 their program every year, take a look at how the program is
9 working, and then make adjustments accordingly. It's
10 designed to be a dynamic document.

11 [Slide.]

12 MR. CAMPER: It did have some impact on agreement
13 states. This is probably the slide that I most hate to have
14 to speak about, because it does address the "C" word which
15 we all love so much. But it did have some impact upon the
16 agreement states. Due to the safety significance on
17 agreement states and NRC licensees, the rule was an item of
18 compatibility, and that all definitions were Division 1 item
19 of compatibility, including misadministration.

20 10 CFR 35.32, which is the part that actually
21 contains the objectives, you might recall that there are
22 five objectives that the licensee is to deal with in this
23 particular rule. I don't have a slide going through all of
24 the objectives and the definitions of misadministration.
25 You're probably familiar with that as much as you'd like to

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1 be at this point.

2 35.33 was also a Division 2 compatibility and
3 that, you might recall, is the reporting requirements for
4 misadministration. Then, of course, there is a requirement
5 to implement these requirements by January 25, 1995. So you
6 still have some time before you really have to focus upon
7 this intensely.

8 [Slide.]

9 MR. CAMPER: This slide depicts the cover of the
10 Regulatory Guide 8.33. It is a very extensive guide that
11 was set up in a fashion that is clearly modality driven. We
12 go through all the possible things that a licensee needs to
13 be concerned about for brachytherapy, teletherapy, gamma
14 stereotactic, radio surgery, routine nuclear medicine
15 therapy procedures and so forth.

16 The licensee can then pick and choose the guidance
17 from those modalities which they employ in their
18 institution. Then the objectives are interwoven throughout
19 the modality approach in this particular guide.

20 This guide also was set up in such a fashion that
21 a licensee simply cannot commit to using it. We never like
22 for licensees to commit to a regulatory guide. It does
23 carry certain complications. With this one, it would be
24 very difficult because of the way it's structured. It
25 clearly is a guidance-type document that they simply can't

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1 commit.

2 And if they do, we would be asking questions in
3 the license review process because it's clearly not
4 structured that way, although there will probably be some
5 that will, despite having said all that, because there
6 always are.

7 [Slide.]

8 MR. CAMPER: This slide is a little noisy and I do
9 apologize for that. Probably can't see it on the front row
10 and I know you can't see it in the back, right? But it is
11 an important slide. If nothing else, just realize that this
12 table was contained within the statements of consideration
13 for the rule itself and it's very, very useful.

14 If you could read it -- in fact, if I could read
15 it, it says procedure on the left, recordable event in the
16 center, and misadministration on the right. It's a nice
17 snapshot to refer to as a regulator as to what is captured
18 now under the concepts of recordable event and
19 misadministration.

20 Again, if we could see this thing, you would find
21 that under this category called recordable event, which is
22 the one in the center, you would find that the thresholds
23 identified there for the various procedures on the left are
24 what used to be misadministration.

25 Now the licensees deal with those events

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1 internally to their institution. They do not report them to
2 us. On the right, you would find that the values for the
3 misadministration were essentially doubled. We like to
4 think of those as being consensus standards. We had 26 days
5 of public meetings. We talked with a lot of groups, not
6 only agreement states. We talked with AAPM, American
7 College of Radiology, Society of Nuclear Medicine, and on
8 and on.

9 Out of all those meetings, we came up with those
10 values which were essentially doubling of the values that
11 existed as misadministration before. Now, we'll never get
12 total agreement upon whether those are the right numbers or
13 not, but at least we can say that the numbers were consensus
14 standards developed through those meetings and I think the
15 numbers are in the right ballpark.

16 I think the most important thing to point out
17 about this particular slide, which is in the upper righthand
18 corner, and that is where it says that the new threshold for
19 diagnostic misadministration is five R whole body, 50 R
20 organ. That is a dramatic change. It is consistent with
21 NCRP commentary number seven. What it really does in the
22 final analysis is that the 400 or so diagnostic
23 misadministration that we saw at a fairly constant rate for
24 ten years simply will not trigger that threshold. They will
25 go away.

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1 We'll probably see one or two diagnostic
2 misadministration per year, at most. I suspect there will
3 be some years when we won't see any at all. To give you
4 some idea of what that really means, for a diagnostic
5 misadministration to occur today using technetium, the
6 mistake that has to occur has to be roughly on the order of
7 a magnitude. We're talking about 150 to about 250
8 millicuries of technetium incorrectly administered,
9 depending upon which reagent it's tagged to, to get to that
10 level of exposure.

11 So it's a big, big problem and worthy of being
12 reported, and I think most of us would agree. But all the
13 diagnostic misadministration that used to be reported
14 because they triggered the two R to an organ, which was the
15 bladder dose, will no longer be reportable. This is a
16 tremendous relief to the licensed community.

17 [Slide.]

18 MR. CAMPER: We are going to hold a public meeting
19 on the implementation of the quality management rule, and
20 I'll talk a little bit more about that in a moment as I
21 discuss with you the Commission's override of the OMB
22 disapproval.

23 But this public meeting will take place on the 9th
24 of November at the Marriott Hotel at Dulles Airport. We are
25 doing this because in the staff's recommendation to the

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1 Commission that it override OMB, we suggested that a meeting
2 take place. OMB had felt this would be important because
3 there seemed to be a lot of confusion in the minds of
4 certain licensees as to what the requirements of the rule
5 was and what the burden really was in terms of
6 implementation.

7 I would encourage you, if you can, to attend this
8 meeting. It should be very interesting. I will show you in
9 a moment a little bit more about this particular meeting,
10 the list of invitees and so forth, and we think it's going
11 to be a very, very interesting meeting.

12 We are currently seeking to award a contract to
13 one of three national labs to review those quality
14 management programs which were submitted. The staff has
15 prepared a standard review plan which the contractor would
16 follow in reviewing that program, as well as standard types
17 of deficiency letters designed to address weaknesses or
18 omissions that licensees might have in the QM programs.

19 I'll talk to you a little bit more about
20 inspection of the programs and I will talk to you a little
21 bit more about the enforcement policy for the program.
22 We're going to go into those two things, the inspection
23 program and the enforcement program, at fairly great length
24 during this public meeting on November 9.

25 [Slide.]

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1 MR. CAMPER: This slide is, again, a little noisy,
2 but I like to show it because it is an example of how simple
3 it can be to address the written directive component of the
4 quality management rule. A lot of licensees felt that they
5 had to go out and create some new form as a written
6 directive. Well, that's not, in fact, the case at all. You
7 could modify existing departmental forms to incorporate the
8 requirements of a written directive.

9 This is simply an example. Dr. Myron Pollycobe,
10 our Medical Visiting Fellow, got this particular form from a
11 colleague of his that use it in his department. Again, if
12 you could read it, you would see that there is a line item
13 there for the signature of the authorized user and places
14 where you fill in the amount of radioactivity to be
15 administered in the procedure. Very simple form, very easy
16 way to address the written directive component of the rule.

17 We're going to share this with the representatives
18 on the November 9 meeting.

19 [Slide.]

20 MR. CAMPER: This slide is something that we're
21 going to be trying to say very hard to the -- we're going to
22 work very hard to say this to the meeting participants on
23 the 9th of November. I've used this slide in a lot of
24 talks. On the left, it's showing someone in the Department
25 of Nuclear Medicine saying "Eeeks, they're here." The guy

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1 on the right, the big, ugly, ghoulish guy with the arm band
2 on that says "NRC," says, "No, we really are here to help."

3 Many people have this perception of an NRC
4 inspection or that perception in dealing with NRC in
5 general. We're going to try very hard during this November
6 9 public meeting to make it clear we really are here to
7 explain this rule and to try to help you with its
8 implementation.

9 That's all for the slides. I'll need to flip the
10 others in a moment, but not yet.

11 Let me make a few comments about the rule and what
12 we're doing to implement it. Some of you are probably aware
13 that the Office of Management and Budget disapproved the
14 information collection requirements associated with the
15 final amendment promulgated in our rule.

16 We had received a letter on the 26th of June from
17 Mr. James McRae, the Acting Administrator and Deputy
18 Administrator for the Office of Information and Regulatory
19 Affairs with OMB. In this letter, OMB concluded that this
20 information collection request is not necessary for the
21 proper performance of the functions of the agency, that the
22 information will not have practical utility for the agency.

23 On the 12th of August, the Commission, exercising
24 its statutory authority, did, in fact, override OMB's
25 disapproval of our information collection requirements. On

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1 the 14th of August, we sent a letter from Mr. James Taylor,
2 who is our Executive Director for Operations, in which we
3 discussed OMB's override.

4 A number of statutory kinds of considerations are
5 cited in this letter. I won't bore you with those. But I
6 will share with you what we had to say to OMB about our
7 override. The Commission, which is the agency charged with
8 substantive responsibility for making such judgments,
9 continues to believe that it's requirements for written
10 quality management programs and misadministration reports,
11 if complied with, has a reasonable likelihood of decreasing
12 misadministration; for example, wrong dose or wrong patient,
13 with a small incremental cost to the licensees.

14 Without the reporting and recordkeeping
15 requirements, it would not be possible to implement and
16 enforce those regulations effectively. The Commission will
17 continue to monitor implementation and inspection under the
18 rule to assure that it provides the Commission with
19 necessary information without imposing undue burden on the
20 private sector.

21 If the Commission finds the rule, in whole or in
22 part, to be overly burdensome or ineffective, we will
23 consider modifying or deleting portions of the rule.
24 Further, the NRC will hold a public workshop with the
25 medical community and other interested parties to assure

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1 that there is mutual understanding as to the intent of the
2 rule, especially its information collection requirements,
3 and to discuss effective implementation.

4 In particular, we will discuss the extent to which
5 we can use the industry's self-auditing guidelines.
6 Following the workshop, the Commission will develop
7 additional guidance on compliance with the rule written in
8 clear language -- that ought to be interesting --
9 appropriate to the medical community. And the Commission's
10 vote was unanimous in its override.

11 On September 10, we did send a letter to all
12 medical licensees, the subject of which was the announcement
13 of the NRC override of OMB's disapproval of the information
14 collection request for the quality management program and
15 misadministration rule.

16 In that letter, we did tell licensees that the
17 rule became effective on the 27th of January of 1992, and
18 will continue in effect through August 31, 1995. NRC will,
19 because of probable confusion caused by OMB's disapproval,
20 exercise enforcement discretion, not to take an enforcement
21 action for a violation occurring between OMB's disapproval,
22 which was the 26th of June, and the date of this
23 announcement, which was September 10, 1992.

24 Now, let me go to the other slides.

25 [Slide.]

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1 MR. CAMPER: The public meeting, as I said, will
2 take place on the 9th of November. What you see here is an
3 agenda for that meeting. The meeting is designed to be not
4 only informative in nature, but high participatory in
5 nature.

6 We're going to discuss the actual language of the
7 rule itself, 35.2, which is the definitions; 35.32, which
8 are the objectives of the rule; 35.33, which is the
9 reporting requirements; and then, briefly, the regulatory
10 guide. We're also going to discuss with them the NRC
11 inspection and enforcement program for this rule. We're
12 going to discuss ACNP's practice audit program.

13 ACNP will, in fact, be making an hour-and-a-half
14 presentation. We're going to have presentations and
15 comments by other organizations invited, which I will show
16 you a list of in a moment, on audit or quality assurance
17 programs, and then, finally, a general discussion of the
18 rule, NRC inspection and enforcement, and all other audit or
19 quality assurance programs, as well as time for general
20 comments by all participants.

21 [Slide.]

22 MR. CAMPER: This slide is a list of those
23 organizations which have been invited. I think there are 30
24 of them there or something close to that. What we tried to
25 do with this particular list of participants is to identify

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1 those organizations whose members could be affected in some
2 fashion by the quality management -- the implementation of
3 the quality management rule.

4 I think as you look down through there, I think
5 we've captured most of them. Again, this will be a highly
6 participatory meeting. We're inviting questions about the
7 rule, its implementation, and comments about their audit
8 programs.

9 Some of these organizations, in addition to the
10 ACNP, JCAHO, for example, which we're all familiar with,
11 have audit programs.

12 [Slide.]

13 MR. CAMPER: With regard to the inspection program
14 itself, we're going to make it clear to the participants
15 that this is to be a performance-based rule, that we've
16 instructed our inspectors to inspect as a performance-based
17 program.

18 What that really means is we want them to look at
19 the overall outcome of the licensee's implementation of the
20 quality management program as opposed to line-by-line items
21 of compliance. It means sampling records, not looking at
22 every record. It means interviewing licensees' employees to
23 determine if, in fact, they know that a quality management
24 program exists and our written directives being used.

25 If we get positive responses, then that should

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1 flavor the inspection accordingly. But if you ask questions
2 like have you seen the written directive or are you familiar
3 with this hospital's quality management program, and the
4 technologist says I have no idea what you're talking about,
5 well, then, of course, you would adjust your inspection
6 accordingly.

7 But it's look at the big picture, look at the
8 forest, not the trees. We have or are currently preparing a
9 temporary instruction for our regional offices to use in
10 inspecting this rule. We're going to share language with
11 the participants contained within that temporary
12 instruction.

13 We're going to invite their comments. Before
14 memorializing that temporary instruction into its final
15 format, we will incorporate, to the extent that we can,
16 comments or suggestions that are made during that public
17 meeting. We will make it clear that it's in that status.

18 As I said before, the emphasis will be on the
19 overall program. Rather than specific compliance, we're
20 going to discuss this at the public meeting in fairly great
21 detail.

22 [Slide.]

23 MR. CAMPER: The enforcement policy will also be
24 discussed. We are currently preparing a modified
25 enforcement policy, which we will submit to the Commission

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1 sometime shortly after this meeting. Once again, we're
2 going to share the modification of the language that the
3 staff intends to propose to the Commission.

4 Basically, what we're really doing in this, you
5 might recall there were some examples of severity levels
6 cited in the rule, what we're going to do is say, look, the
7 emphasis should really be upon substantial program failure
8 or programmatic weakness, not upon isolated
9 misadministration events.

10 We are redefining or going to suggest a
11 redefinition of certain of the definitions for Appendix 2 in
12 terms of severity levels, and we think this is going to be a
13 very positive step that the community is going to be -- it's
14 going to be well received in the community, because what it
15 really says is, look, we're going to look at the big
16 picture. If the misadministration occurs, just because a
17 misadministration occurs doesn't mean you have a bad QM
18 program. It can simply be an isolated error.

19 But if a misadministration occurs in concert with
20 the fact that you don't have a quality management program or
21 that there is substantial failure in the quality management
22 program or clear programmatic weakness, then the severity
23 level indicated is higher, as opposed to currently if one
24 looks in the examples today, you will find that a
25 misadministration is a Severity Level 3, period.

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1 We want to change that. We want to make it more
2 oriented toward programmatic breakdown. As I've said
3 already, we would reduce the severity level for the isolated
4 misadministration, make it a four, not a three. Then,
5 finally, we're going to make it clear to the participants
6 that before this language goes to the Commission in a
7 Commission paper, we will incorporate, to the extent
8 possible, their suggestions and recommendations.

9 We cannot debate with them whether or not a
10 misadministration should at all ever be a Severity Level 2.
11 That's not the point. What we will try to get from them is
12 what do you think about this adjustment in terms of its big
13 picture; is the thrust correct. And I've got to believe
14 that they will say that it is.

15 So that promises to be very interesting.

16 [Slide.]

17 MR. CAMPER: Again, we're going to talk about
18 industry self-audit at great length. We will have an hour-
19 and-a-half presentation by ACNP. Other organizations have
20 audit programs. We're going to provide them with the
21 opportunity to make comments about their audit programs.

22 Then, finally, we're going to share with them our
23 concerns as regulators about our expectations with regard to
24 their self-audit programs. For example, self-audit programs
25 are voluntary in nature. The number of self-audit programs

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1 conducted by the ACNP during the last five years is a fairly
2 small number, something like 53.

3 At the same time, we've done thousands of
4 inspections in medical facilities. The ACNP, we've already
5 had a meeting with them, representatives. What they really
6 are looking for is some type of deemed status. The way that
7 would play out is that if one of their members is
8 participating in a practice audit program, they could submit
9 a commitment to do that in lieu of developing and submitting
10 a quality management program, for example, and then our
11 inspectors would not inspect that component of their
12 program. That's a possible avenue of deemed status.

13 Now, to get to that point, it is incumbent upon us
14 to make sure they understand what our needs and expectations
15 are as regulators. The need, for example, to make some of
16 this information public, if need be; the need to share with
17 us significant findings that might lead to enforcement
18 actions and civil penalties.

19 So the practice audit program has a long way to go
20 if they're ever going to get the deemed status. However,
21 we're quite open to that as a possibility. Ultimately, if
22 we were to reach that particular conclusion, I would imagine
23 that we would enter into some kind of understanding with
24 ACNP or what other organization whose practice audit program
25 we were to approve.

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1 I really don't know how that's going to turn out,
2 but we're certainly quite open about the idea and want to
3 discuss it at great length.

4 That's really all I had to say about the quality
5 management program. I think hopefully you will come away
6 with a flavor for how we're implementing this rule. We're
7 going to go to a great deal of effort to try to make the
8 meeting on November 9 as participatory as possible and to
9 explain the rule and to answer their questions.

10 We hope that will be well received. Again, if any
11 of you have the opportunity to attend, I think it would be
12 worthwhile to do so. Hopefully, when it's all said and
13 done, a lot of the confusion or apparent confusion that has
14 existed about the requirements of this rule and its burden
15 will be cleared up.

16 That's all I have to say about it. If you have
17 any questions, I'll be happy to try to answer them.

18 MR. GODWIN: Godwin, Alabama -- Arizona. I'll
19 tell you what. Gotcha. It's interesting, two aspects of
20 your presentation. I find the collection of people who have
21 been invited to the November 9 meeting totally devoid to the
22 people who regulate most of the industry.

23 MR. CAMPER: Well, the organizations you see
24 depicted there, Aubrey, are organizations in the medical
25 community. This does not exclude the agreement states.

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1 It's certainly not meant to. It's professional
2 organizations that we invited.

3 MR. GODWIN: You're saying that the conference, of
4 course, is not.

5 MR. CAMPER: I'm sorry?

6 MR. GODWIN: The conference would not be a part of
7 the agreement states group. You know, it just seems like
8 you would have had something about the states being a part
9 of that, particularly since you're considering such radical
10 approaches that we may have major problems with it in the
11 states of allowing self-inspection.

12 MR. CAMPER: Let me just say that the list of
13 participants are professional organizations whose members
14 may be affected by the implementation of the QM rule and who
15 may have audit programs themselves. It is certainly not
16 meant to exclude the agreement states. It's a list of
17 another type of entity.

18 MR. GODWIN: Going on from that, then.

19 MR. GLENN: I would like to make point, and that
20 is Thursday we're going to spend the whole day talking about
21 these same issues, as well; additional issues, but this
22 issue, as well.

23 MR. GODWIN: Well, I guess I'm most concerned
24 about this idea of allowing these professional organizations
25 to, in fact, inspect themselves. That is self-inspection.

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1 Every time I talk to the lawyers about it, everybody talks
2 about third party when really it's self-inspection.

3 It's really a step back from public health and
4 safety, I think, particularly when you take the EPA risk
5 estimates of 100 millirems whole body represents about
6 three-in-a-thousand deaths and consider the
7 misadministration, i.e., one where someone is given a
8 diagnostic dose or therapeutic dose that wasn't needed.

9 That has nothing to do with the way you define it
10 in your rule. But if you have unqualified physicians
11 prescribing this stuff, they're going to easily reach 100
12 millirems, and you're talking about a three-in-a-thousand
13 risk. That's a significant risk and I think you all really
14 ought to look at that as to how you interpret who can
15 prescribe.

16 MR. CAMPER: I appreciate your comment. We
17 totally agree, as regulators. We have the same concerns
18 that you do. Sort of as background information, try to
19 understand that just before the Commission exercised its
20 override vote, the Chairman received a letter from the
21 American College of Nuclear Physicians, Society of Nuclear
22 Medicine, asking it to consider the fact that ACNP had a
23 self-audit program and what it might mean in terms of the
24 rule.

25 The Commission decided that it wasn't necessary -

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1 -and they asked for a meeting to discuss it. Sort of the
2 eleventh hour. The Commission decided that such a meeting
3 was not necessary as it related to its decision on the OMB
4 question. But in the process of the meeting where it
5 exercised its override, it did feel that it was important to
6 go to the community, explain the rule, clear up certain
7 confusion, and, as part of that process, to take a look at
8 what ACNP had to say about its practice audit program, how
9 it might effect implementation of the rule.

10 Well, out of that ACNP effort grew additional
11 discussion amongst management at NRC that looked another
12 organizations, as well, that have audit programs. And if
13 we're going to take a look at ACNP's program in the first
14 instance, let's see what other organizations, such as JCAHO
15 and others, ACR, for example, might have to say about self-
16 audit and see if it's possible, is it feasible, will it
17 work.

18 I really don't know yet if it's going to
19 materialize. I do know we need to take a look at it. I do
20 know we need to be open-minded. I do know that we need to
21 explain to them what our concerns are as regulators.

22 I do know that if they ever hope to achieve deemed
23 status, they will probably have to make some significant
24 adjustments in their programs and change how they do
25 business. But is it possible? I would think so. We just

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1 need to explore it. But believe me, as regulators, we share
2 the same kinds of concerns that you do about self-audit,
3 particularly when it comes to radioactive materials, no
4 question.

5 Other questions or comments?

6 [No response.]

7 MR. CAMPER: Thank you.

8 MR. FRAZEE: Larry, it seems to me that it
9 originally it was the high rate of misadministration, per
10 se, that got us into thinking about the quality management
11 rule. The outcome was a rule which did two things; it
12 improved the definition of misadministration and it imposed
13 a quality management rule.

14 Now you're telling us that the focus of the NRC's
15 inspections, when you're reviewing the quality management
16 rule, is the outcome, which I think that means have there
17 been misadministration. At one and the same time, you've
18 changed what constitutes a misadministration in terms of
19 numbers and are still imposing the rule.

20 I guess the question that I have is particularly
21 in light of all the heat that you took about the QM portion
22 of it, did the Commission or did the staff consider taking
23 it one step at a time? Make the change in misadministration
24 definition and then look at what did it really mean, what
25 was the real impact of that, and did the numbers still

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1 warrant going ahead with the quality management portion of
2 it.

3 MR. CAMPER: The answer is yes, in different ways.
4 Let me try to explain. First of all, I don't think it's the
5 frequency of occurrence of misadministration is what drove
6 us to develop this rule. In fact, clearly, the frequency of
7 misadministration was very small.

8 What drove the Commission to have an interest in
9 the quality management rule was the fact that, particularly
10 in the therapeutic arena, some fairly serious consequences
11 were occurring as a result of misadministration, although
12 they occurred very, very infrequently something like ten-
13 to-the-minus-four, I believe.

14 They felt that, nonetheless, something needed to
15 be done rather than to continue to be in a reactive mode
16 year after year, seeing these things occur and doing nothing
17 about it. Consequently, they felt that amongst the various
18 alternatives available to them, policy statements,
19 information notices, rulemaking and the like, that
20 rulemaking was the way to go.

21 What the quality management rule really did in the
22 final analysis was to draw in to active involvement the
23 authorized user by ensuring and requesting or requiring that
24 a written directive was in place prior to administration,
25 signed by the authorized user.

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1 So that before, Iodine-131, for example, to treat
2 thyroid carcinoma, was administered to a patient, there was
3 clear active involvement of the authorized user. If one
4 looks over the history of misadministration, particularly
5 iodine, you find time and time again verbal orders as
6 opposed to written orders. You find technologists
7 communicating amongst themselves or with administrative
8 support personnel about what is the material to be ordered.

9 Unfortunately, in many of those cases, the
10 authorized user was absent involvement and it led to serious
11 problems. So it really is all about that. But, no, the
12 change in the definitions of misadministration and the
13 quality management program were done as a singular project.

14 We do intend to go back and revisit the outcome of
15 the quality management rule at about three years and then
16 ultimately, once definitions for misadministration are
17 uniform throughout the 50 states and so forth, we do intend
18 to look in the future at the number of misadministration
19 that are occurring in total, the nature of those
20 misadministration, and, having done that, what have we
21 learned and what do we need to do then, either regulatorily
22 or in terms of imparting additional knowledge and
23 information to the licensed community.

24 MR. FRAZEE: Are there any other questions? We
25 have plenty of time.

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1 [No response.]

2 MR. FRAZEE: We've heard from NRC on these
3 important and controversial issues, but they are relatively
4 small in size of their text. We're now going to turn to the
5 State of Illinois for a view on what we states are going to
6 be faced with as we implement what is probably the most
7 massive, as well as fundamental change that any of us are
8 ever going to see in our lifetimes.

9 First, we're going to have Steve Collins. Steve
10 is well known to us, probably because he's worked in a
11 number of agreement states, four by this count. I think
12 that his career goal is to work in every agreement statement
13 before he retires.

14 Steve has a Master's degree in Health Physics from
15 the University of Arkansas and he's currently the Chief of
16 the Division of Radioactive Materials in the Illinois
17 Department of Nuclear Safety.

18 He is also Chair of the CRCPD Committee that is
19 charged with dealing with Part D.

20
21 PART 20 PROVISIONS

22 STATUS OF SSR PART D

23
24 MR. COLLINS: And Part D is the equivalent of Part
25 20. The CRCPD tasked this group, not too long ago,

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1 actually, less than a year-and-a-half ago, with coming up as
2 quickly as possible with the model state regulations that
3 would incorporate all the equivalent provisions of Part 20
4 and 19 and associated changes with that.

5 They did put some constraints on the group. They
6 said we want you to change Part 20 only as needed,
7 absolutely necessary to incorporate the provisions that
8 would make it generally applicable to NARM and to machines,
9 not to tinker with other things that didn't have to be
10 tinkered with at the time.

11 In other words, get it out on the street quickly
12 so people could use it and meet the everybody-get-it-
13 effective-at-the-same-date deadline, and then the next year
14 we could work on coming back and fixing things that the
15 states really felt they could improve upon, and that's what
16 we have done as a conference committee.

17 The State of Illinois wasn't exactly happy with
18 everything the conference put out, the way they did. So
19 after I talk, you're going to hear from another Illinois
20 person to add to the laundry list of things that I'm going
21 to talk about.

22 The status of it is -- what your program indicates
23 I'm talking about. The status is that group is meeting this
24 Thursday afternoon, Friday and Saturday to review all of the
25 comments that we've received from all of the states on that

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1 proposed rule.

2 So far, we have received comments from the State
3 of Illinois, about 200. Louisiana has promised that they
4 brought theirs with them and they'll be providing me a copy
5 before we leave here. It's on diskette. Other than that, I
6 haven't heard from you yet and it's 15 days past the 45-day
7 comment period that I mentioned in the letter.

8 So we would like to hear from you while we're
9 here. If you've got staff working on it, please call them
10 and have it to fax the comments to the NRC State Programs
11 Branch, attention Kathy Schneider, and we will consider
12 those at the end of this week when we meet.

13 What did we do in the model state regulations? We
14 took Part A and we showed, with strikeover and redline or
15 shading, if you want to call it that, the changes.
16 Basically, we took most of the definitions out of Part D,
17 Part 20 and moved them into Part A and we didn't change too
18 many of those because all of those definitions were
19 considered to be Division 1 compatibility.

20 Now, when I say we made no changes, if we changed
21 the word "radioactive material" to say "radiation machines"
22 or if we changed "byproduct material" to say "radioactive,"
23 or if we changed it just to say "source of radiation," those
24 changes I'm not going to cover today. Those are things that
25 really don't change the content of the rule. They just make

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1 it broadly applicable.

2 We did change the definition of high radiation
3 area to make a specific statement in the definition, as well
4 as in the rule, that said that it does not include rooms
5 with diagnostic x-ray systems used solely for the healing
6 arts. If you look at some of those definitions, high
7 radiation area, every general purpose radiographic machine
8 that exists would meet that definition the way it was
9 changed, and we don't want those rooms with patients going
10 in for chest x-rays posted with high radiation area signs.
11 So it specifically excluded it.

12 We had proposed a change in the definition of
13 entrance and access point to clearly indicate that the
14 extremity of an individual could be put in, not just a whole
15 body. That way, the x-ray defraction units that have had
16 some severe injuries would be covered in that requirement to
17 have an inner lock or something on entrance and access
18 points would apply.

19 We added a definition for SI to say that that is
20 the abbreviation for the System International units. We
21 have not made changes yet with regard to the policy on
22 metrication. The conference put out a policy statement July
23 1 that said put SI units first, followed by special units.
24 We have done that, but there are other things, like is five
25 millimeters really .197 inch or can we call it .2.

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1 I would say let's call it .2. In the nuclear
2 power industry, you do what you want to. I understand you
3 might not want to do that everywhere there. But when you're
4 talking about DOT standards, I don't see any real big
5 difference between three feet and a meter.

6 When you're talking about 30 millicuries for
7 nuclear medicine applications, I don't want to talk about
8 1.11 giga Becquerels. One giga Becquerel is close enough.
9 My mind doesn't see that much difference. If we cause the
10 docs to have to start giving 27.2 millicuries instead of
11 29.99 so they can release the patient or not admit the
12 patient, then that's fine, too.

13 We suggested adding a definition of special
14 nuclear material because that term is used in the definition
15 of special nuclear material in quantities not sufficient to
16 form a critical mass and in some other places in the new
17 rules. So we thought it should be defined.

18 We proposed changing the section on prohibited
19 uses, which says, about two lines long, to make it clear
20 that devices similar to Lixiscope, if they are either
21 certified by CDRH or they're in the Registry of Sealed
22 Source and Devices, they've been evaluated by someone that
23 knows how to do it, can be used, because right now there's
24 just a blanket prohibition and some overzealous people have
25 interpreted that to actually prohibit the use of Lixiscopes.

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1 That's about all the changes we've made to Part A.
2 Then the equivalent to Part 20, the Part D, there are some
3 definitions left there, like non-stochastic effect. We do
4 read the ICRPs, so we added a statement that deterministic
5 effect is the same thing for purposes of these rules.

6 Effects, we said probabilistic effect is the same
7 for purposes of the rules. On the section that has to do
8 with compliance with the summation of internal and external
9 exposures -- well, and several other sections.

10 The NRC has footnotes throughout their rules. A
11 lot of states can't put requirements or limitations of
12 requirements in footnotes. So we took all those footnotes
13 and converted them into sentence statements and actually put
14 them in the paragraph of the rule where they applied.

15 In the determination of prior occupational dose,
16 that particular methodology or procedure for obtaining
17 records and how to determine prior occupational dose was in
18 the subpart in Part 20 that has to do with records, keeping
19 and maintaining records. We didn't really think that was
20 the proper place for it, so we moved it up into D.205, near
21 the beginning, where we felt it was logical and left the
22 little bitty part of it on recordkeeping back in the records
23 section.

24 There was a footnote there that we also moved in
25 the requirement, and that was because it's not just a

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1 recordkeeping requirement. There's a lot of other stuff in
2 it.

3 The dose to an embryo/fetus, and you will hear
4 some more about that later, we added a footnote explaining
5 that NCRP-91 provided guidance that 50 millirem per month is
6 what was really intended with regard to the limit for the
7 embryo/fetus. So we didn't make it a rule, we didn't change
8 Part 20 on a basic radiation protection standard and get
9 into a compatibility fight, but we did put a footnote in
10 there to provide guidance to the fact that it's supposed to
11 occur over a uniform rate.

12 We also rewrote part of that section to clarify
13 what we thought was confusing. That is someone does not
14 declare until fairly late in the pregnancy and they've
15 already received more than 450 millirems, that during the
16 rest of that pregnancy, they're allowed, regardless of what
17 they've received already, to receive another 50 millirem,
18 4.5 millisieverts, for all of you that's already converted.

19 For the next section that had to do with existing
20 facilities, it was primarily a shielding question for Cobalt
21 teletherapy or, for us, linear accelerators, as well, or
22 other irradiation facilities. The NRC specified that all
23 you had to do was write in and they would grant an
24 exception, essentially.

25 The statements of consideration, to me, made it

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1 pretty clear that they were going to almost automatically
2 grant this going from 100 millirem to 500 millirem for your
3 level of radiation at exterior. We haven't got NRC ruling
4 on this yet, but we put in a provision that said you don't
5 have to apply for it, it's automatically granted for any
6 facility that existed before the effective date of the rule.
7 So the retrofit requirement was put in there as it's
8 granted.

9 As I did when I was in the State of Louisiana, I
10 took the standard leak test condition that you would use for
11 a broadly-based license that has several different types of
12 source. We've actually got the leak test condition in the
13 rules now in Part D. That should save you about two pages
14 on most every license that you put out for a sealed source.

15 We added a prohibition specifically in the rules
16 so that you can now easily cite violations if somebody
17 tampers with a film badge or a TLD to deceptively indicate
18 exposure to that device. All these people playing games
19 with somebody on vacation, you're getting a high film badge
20 reading. You might not be able to pin down who did it, but
21 you will be able to cite a violation of the licensee or
22 registrant for it.

23 In the section on control of access to high
24 radiation areas and very high radiation areas, we added a
25 separate paragraph in each one of those to cover those when

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1 those areas are created by radiation machines. What we did
2 there was specified also that if you have controls that are
3 already in place in accordance with other parts of the
4 rules, you don't have to comply with the Part D or the Part
5 20 equivalent.

6 Most of us have access control to medical linear
7 accelerators well defined in F.9 or your equivalent, and for
8 industrial accelerators in Part I or H. I think it's Part
9 I, I think. So we just basically said if you already comply
10 with those, you don't have to change to the new Part 20 type
11 requirements. That will be one piece of it that you will
12 really want to look at carefully to be sure you really want
13 to do that.

14 In that same section, there was a term, a vague
15 term, "high level of radiation" used for one sentence there,
16 when the whole text of the paragraph had to do with very
17 high radiation areas, which was 500 rads in one hour at a
18 meter. So we replaced that undefined term with specific
19 language that made sure that it couldn't possibly be
20 misinterpreted by the licensee, registrant or inspector.

21 The section that has security and control of
22 sources, sealed sources, we changed to make that sources of
23 radiation and rewrote it to clarify that it did not apply to
24 radioactive material in patients, because it talks about
25 control or provide continuous surveillance and we wanted to

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1 make sure that we didn't have to do that for patients.

2 We also -- at the meeting on Friday, I'm going to
3 try to totally rewrite that section to make it much clearer.
4 There is a problem that the next speaker is going to talk
5 about that we think we have fixed in Illinois. So I'm going
6 to be proposing to change that section again.

7 On exceptions to posting, we have added a
8 statement to clarify that rooms that only have radiation
9 machines that are used solely for the healing arts purpose
10 are not required to be posted. So earlier I talked about
11 high radiation area definition. Well, here, if it's got
12 only x-ray machines in it, diagnostic type, they don't have
13 to be posted at all.

14 What we did in the next paragraph that has to do
15 with labelling containers, we said labeling containers and
16 machines and we, at the request or guidance of the
17 conference, moved the labeling requirement from Part F to
18 Part D, so that this equipment may be harmful if it produces
19 radiation re-energized. That is now in Part D. The Part F
20 Committee hasn't yet taken it out of theirs, so right now
21 there is a redundancy and they had the same language.

22 Examples to labeling requirements. The examples
23 used in Part 20 all had to do with nuclear power plants. So
24 we put in an example that had to do with process type
25 facilities that are more pertinent to agreement state

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1 applications.

2 Procedures for receiving and opening packages.

3 The latest amendment that NRC issued that incorporated some
4 of the previous things, like moisture density gauge
5 licensees didn't have to do a survey every time they'd come
6 back to the facility, because all of a sudden licensees that
7 previously didn't ever have to have a survey meter were now
8 going to have to buy one.

9 We've already incorporated that exemption so that
10 the current requirements do not have to change for that
11 particular category of licensees or similar licensees.

12 The section on waste disposal, we added a
13 provision that actually authorizes the storage of greater
14 than Class C waste until a disposal facility is authorized
15 to receive the waste. You may want to look at that. You
16 may decide that you don't want to do that. That might
17 authorize something that may never exist.

18 On the recordkeeping section, we made a specific
19 statement that you could SI or special units, but that you
20 couldn't mix them in any one particular record. You
21 couldn't mix the units and switch from one to the other.

22 In that recordkeeping section, the section that
23 has to do with surveys, records of prior occupational dose,
24 records of planned special exposures, and records of
25 individual monitoring, we added a statement that had to do

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1 with the fact that the licensee or registrant has to make
2 provisions to transfer the records to the agency after
3 termination.

4 That's going to require some development of a
5 policy statement on your behalf or else you're going to have
6 more than you can do. But that kind of ties in carefully
7 with the decommissioning rule, as well as the fact that a
8 lot of states already have, because I think the model state
9 statute has a provision and I think that's the reason most
10 states have it, that those records not get lost when a
11 company goes out of business.

12 We added to the record for leak tests, specifying
13 units in the records. That's exactly the same as what's in
14 the standard license conditions now. We made it clear in
15 the records of individual monitoring results that
16 assessments of those done before the rule change date do not
17 have to be recalculated just because we're now going to
18 effective dose equivalent and it might have previously been
19 some other form. You don't have to recalculate those.

20 In the reporting of lost or stolen sources, we
21 added the word "missing." Now you have to report missing
22 sources. Maybe it's not lost, but you don't know where it
23 is. We want to know just in case it shows up. We want to
24 find out from you, not the press. We also included
25 radiation machines in that in a fashion that has not been

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1 done before for the reporting requirements.

2 Several of us have had to respond to places where
3 this -- it's almost always been industrial radiography, x-
4 ray machines were discovered on the side of the road or in a
5 field or something like that. So that's the reason we put
6 that in there.

7 In reports of exposures and levels and
8 concentrations, we have added a clarifying statement to make
9 sure that it meets what the statement of consideration had
10 for Part 20, and that was that the embryo/fetus dose is
11 reported to the record of the declared pregnant woman.
12 Records of individual monitoring, that whole section, which
13 is in Part 20, is in brackets in the Part D to indicate that
14 it is optional, because typically most of the states have
15 not ever done that, participated in that.

16 That's saying certain categories of licensees must
17 report summary results of their personnel monitoring to the
18 NRC on an annual basis.

19 Then there were three sections that are not in
20 Part 20 at all that were in the previous -- or in your
21 current Part D. That had to do with notification and
22 reports to individuals, which pretty well just provides a
23 cross-reference to Part J or your 10 CFR 19 equivalent. It
24 says when to report to the agency -- or when you report to
25 the agency, you also must report it to the individual. So

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1 we left that in.

2 Reports of leak tests, the report a leaker in five
3 days requirement was added from the standard leak test
4 condition. And we retrained the provisions that had to do
5 with vacating premises, that says you've got to notify us 30
6 days in advance before you intend to vacate a facility.

7 That's all of the changes we made to those current
8 rules. In the same package that you received with that A, D
9 and J, you received a proposed change to that Part D that
10 had to do with wearing of film badges and how to compute an
11 effective dose equivalent, to try to solve the unreal
12 overexposures of cardiologists and interventional
13 radiologists that wear lead aprons, where most of the body
14 is really shielded, but, by definition, if the arm, elbow
15 and above is exposed, just one of them, or the head, that
16 that's a whole body exposure.

17 Well, when we're converting a concept to go to
18 effective dose equivalent, we want to try to bring some
19 science and some reason into this to say that most of the
20 body is shielded, let's try to get real and make risk
21 compared to risk for these guys, too, and also to avoid all
22 of these overexposures that aren't really overexposures that
23 we spend a lot of time investigating.

24 So there was a proposed change to two sections of
25 the rules there that basically would have said that the

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1 effective dose equivalent may be considered to be three-
2 tenths of the collar badge reading worn outside of the
3 apron. That is based on an article which has been published
4 in Health Physics. There's been some two or three articles
5 done on that.

6 We could have actually gone with a factor of .2
7 and still been conservative, but, being good regulators,
8 there's not that much data available and we decided we
9 wanted to do it. So that's a parallel track. If we get
10 nothing but favorable comments from most of the states, we
11 could go ahead and put that in the model in brackets at the
12 time we finalize this, but so far we haven't really heard.

13 The next speaker, Kathy Allen, will be telling you
14 a little bit about what Illinois decided to do with that and
15 why. That's all of the comments I have at this time. Ready
16 for a question.

17 MR. TEDFORD: Chuck Tedford, Alaska. Apparently,
18 you forgot the Subcommittee meeting that we held yesterday
19 down in the men's head with regard to a comment that was
20 made. The comment that was made to you, Steve, was that I
21 thought that since this was a conference committee that was
22 taking a look at it, that there were other states who used
23 these exposure guidelines in their regulations and didn't
24 need all of the other opportunities that are involved with
25 an agreement state looking at the radioactive material part.

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1 I thought it would be nice for you to provide your
2 sagacious advice to them, maybe just to asterisk the key
3 parts that they could put in their regulations that would be
4 applicable since this is a conference group.

5 So for the record, I suggest that when the
6 Committee meets, that you look at just the highlights of
7 this that could be utilized by the non-agreement states, as
8 well.

9 MR. COLLINS: For the record, I did exactly what
10 the conference asked me to do, but that's a good idea,
11 Chuck.

12 MR. LEVIN: Stuart Levin, Pennsylvania. We took a
13 look at the new Part 20 that you sent out because we will
14 probably have to get something in there for a limited
15 agreement. One of the things that you didn't mention, but I
16 don't know if it's new or not, you have two definitions of
17 the word "exposure." One of them is underlined and the
18 other one isn't.

19 Our lawyers tell us that will not fly in the
20 regulations. So if anybody had tackled that problem or
21 whatever, I'd certainly like to hear about it.

22 MR. COLLINS: We tackled it in Illinois and, based
23 on your statement, I figure you're going to figure we messed
24 it up even worse. We took out the underscore or the
25 exposure X and basically said exposure means, and we put the

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1 ICRU definition, then we put semicolon or, and then we put
2 that other little definition, and then we added an agency
3 note that says the context makes it clear.

4 We got to looking at this and said, you know, from
5 the history of the five people that were meeting to discuss
6 this and we got to thinking about the amount of money we
7 were spending talking about it in Illinois, and decided that
8 we had about two times when it had really caused a little
9 bit of problem for maybe an hour each time in the last 15
10 years. Decided the fix was just to get on with the next
11 problem.

12 Ruth?

13 MS. MCBURNEY: Ruth McBurney, Texas. With the new
14 limits to members of the general public, one of the concerns
15 that some of our licensees and especially registrants have
16 expressed is are we going to address retrofits for radiation
17 machines for shielding purposes.

18 MR. COLLINS: That's what I was saying. We
19 granted -- we said there will no retrofit. That's
20 essentially what we did. Now, I'm going to change the
21 wording of that section a little bit more than what you've
22 got in your hands, because that section makes it appear that
23 just because there was a machine in place at the effective
24 date of the rule, and it says in the facility, it doesn't
25 say in just that room of the facility that you never had to

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1 worry about it anymore.

2 We're going to make sure that that's clarified to
3 indicate that if you have a machine in a room and you don't
4 change -- or if you do change out that machine, that that
5 room does have to be evaluated at the time. Or if you take
6 a room that has, let's say, a Cobalt unit in it and you also
7 add a high dose rate remote after-loader or you add an
8 accelerator, so you've got two in the room, but you've got
9 more sources that are stored there, and the shielding is
10 actually determined based on the leakage radiation of sealed
11 sources instead of something else, you would have to
12 reevaluate it at that time.

13 So clearly the concept is as long as you keep
14 cooking the way you're cooking, don't change anything else.
15 We don't intend for you to have to apply for us unless some
16 big change is made.

17 MR. TEDFORD: Chuck Tedford, Alaska. One more
18 comment along that line. What Ruth said brought another
19 point to mind. NCRP-49, which is the shielding criteria
20 guideline now for diagnostic installations, uses 500 MR.
21 Simply stated, it's incorrect with the 100 MR that's been
22 cranked in.

23 Another point that we've implemented, which I
24 think is very good, some states are also doing their own
25 shielding calculations or their own shielding consultation,

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1 if you will, and that's a conflict of interest.

2 If you look at NCRP-49, it indicates that somebody
3 who is a qualified radiation physicist or health physicist
4 should look at the shielding designs and that the state
5 should comment on it.

6 MR. COLLINS: The actual way the rule has been
7 changed, the previous 500 MR and the current 100 MR are not
8 exactly parallel. One of them is 100 millirem to a real
9 person. Another one was 500 millirem to somebody under a
10 really constrained set of assumptions.

11 So the original evaluation, when they go through
12 all the paperwork, they're going to find in almost all cases
13 that the shielding is still okay. We just don't care to
14 drive them through that unnecessary exercise and give us the
15 paperwork and make us do it to prove it.

16 So we went through and looked at all of that to
17 say that this is just a useless paperwork exercise, let's
18 let them do it as they modify facilities because most of the
19 facility modifications are occurring faster than the five-
20 year renewal processes of the licenses, with the exception
21 of teletherapy, which we're all driving out of business with
22 these anyway.

23 MR. BAILEY: I just have one question and you may
24 have answered it already. Ed Bailey from California. Did
25 you address the patient-to-patient dose, where you've got

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1 implants in one room and patients in an adjacent room?
2 Would they be subject to the 100 or the 500?

3 MR. COLLINS: No. We didn't address that in Part
4 20 because there's some wording that addresses that in Part
5 35 a little bit, and we want to handle that particular
6 situation in Part 35, rather than in a generic provision for
7 radiation safety. We think that should stay in Part 35
8 strictly for the medical environment.

9 So we did think about it and talk about it a
10 little bit and decided it wasn't our place, and that's Terry
11 Frazee's group.

12 MS. SCHNEIDER: Kathy Schneider, NRC. I just
13 want, again, to reemphasize to the people here that the
14 meeting we're having at the end of this week, some of the
15 changes Steve brought up we will be relooking at. Some of
16 them won't stay in because we've been going through the
17 process of getting NRC concurrence.

18 For Chuck's concern about -- for x-rays, let me
19 just raise this again. This is a conference document. The
20 model regulations are such so that when all the Federal
21 agencies concur on it, if you follow those regulations,
22 you'll have a program that's both compatible with NRC's and
23 equivalent with FDA's.

24 So the goal here is to have an all-encompassing
25 regulation and for those states that want a limited portion,

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1 to cut it down. An area -- for a state that's not an
2 agreement state, then you have your option to choose. But
3 to start having two different Part Ds or even asterisking, I
4 think, causes a little bit more confusion.

5 MR. COLLINS: We are hoping that after this
6 meeting, within two weeks, hopefully, after the meeting, to
7 be able to send out the new and improved version with
8 diskettes to everybody so that you can, if you haven't
9 already started, get started right away.

10 Illinois has theirs ready to introduce January the
11 7th or 10th, whenever, in January, because we have to do a
12 rulemaking within one year or start over. And, remember,
13 the NRC wants us all to have this rule effective January 1,
14 1994.

15 So Kathy has been working very hard in NRC. If we
16 don't make too many drastic changes this week, we'll have
17 concurrence. We will know that if we do it that conference
18 way, that we'll have no compatibility problems because
19 concurrence will be established by December 31 of this year
20 or thereabouts.

21 Aubrey?

22 MR. GODWIN: Aubrey Godwin from Arizona. As I
23 recall that medical practice section, the brachytherapy
24 refers to having procedures, which I think implies that you
25 will go back to Part 20 standards for the adjacent patient,

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1 if I remember that correctly.

2 So I guess you, in effect, have changed the
3 adjacent patient down to 100 millirem, if I remember that
4 part correctly. But one other comment. This bit of taking
5 exposure records and survey records from the defunct
6 licensees, our lawyers in Alabama had a heart attack when I
7 even considered that because they said the agency was
8 picking up liability.

9 That was not strictly a government function and we
10 suddenly fell into a different liability class from a
11 government agency, and that if we lost a record for somebody
12 and they asked for it, we may have an interesting failure to
13 adequately safeguard records defense we'd have to do. So we
14 might ought to look real careful at how we go about that.

15 They say don't take a record unless you're ordered
16 to by a judge, is what they advised us.

17 MR. TEDFORD: Chuck Tedford, Alaska. I just want
18 to respond to Kathy's comment. I'm not suggesting that you
19 have two sets of regulations. I'm simply suggesting that
20 when you get through with it, you take about ten minutes, go
21 down and asterisk those particular points or sections that
22 seem to be applicable exclusively to non-agreement states.

23 MR. COLLINS: One person has written a letter to
24 the conference, I think, and suggested that we have two
25 different Part Ds, one for x-ray and one for materials.

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1 MR. BAILEY: Ed Bailey from California. I think
2 this is an old argument. I can remember when we were
3 working on another part, they wanted us to separate out
4 licensing state from agreement state. My remembrance was
5 that these were suggested state regulations. They're the
6 regulations that if we had an ideal situation across the
nation, these would be the rules you would use.

8 Ideally, every state would be a licensing state
9 and every state would be an agreement state, and, therefore,
10 doing -- it takes longer than ten minutes, trust me. We
11 tried to do it in Part W and some others.

12 MR. COLLINS: Terry Frazee, I sure hope you picked
13 up on that fact that Part 35 does need -- or Part G does
14 need a fix, because we're not going to do it in our group.

15 MR. FRAZEE: I know a lot of things that need
16 fixes. Just one second. How many states will have some
17 comments for Steve by the end of the week? Is there anyone
18 besides Louisiana? I'm not holding my hand up because we're
19 not. Okay.

20 Steve, you get to proceed. Within two weeks after
21 this meeting, you will have something new out to us, right?

22 MR. COLLINS: Pretty close.

23 MR. FRAZEE: There has been a change to the agenda
24 and Steve is not giving the next session. We have, however,
25 saved the best for last. In fact, our last speaker is so

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1 good that she's going to give both these presentations.

2 Kathy Allen has a B.A. in Biology from Wisconsin's
3 Rippon College. She has been a radiation worker, knows
4 whereof she speaks, and has been a health physicist for
5 Amersham, with responsibility for transportation issues,
6 licensing and license certification, emergency response, and
7 general safety.

8 She's now with the Illinois Department of Nuclear
9 Safety and has been for the last five years. Currently she
10 is responsible for regulations development and
11 implementation. Thus, her first topic will be on
12 implementing the Part 20 changes in Illinois.

13 Her second topic is a spinoff of Part 20 and is an
14 especially tough issue for those of us who are male
15 chauvinist and father-figure types. In the eyes of the law,
16 Kathy Allen is not pregnant and she's now going to explain
17 how this can be, as we, as well as our licensees have to
18 deal with the undeclared pregnant worker.

19 Kathy, come on and tell us first how you're going
20 to change Part 20.

21

22 STATE EXPERIENCE IN ADOPTING PART 20

23

24 MS. ALLEN: Thanks. This talk is supposed to be
25 state experiences in adopting Part 20. Our experiences were

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1 mindboggling. I got a lot more gray hair because of it. We
2 spent about seven staff members from the x-ray department
3 and materials side of the things, spent almost two entire
4 very intense months doing nothing but our equivalent to Part
5 20.

6 A lawyer was involved, too, not that her time
7 counts any different. We looked at both Part 20 and Part D.

8 [Slide.]

9 MS. ALLEN: Of course, the first change we have,
10 and our licensees are probably going to scream about, is
11 that curies are no longer listed first. The SA units are
12 first, as Steve had said, with conversions in parentheses
13 afterwards.

14 Other changes that we made, footnotes incorporated
15 into the text and if it was something that was not
16 substantive, but just a guidance type thing, we put them in
17 as agency notes. We also have a problem with funding and
18 reprinting all these regulations can be fairly expensive.

19 So rather than reprint the tables or the
20 appendices, A, B and C, we incorporated them by reference.
21 It saved us a lot of proofing time and a lot of
22 incorporation time and photocopying time.

23 For licensees that request copies, we'll be happy
24 to provide them, but for most gauge licensees and a lot of
25 our registrants for x-ray machines, they don't have a desire

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1 to have ALIs and DAC tables.

2 We began -- at the beginning of Part 20, we
3 figured we'd just march right through it and make some
4 changes. I apologize to people on Part D. We didn't mean
5 to trash your work, but we did make some changes. Under the
6 general provisions part, there's a statement that says
7 "However, nothing in this part shall be construed as
8 limiting actions that may be necessary to protect health and
9 safety."

10 You didn't even get off the first page and our
11 lawyers had a problem with this. They indicated that this
12 statement could be used to defend a licensee's refusal to
13 perform certain duties that they had agreed to do. For
14 instance, if a licensee was required by license condition to
15 do surveys on a weekly basis, they could choose, for
16 purposes of protecting health and safety, including the
17 safety of the worker, just to do them on a monthly basis or
18 a quarterly basis, because ALARA and Part 20 allows you to
19 do that.

20 The statements of consideration say that this was
21 meant for emergencies only. So all we did was add in a
22 phrase, so it now reads "Nothing in this part shall be
23 construed as limiting actions that may be necessary to
24 protect health and safety in an emergency."

25 That was easy. Then we got to the definitions

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1 section. Most of our definitions are the same and we moved
2 them over to a different section, like Part D did. We got
3 into some areas where we have a different view of the world
4 than NRC does.

5 We decided that we couldn't make it through the
6 definitions section without having a big argument. So we
7 went through the rest of the rule and came back. And we
8 stayed there for quite a while, too.

9 Basically, NRC has divided the world into three
10 areas; restricted area, unrestricted area, and the
11 controlled area. The doses that are allowed to be received
12 in these areas depend on where you are, not who you are,
13 unless you're in a controlled area, then it depends on who
14 you are and where you are.

15 For example, in a restricted area, anyone who goes
16 in that area, if you're a radiation worker, if you're the
17 Governor there for a photo opportunity, you're an
18 occupational worker and you can receive five rem in a year.

19 If you're in an unrestricted area, it doesn't
20 matter who you are. You should limit the dose to 100
21 millirem in a year. If you're in a controlled area, if
22 you're a member of the public, you can receive 100 millirem
23 in a year. If you're an occupational worker, you can
24 receive five rem in a year.

25 Well, we felt a little uncomfortable with this and

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1 trying to explain it to our licensees. So we went through
2 the rule to see how the words were used. And as a result,
3 we made the following change.

4 [Slide.]

5 MS. ALLEN: We have a statement. We've gotten rid
6 of controlled areas. We're selling these buttons to pay for
7 my trip here, so if anybody's interested. We decided to
8 delete controlled area. 20.1301(a)(2) reads that doses in
9 unrestricted areas are not to exceed two millirem in any one
10 hour. A radiation area is defined as a location where
11 there's five millirem or greater in any one hour.

12 Therefore, that's also called a restricted area.
13 The dose in the controlled area is not specified. By
14 definition, it should be less than five millirem in an hour,
15 but there is no requirement that it be kept below two
16 millirem in an hour. Question 93 of the standard -- the
17 question and answers sent back and forth that NRC has
18 published states that occupational workers must receive
19 training.

20 If an occupational worker receives all
21 occupational exposures in a controlled area, Part 19 does
22 not require that worker to be trained. They highly
23 recommend it, but Part 19 does not address workers in a
24 controlled area receiving occupational doses.

25 The definition of controlled area includes access

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1 restricted for any reason. For example, if you have an area
2 where you keep all your chemicals, that could be considered
3 a controlled area. We feel that that's beyond the scope of
4 our regulations dealing with radiation safety, so we decided
5 to pretty much cut that part out.

6 [Slide.]

7 MS. ALLEN: What we did is under the definition of
8 unrestricted area, we added an agency note that will still
9 allow controlled areas designated by the licensee, if
10 they're areas controlled for purposes other than radiation
11 protection. We will also continue to allow licensees to
12 submit license requests to add in NRC's view of what a
13 controlled area can be.

14 For example, many broad-scopes use a red, yellow
15 and green system, green being unrestricted, red being
16 restricted, and the yellow hallway system interconnecting
17 all the restricted labs being a type of controlled area,
18 where in any one hour you could go above two MR per hour.

19 We want to deal with that on a case-by-case basis
20 with our licensees. We didn't do this to give Jim Lynch a
21 headache, either.

22 Once we committed to deleting controlled area and
23 using it as an option for licensees, the rest of the rule
24 was pretty straightforward, so we changed some other
25 definitions.

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1 [Slide.]

2 MS. ALLEN: For example, occupational dose. It no
3 longer matters where you are, but who you are or what you
4 are doing. If you are an individual assigned duties that
5 involve exposure to radiation or radioactive materials, then
6 you are considered an occupational worker and your dose will
7 be an occupational dose.

8 [Slide.]

9 MS. ALLEN: We modified the definition of member
10 of the public. We simplified it to basically say a member
11 of the public is any individual who is not occupationally
12 exposed. These are just abbreviations of the rules.

13 [Slide.]

14 MS. ALLEN: Then we took public dose and basically
15 said that's the dose you receive as a member of the public,
16 refer back to member of the public for the definition of
17 what you are.

18 [Slide.]

19 MS. ALLEN: Then we went on to the determination -
20 - we got out of the definitions then. Now we're into
21 another section. Determination of internal exposure. Our
22 lawyers and the committee that approves regulations has a
23 problem with the terms "suitable" and "timely." They're not
24 very well defined.

25 So what we did is under the determination of

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1 internal exposure section, we added in a few words to
2 basically describe what we mean by timely and suitable.
3 Basically, timely would mean if you take air samples, you
4 should be taking them during normal conditions of operations

5 [Slide.]

6 MS. ALLEN: In determination of internal exposure,
7 you evaluate quantities of material after exposure to
8 materials that could result in an intake.

9 [Slide.]

10 MS. ALLEN: Then we went on to prior occupational
11 dose. When we went through that particular section in the
12 regulation, we had some problems understanding what records
13 were required when. It requires a copy of your dose record
14 to date, year to date, and it also requires, under certain
15 circumstances, your entire dose history, and it's highly
16 recommended that you get copies of a person's entire dose
17 history.

18 With all the "mays" and "shalls" and "ands" and
19 "ors," we had some confusion as to what was really
20 necessary. So we pretty much just rearranged the whole
21 section. I hope you like it. What we did is for every
22 licensee and registrant, you must receive year-to-date
23 occupational exposure records and you may receive that as a
24 copy of the record from the individual.

25 The lifetime occupational dose is just a

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1 recommendation as an agency note. We had some disagreement.
2 Not all of us agreed that it should be this way, but the
3 bottom line is there's no more 5(N-18). It's five rem in a
4 year. And if you're not going to do planned special
5 exposures, there's really no need, from what we could tell,
6 to have these people to get that information, although good
7 health physics practice probably tells us we should. We
8 couldn't find a regulatory basis for it.

9 Facilities that anticipate needing PSEs, of
10 course, have to get the lifetime dose. Then we skipped on
11 to the security of stored material. NRC says you must
12 secure from unauthorized removal or access licensed
13 materials that are stored in controlled or restricted areas.
14 IDNS, of course, since we got rid of controlled areas, we
15 don't care where it's from. We don't care if it's
16 restricted or unrestricted.

17 The bottom line is if you lose a source, we want
18 to know about it. So for patients that have a marker source
19 taped to them and they walk out of the hospital, they could
20 argue, under NRC's rules, well, that was in a restricted
21 area and it walked out; therefore, it's not a problem with
22 security. We'd say we don't care where it came from, if
23 it's radioactive material, you've lost control.

24 Control and surveillance of material, we basically
25 added more words to the word "control." We say that you can

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1 use devices or administrative procedures to prevent
2 unauthorized removal of sources. That just gives them a
3 little bit more flexibility and explains to them what we're
4 looking for.

5 For x-ray machines, we want the machines to be
6 secured from unauthorized removal and use administrative
7 procedures or devices to prevent unauthorized use of those
8 machines.

9 For posting requirements for high and very high
10 radiation areas, we allow over-posting of the perimeter.
11 For example, if you have a radiographer, rather than having
12 a bunch of different signs posting the high radiation area
13 and radiation area, we authorize in the rules posting the
14 high radiation area at the perimeter of the -- when the
15 radiographer marks out the area.

16 Under exceptions to posting, NRC tries to restate
17 the medical release criteria in their rule. We found that
18 our rule was a little bit trickier. There are also surveys
19 that need to be performed. It's not just based on patient -
20 - the dose to the patient or the content of materials.

21 So we just sent them back to Part 30 -- our
22 equivalent to 35. We said if you want to release the
23 patient, do so in accordance with the other part of the
24 regs, rather than trying to restate it.

25 [Slide.]

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1 MS. ALLEN: Procedures for receiving and opening
2 packages. NRC and Part D both say do a survey within three
3 hours after normal -- if a package is received during normal
4 working hours and three hours -- if it's received outside of
5 normal working hours, within three hours of the next working
6 day.

7 There was some discussion as to what if it's
8 received December 24th and people are gone for two weeks.
9 You could have a leaking package sitting there for quite
10 some time. We discussed this back and forth whether or not
11 we should impose some other requirements. So we say do a
12 survey within three hours of receipt if it's delivered
13 during normal working hours, or, no matter when it's
14 delivered, if a package is damaged, a survey must be
15 performed within three hours.

16 We pretty much do this as a license condition
17 anyway, so we just decided to put it in the rules. And if
18 it's not damaged, you can perform the survey within three
19 hours of the next working day.

20 [Slide.]

21 MS. ALLEN: Under disposal of specific wastes,
22 we've added I-125, authorizing people to get rid of I-125.
23 It also -- I don't know if you can tell, but the liquid at
24 the bottom is crossed off. We allow disposal of iodine,
25 carbon and tritium, per gram of medium for scintillation

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1 counting to be disposed of.

2 That way you can get rid of the test tubes and
3 everything without having to dump everything out and just
4 get rid of the liquid part.

5 Another change that we made was the reports of
6 individual monitoring NRC's Part 20.2206. It requires
7 certain licensees to file annual exposure reports to NRC.
8 We don't have the money to deal with these reports being
9 sent to us and there's no requirement that we get them and
10 send them to NRC. It's not a matter of compatibility, so we
11 dropped it.

12 That's it for the slides. Steve mentioned the
13 authorization to do effective dose equivalent calculations
14 for people wearing aprons. I feel like David Letterman. We
15 came up with ten reasons why we didn't want to do this.

16 Number ten. It was unclear on how to maintain
17 these records. Can you just write the indication on the
18 film badge record that you did this or should a separate
19 record be developed and maintained indicating what kind of
20 calculations you did?

21 It's much easier for the inspectors if everyone is
22 just held to five rem in a year. The inspectors can just
23 look and say, oh, here's something that's 4.9, here's a six,
24 gee, that's a problem. It's not clear that there is a need
25 to allow calculations.

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1 Since there is no quarterly reporting limit
2 anymore, some people in our x-ray department have said, yes,
3 there's a lot of incidents of overexposures, but with the
4 five rem limit in a year, you're not going to see that
5 anymore. It's mostly because people, for a particular
6 quarter, have shot over their quarterly dose.

7 Number seven is calculations have not been
8 sanctioned by an international agency. Number six, ICRP is
9 working on guidance documents for weighting factors for
10 external doses. We'd rather see some guidance document from
11 an international agency before we would put this in our
12 regulations.

13 Number five, the calculations don't apply or have
14 not been shown to apply to every energy and configuration
15 for a specific set of circumstances. It's too easy for
16 people to sort of expand that as time goes by.

17 Number four, we would rather entertain requests on
18 a case-by-case basis. It's up to the licensee or registrant
19 to apply for approval to do that. We don't see a problem
20 with referencing the particular document in the Health
21 Physics Journal, but we'd also like to evaluate how they're
22 doing their calculations.

23 Number three, automatically authorizing people to
24 do this, to do the calculations, some people don't think our
25 registrants are very nice. They think that we'll be

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1 rotating people through.

2 For example, if you've got a tech that is getting
3 pretty high to a particular dose, you'll just rotate them
4 through Fluro, have them wear a film badge and say, well,
5 now we can change out their doses and recalculate them, and
6 so this particular tech can stay.

7 Number two, the badges could get mixed up.
8 Although we did like the yellow-belly red-neck combination,
9 what if you only have green and blue? We felt that it was
10 uncertain. There's a good chance that the badges could get
11 mixed up.

12 Our number one reason for not accepting this was
13 there was no guarantee an apron would be used during the
14 entire time that the film badges were being worn. Most of
15 them do it for every procedure, but if this person is on
16 rotation through different departments, does that mean that
17 every time they do anything else, they have to wear the film
18 badge in order to take advantage of these calculations.

19 That's all I had. Are there any questions?

20 [No response.]

21 MS. ALLEN: Oh, good. They all agree. Terry
22 wanted to know if we would provide copies of our regulations
23 to states that request it. I'm getting a nod yes, we would.
24 Of course.

25 MR. BAILEY: Ed Bailey from California. I've just

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1 got one question. Why did you choose to strike out
2 controlled rather than restricted? California has not had
3 restricted areas ever. We've always had controlled and now
4 we're going to have to change everything. Could we flip,
5 two out of three or something?

6 MS. ALLEN: We thought of you and that's why we
7 wanted to do it.

8 [Applause.]

9

10 DEALING WITH AN UNDECLARED PREGNANT WORKER

11

12 MS. ALLEN: I will switch gears, then. Sorry if
13 you're bored of listening to me. I could change my voice.
14 Now, consider this next talk an exercise in separating out
15 your emotions from what the rules say.

16 One thing I did not mention is that Part 20
17 requires notification -- for a declared pregnant worker, you
18 must declare that you are pregnant and inform your employer
19 of the estimated date of conception. For some people, they
20 don't know the date of conception at the time that they wish
21 to inform their employer.

22 For example, people take home pregnancy tests.
23 They say, oh, the stick is blue or whatever and they decide
24 to go in and tell their employer that they're pregnant. It
25 may be a couple months before they get a doctor's

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1 confirmation of estimated date of conception.

2 These licensees should still be required to try
3 and limit the dose if the woman has decided to declare
4 herself as being pregnant. It shouldn't have to wait for
5 both pieces of information to come together before that
6 woman is officially declared a pregnant worker. We don't
7 think this is a very practical problem, but we decided we
8 would just make it clear in our regs.

9 The recordkeeping requirement still requires you
10 to eventually get a date of conception, and that may be
11 after the birth, then you subtract nine, and say, well, that
12 was it. Having been a licensee and having to deal with
13 exposures and trying to develop programs for exposures to an
14 embryo/fetus, I was very glad to see the limits in the new
15 Part 20. Finally specified in the regulations these are the
16 limits.

17 Having been a female watching the Johnson Controls
18 case, I was also glad to see that the declaration of
19 pregnancy was an option for the female worker. I thought
20 these changes were rational, straightforward, good
21 approaches to a problem that many licensees have been
22 dealing with for years.

23 But I know, based on previous experiences, that
24 employers tend to be overly protective of their employees
25 who are pregnant. We're in such fragile states, you know.

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1 I didn't anticipate that I'd be standing here talking about
2 Part 20 and declared pregnant workers.

3 I had an opportunity to meet with Commissioner
4 dePlanque at one time and at lunch, she said, so, what do
5 you all think about declared pregnant workers. And we said,
6 well, that's a pretty good concept, it'll take some
7 adjusting to. And that was pretty much the end of the
8 discussion.

9 If I knew then what I know now, we'd still be
10 eating lunch and talking about this. An indication of some
11 of the problems, there's a July 28, 1992 memo, NRC memo from
12 Frank Congel, Office of Nuclear Reactor Regulation, and
13 Richard Cunningham, NMSS. The discuss a particular power
14 plant's requirement that a woman inspector sign a statement
15 acknowledging an administrative dose limit that is
16 discriminatory.

17 An example attached to that memo indicates that if
18 you are a fertile female, you are limited to a 500 millirem
19 dose per calendar quarter. No dose restrictions for men.
20 If you are incapable of having a child, you may provide a
21 signed acknowledgement to void that particular policy.

22 This policy also doesn't mention what happens if
23 you sign a waiver saying that you're not a fertile female
24 and you end up pregnant sometime down the road, what kind of
25 repercussions there are.

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1 Also attached to that memo is a copy of another
2 memo dated March 4, 1992, detailing an event where a female
3 inspector was asked to sign a statement that she was not
4 pregnant before gaining access to conduct an inspection.
5 This memo states that denial of access is a violation of the
6 rules allowing unfettered access to NRC employees, following
7 proper ID and compliance with "applicable access control
8 measures for security, radiological protection and personal
9 safety."

10 One of the questions I raise is what if the
11 control measures that the licensee wants to put in place
12 require that all female employees or all females visiting a
13 site go through extensive training, basically taking 8.13
14 and expanding it to three or four hours worth of training.

15 Well, sure, we'll let you on-site. We're not
16 restricting your access, but you must sit here and read this
17 document, watch this training video, answer a bunch of
18 questions. You could almost expand it for a whole day. How
19 would NRC or our particular agencies respond if a licensee
20 were to put up this block in front of us?

21 What if the inspector wishing to gain access was
22 obviously pregnant? It shouldn't matter whether she's
23 declared or not. If declared, you're watching the dose so
24 that it doesn't exceed 500 millirem during the gestational
25 period. If undeclared, it shouldn't matter. If you've

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1 decided that you can perform your duties or your employer
2 has decided you may perform your duties, you should be
3 allowed access to that particular facility.

4 What if one of our inspectors, declared or not,
5 were to try to perform an inspection at a licensee's
6 facility and was completely denied access? Steve and I had
7 an opportunity to go down to one of the facilities that was
8 decommissioning in our state. Steve informed them that I
9 was pregnant and they said, well, gee, she can't come, we
10 don't allow pregnant workers on-site.

11 Steve informed them that I was not declared
12 pregnant, I just happened to be pregnant. I was not one of
13 their employees. I was one of his, and, therefore, I was
14 still coming. I was also going to the cleaned up area to
15 take confirmatory samples. Therefore, I shouldn't have
16 gotten any exposure, so I don't know what they were so
17 worried about. Maybe we'd find something, I suppose.

18 We also had another inspector who went to another
19 site that was being decommissioned to do more confirmatory
20 measurements. We got several phone calls at the department
21 saying what are you doing sending a pregnant worker to this
22 facility, she shouldn't be allowed here.

23 Well, we're not really worried about her exposure.
24 We're just worried about her climbing around on the bricks.
25 Yeah, yeah, we're worried that she might fall or something.

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1 Well, we've resolved that situation. She gave birth, so
2 she's no longer a problem, I suppose.

3 If a licensee sees a female inspector coming up
4 and says you may not have access, I'm sorry, our rules, our
5 procedures say absolutely not, what's the worst that can
6 happen? From the licensee's standpoint, they take the hit,
7 they pay a fine, maybe a thousand dollars. Would that be
8 cheaper for them in the long run than possibly being named
9 in a lawsuit?

10 I'm not necessarily agreeing with any of these.
11 I'm just putting ideas in your head to think about. Each
12 licensee has the right to hire lawyers, and, believe me,
13 they do. They advise the companies on which lawsuit they
14 want to fight.

15 Would they prefer the lawsuit discriminating
16 against a pregnant worker or would they rather have the
17 harmful exposure lawsuit? They would rather litigate than
18 cooperate, I think. Yesterday, we heard many examples of
19 licensees that just keep hiring lawyers and throwing them in
20 our way. This is just another issue that they may decide
21 would be worth fighting in court rather than allowing a
22 worker to be potentially exposed.

23 This all sort of came to a head. I was told FEMA
24 had problems with pregnant employees participating in
25 exercises. Since drills are supposed to be observed as real

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1 events, you're supposed to assume there's real radiation out
2 there, real radioactive material in the air; therefore, real
3 pregnant women shouldn't be really participating in a real
4 type of emergency.

5 Well, I didn't agree with that, so I fought that.
6 Drills are supposed to be training exercises and you
7 shouldn't be restricting training to employees based on
8 their status. My job on the emergency team is sitting in
9 the back of a Winnebago and telling people where to go to
10 take samples. I didn't think I was in much danger.

11 But what are your state policies? Do you allow
12 pregnant employees to participate in drills? Do you allow
13 them to participate in training exercises, declared or not?
14 What would you do in a real emergency? Drills aside, now if
15 you've got a real emergency and you have to start calling
16 somebody, who are you going to call?

17 Are you going to call only undeclared pregnant
18 workers? Are you going to restrict and say, well, gee, I
19 know Kathy's pregnant, I certainly wouldn't want to send her
20 out on an emergency, so I just won't call her. Well, that's
21 not fair either, because how would you know who is pregnant
22 and who isn't. For a while, you didn't know I was. Now
23 it's pretty obvious, I suppose.

24 How do you deal with other emergency workers that
25 are not in your control? For example, our state has a

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1 program where we go to the counties and do training for the
2 county people who are responding. How do you deal with Red
3 Cross volunteers that show up pregnant and may be dealing
4 with contaminated victims?

5 How do you deal with traffic officers standing in
6 the plume directing traffic to evacuate a particular area?
7 How do you deal with bus drivers that have decided that
8 they'll go in and evacuate a school full of children?
9 Should we include this kind of training with the counties?

10 We already tell them the hazards involved with KI
11 and the reason that we may be distributing it. Why not
12 include this part in the training?

13 I've talked to many HPs, friends, whatever, and
14 I've said if I got a call, I would probably go and respond.
15 This makes everybody's emotions just go nuts. How dare you
16 expose that child to radiation? I do it for two reasons.
17 One is I feel I've been trained enough to make that decision
18 and I can evaluate the situation and may or may not go.

19 The second is just to bug people, I suppose. Many
20 professionals have stated, well, gee, you've got to stay
21 below 500 millirem if you go to an emergency and, you know,
22 that's going to be really tough, we're going to have to
23 watch your dose separately. And I have to remind them that
24 Part 20 does not apply to emergency workers and that
25 includes the dose to the embryo/fetus.

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1 As a last resort, when they try to convince me I'm
2 wrong, they say, well, what would your husband think. I
3 tell them my husband is a CHP and he believes what I say.
4 One last thing to consider. Long after the baby is
5 delivered, some women to continue to breast feed for many
6 months, some people do it for years, it seems.

7 We're very concerned about misadministration,
8 administering iodine to patients that may be breast feeding.
9 We don't consider emergency workers that are breast feeding
10 that may be exposed to iodine, as well. I'm not saying we
11 need to change it, just thought I'd give you something to
12 chew on.

13 Any questions?

14 [No response.]

15 MR. FRAZEE: All right. I want to thank the
16 panelists and I think we should give them a round of
17 applause.

18 [Applause.]

19 MR. FRAZEE: It appears that Vandy is coming to
20 close us out.

21 MR. MILLER: Another great panel. Let's give them
22 one more big hand.

23 [Applause.]

24 MR. MILLER: Whether declared or undeclared, we
25 are ready for lunch. See you back at one.

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1 [Whereupon, at 12:00 p.m., the meeting was
2 recessed for lunch, to reconvene this same day at 1:00 p.m.]
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AFTERNOON SESSION

[1:08 p.m.]

1
2
3 MR. MILLER: If we could move to our seats, we'll
4 get ready for the afternoon session. Before we get started
5 with the afternoon session, let me just mention that we are
6 meeting with a few states during this meeting on a stand-up
7 type meeting basis.

8 In fact, we had one immediately when this session
9 starts. I just got out of another meeting at lunchtime. So
10 if we have not contacted you as a representative from your
11 state and you feel that you have something that you need to
12 discuss with us, see your agreement state officer.

13 We gave the agreement state officers at least ten
14 states that we would like to meet with quickly and they have
15 already contacted you individually. But if there is a state
16 and you have not been contacted and you would like to meet
17 with us, let your agreement state officer know about that
18 and we'll try to find a place to squeeze you in.

19 Tomorrow at noon, when you break with your
20 business meeting for the morning, we will then, our staff
21 will meet with the agreement staff, and the agreement state
22 staff, as we see it, is the past President or the past
23 Chair, the current Chair, and the Chair-elect. So those
24 individuals will be meeting with us in the Presidential
25 Suite at lunch tomorrow.

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1 I've asked each one of them to give me their menu
2 so that we could order your lunch and have it delivered at
3 that time. That is a dutch treat, by the way. I tried to
4 get Carl to pay for it, but he left his charge plate at
5 home. And I've never had one, thank you.

6 Now, this brings us to the afternoon session. I
7 must say that Lloyd Bolling deserves an awful lot of credit
8 because when he and Dennis Sollenberger were working on this
9 agenda, I said to them things are not making good sense
10 here, let's go back and look at whether everybody has
11 requested to be put on the agenda for this year and make it
12 make more sense.

13 But even at the end, I was not too comfortable.
14 But to tell you, so far, it looks like we really did include
15 some very important topics for you and they were based on
16 your desires, by the way, and that goes to prove that two
17 heads is better than one, because you certainly have given
18 us some good topics. So far, we have really had some very
19 fruitful discussion.

20 That leads us to this next fine panel, which is
21 headed up by Bob Kulikowski. He's going to Chair this panel
22 titled Materials Regulation. As you well know, Bob is not a
23 stranger to the group either. However, he has been moved up
24 a notch since he appeared before you last. He is now the
25 Director for the Bureau of Radiological Health, City of New

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1 York. Bob?

2

3

MATERIALS REGULATION

4

5 MR. KULIKOWSKI: Thanks, Vandy. As you can see,
6 we have a rather small panel. So I think we will -- I've
7 already talked to Lloyd and to Virgil Autry and what we'll
8 try to do is we'll probably break a little bit early, unless
9 there's a really heated discussion, and maybe we can get the
10 second afternoon session going a little bit earlier, maybe
11 ten or fifteen minutes earlier this afternoon so we can all
12 -- because that's a long panel and it will give us adequate
13 time for that, as well.

14 When Lloyd called me a couple of weeks ago, his
15 first words when he ascertained that it was indeed me on the
16 phone, said "I need a volunteer." And I knew exactly what
17 that meant. I didn't have much of a choice. And a couple
18 of days later, I got the fax of the tentative program and I
19 was sort of gratified to see that -- I thought it was ironic
20 that both topics, both general licenses and transportation
21 were the two topics that were going to be discussed, because
22 these were both of considerable importance to New York City
23 right at the current time.

24 Transportation especially since with the
25 decommissioning of Shoreham, we're getting ready to ship all

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1 the irradiated fuel back off of Long Island, through New
2 York City and down to a reactor in Mexico.

3 So I thought it was pretty ironic that two things
4 that were sort of near and dear to my heart right now or at
5 least that we're very involved in appeared on the agenda.
6 The other thing I wanted to say, I wanted to -- in honor of
7 Joel Lubenau and Jack Hornor, I've worn my transportation
8 tie with trains on it today. Notice that I also happened to
9 match groups. So there's a little bit of everything for
10 everybody.

11 Most of you need no introduction to Ruth McBurney.
12 Ruth is the Director of the Division of Licensing,
13 Registration and Standards, Bureau for Radiation Control,
14 Texas Department of Health, and Ruth has a Master's degree
15 in Radiation Science from the University of Arkansas is a
16 certified health physicist.

17 And even though she wrote down how long she's been
18 with each of the programs, she also, like Steve Collins, has
19 skipped around and, actually, before -- just before I got up
20 here, she said Steve and I were classmates at the University
21 of Arkansas. So I won't mention how long she's been around
22 because it really shocked me, because I thought she was just
23 a recent graduate.

24 So without further ado, lovely Ruth McBurney.

25 MS. MCBURNEY: I paid him to say that.

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1 MR. KULIKOWSKI: No, she didn't.

2
3 GENERAL LICENSE TRACKING SYSTEM
4

5 MS. MCBURNEY: I've been asked to talk a little
6 bit about general license tracking. I guess it's because
7 this is another area that Texas is trying to take a little
8 bit different approach on in rulemaking.

9 Seems like we've been out on several limbs lately
10 in the area of radiography and NORM and so forth. So I was
11 glad to hear Kathy this morning talking about their
12 experiences in taking the first step and applying the Part
13 20 regs to the state program. So maybe they've done a lot
14 of the weeding out of the problems in being the first out on
15 the limb on that.

16 But what I would like to talk about today is the
17 approach that Texas is taking to address the gray area of
18 the general license concept. As most of you know, the
19 general license was established, by rule, as an aid to allow
20 manufacturers to provide a product to customers without
21 having to go through the rigors and delays of a specific
22 license.

23 Also, end users of their product did not have to
24 have any radiation safety experience or training.

25 [Slide.]

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1 MS. MCBURNEY: Under the manufacturer's specific
2 license to make and distribute these devices, the AEC and
3 now the NRC or agreement state would evaluate each device
4 proposed for general license distribution for more than
5 adequate shielding and inherent safety features and user
6 instructions were adequate, and that during normal use of
7 the device, the worker would not be exposed to a
8 radiological hazard.

9 [Slide.]

10 MS. MCBURNEY: You can flip on through the next
11 ones. These are just some pictures of many various general
12 license devices that we are referring to; level gauges, flow
13 gauges, and so forth.

14 [Slide.]

15 MS. MCBURNEY: Over the years, this premise has
16 held up relatively well. These type devices have withstood
17 fires and explosions without a total loss of shielding.
18 They've been damaged by heavy equipment accidents and molten
19 steel with only minor losses in radiation shielding, while
20 maintaining the integrity of the field source of radiation.

21 However, there have been a number of occurrences
22 where generally licensed radioactive material had not been
23 properly handled or disposed of, resulting in radiation
24 exposures to the public, and you probably heard about
25 several incidents where general license devices were either

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1 -- got into scrap and were melted down or something like
2 that, or were lost.

3 The State of Texas and the U.S. Nuclear Regulatory
4 Commission conducted separate surveys of general licensees
5 within their respective jurisdictions. You've probably seen
6 the results of the NRC survey.

7 By using the quarterly reports filed by generally
8 licensed device manufacturers and distributors, the two
9 agencies contacted general licensees throughout their
10 jurisdiction about the device disposition, leak testing,
11 labeling, regulations and so forth.

12 [Slide.]

13 MS. McBURNEY: Basically, the findings of the two
14 groups agree in three major areas. One, there exists a lack
15 of awareness among the general licensees, both regulatory
16 and inventory. Secondly, there is inadequate handling and
17 awareness and there is an existence of a potential for
18 accidents.

19 Though both studies indicate further agreement,
20 for the sake of this presentation, I'm going to limit it to
21 the results of the Texas survey.

22 [Slide.]

23 MS. McBURNEY: We found that 10.9 percent of the
24 devices had not been properly leak tested, 11.3 percent of
25 the devices were not labeled as containing radioactive

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1 material, 17 percent of the devices had been transferred to
2 another license, none of those had the proper transfer
3 reports filed.

4 18.3 percent of the devices had been moved from
5 where they were installed. 43.3 percent of the devices did
6 not have a radiation survey on file with the general
7 licensee, and a whopping 87.8 percent of the general
8 licensees did not have a copy of the rules and regs
9 applicable to generally licensed devices. And 10.3 percent,
10 that's 24 out of 232, of the devices that we surveyed could
11 not be found.

12 Other problems that we've encountered with the
13 quarterly reports since trying to track all of our general
14 licensees have been incomplete addresses. The device model
15 numbers were not indicated or did not correspond with what's
16 in the registry. The contact person was not listed or they
17 had multiple contacts listed for the same company.

18 If there were serial numbers listed on the
19 quarterly report, we could not tell if it was for the device
20 or the source. We've had several problems with maintaining
21 good accountability and in keeping up with who's in
22 possession and the final disposition of the devices has led
23 us to rethink the regulations in this area.

24 Since February 1990, we've formulated and are
25 carrying out a general licensing plan.

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1 [Slide.]

2 MS. McBURNEY: The plan has noted that the need
3 existed to establish a representative licensing system for
4 general licensees.

5 So the first goal of the program was to provide
6 the general licensees with a letter informing the licensee
7 of their responsibilities under our regulations and the
8 general license. The second objective was to establish a
9 database for future contact purposes and for possible use in
10 the event of recall notification of a particular device.

11 The third intention was to establish a fee
12 commensurate to the amount of regulatory costs. That's very
13 important. The fourth goal was to modify the regulations
14 for inclusion of the issuance of a document, what we call a
15 general license acknowledgement, similar to what we did for
16 in vitro general licensees currently.

17 The final objective was to designate a program to
18 carry this out in our division.

19 [Slide.]

20 MS. McBURNEY: In August of 1990, an
21 implementation strategy was added to the plan, stating that
22 after the adoption of rules, all general licensees entered
23 in the database would be notified of the requirements,
24 general license acknowledgements and fees assessed.

25 New general licensees would be required to obtain

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1 a general license acknowledgment and pay the appropriate
2 fee. In September of 1990, an employee was added to our
3 Industrial Uses Program in our Licensing Branch to direct
4 this program.

5 To date, only the database goal has been realized
6 and the other objectives must wait until we get the rules
7 adopted by the Texas Board of Health. However, we have
8 developed or have done some initial development on the
9 general license acknowledgement application, regulatory
10 guide, and the general license acknowledged certificate.

11 We currently have 978 general licensees in our
12 database possessing 2,721 general licensed devices. These
13 numbers are not accurate, by any means. As I mentioned
14 earlier, there are deficiencies in the quarterly report
15 information and we know that probably a lot of these have
16 now gone out of business, and those we don't know about,
17 either, because they have not reported how they disposed of
18 the general licensed devices.

19 [Slide.]

20 MS. MCBURNEY: The licensing of the general
21 licensees will be done practically the same as I mentioned
22 earlier, general license acknowledgement of in vitro
23 licenses and as registration of users of x-ray equipment.

24 When the general licensee accepts delivery of the
25 general licensed device, the manufacturer/distributor would

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1 furnish them a copy of the rules, including our new general
2 license section of the rules, with the device.

3 That would happen and then they would be asked to
4 submit an application within 30 days. It's our intent that
5 if the rules pass to inform the manufacturers of the general
6 licensed devices of our new requirements and to provide them
7 copies of our application form to be distributed along with
8 our rules.

9 If this is accepted, we will use the quarterly
10 reports then. If we do not get them through this mechanism,
11 then we will use the quarterly reports to solicit other
12 applications.

13 [Slide.]

14 MS. MCBURNEY: After the acknowledgement is
15 issued, it would be amended just like a specific license or
16 the in vitro general license acknowledgement and be renewed
17 every five years.

18 This may cause some concern in the area of
19 compliance because we do intend to inspect these, as well.
20 We put them on some sort of inspection interval, probably
21 not real often, but that is certainly causing some concern
22 for Richard Ratliff, our Chief of Compliance, because he may
23 have to add some personnel to get out there and do
24 inspections at all these general licensees, even if they're
25 four or five years apart.

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1 But we hope that our approach to general license
2 tracking will be successful in maintaining regulatory
3 contact and in keeping track of the general licensees, of
4 those that have the general licenses, and also that they do
5 have responsibilities under that.

6 We think that the general license acknowledgement,
7 the annual fee and routine inspections will go a long way to
8 accomplish that. We will be seeking input on our draft
9 rules from interested persons, and that includes other
10 regulatory agencies. So if you get a copy of our draft
11 rules in the mail, we'd appreciate any comments that you
12 might have as we approach this mechanism.

13 Right now, our general license acknowledgement fee
14 for in vitro, the ones we do have in place, is \$80, someone
15 had asked me earlier. But as always, we are having to
16 reevaluate our fees based on current costs. So that may
17 change in the near future.

18 Those are all my comments. If you have any
19 questions, I'd be happy to answer them.

20 MR. QUILLIN: Ruth, this is not a question. It's
21 Bob Quillin from Colorado. It's really a statement directed
22 more at our host here, the Nuclear Regulatory Commission.

23 Earlier this year, the Nuclear Regulatory
24 Commission tried to suspend, I think it was, the license of
25 a manufacturer of generally licensed devices. As part of

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1 that action, they attempted to order this company to no
2 longer receive sources back that they had previously sold.

3 This presented an interesting challenge in
4 Colorado because we had two licensees, interestingly enough,
5 one NRC licensee and one state licensee, who were major
6 users of this particular device.

7 I wrote the NRC about this situation of them
8 unilaterally putting general license manufacturers out of
9 business, putting the criteria on them that affected
10 agreement states, and I never did get a reply. But talking
11 to one of our local low level waste brokers, in this
12 particular case, he told me that if the licensee now had to
13 dispose of these sources, it would cost them around a
14 thousand dollars to dispose of two sources.

15 We had one licensee who had 50 or 60 of these
16 sources. So there's another issue on this, which is the
17 eventual disposal of these sources and how the NRC can
18 affect that disposal by actions they take unilaterally.

19 MS. McBURNEY: That is an interesting comment.

20 MR. KAYSK: George Kaysk, New York State
21 Department of Labor. I was recently advised by a
22 manufacturer from Texas that their devices are approved for
23 transportation -- generally licensed devices -- for
24 transportation out of the installation all over the State of
25 Texas, and they demanded reciprocity from us.

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1 Is that true or not?

2 MS. MCBURNEY: We do have, I think, a few devices
3 that are portable that are generally licensed.

4 MR. KAYSK: Well, I'm talking about portable
5 devices, but these people have no procedures on hand. They
6 have no transportation regulations. They don't understand
7 it. They don't know how to store the gauges properly in the
8 field.

9 Besides, that is in contrast to our other people
10 who have different gauges and have to pay a fee and have to
11 have a manual.

12 MS. MCBURNEY: I would think that to get
13 reciprocity, you would have to have a specific license.

14 MR. KAYSK: That is our contention. But they are
15 very adamant about running around with generally licensed
16 devices all over the state.

17 MR. GODWIN: Godwin, Alabama. There are a few of
18 those -- you're still awake. Excuse me, Kirk. There are a
19 few of the devices that are mounted on skids or whatever you
20 want to call them. They're floating around the country and
21 it's a real problem, both in the general license area and to
22 somewhat less a degree in the regular specific license.

23 For example, on a barge, in some cases, and go
24 charging off around, it's distributed to a barge in Alabama
25 that ended up in Louisiana, passed sort of vaguely through

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1 Tennessee. Have they changed general licenses? Is there
2 different notification? Those things like that sort of crop
3 up.

4 I think we really ought to look at urging the NRC
5 to revise their regs, because many of us just copied theirs,
6 as well as revising our regs to note allow this portable use
7 for these density type gauges. It might be acceptable for
8 some of your static eliminator types and some of your things
9 that are put into aircraft, but we ought to really look at
10 these 100 millicurie to two curie cesium sources that are
11 floating around in this travel mode, particularly since it's
12 very difficult to determine if they meet the DOT
13 requirements for travel.

14 MS. MCBURNEY: I think that's a good thought. I
15 think the original thought on GL devices was that they were
16 going to stay in one place and only be used in that
17 location. So I think we do need to rethink that as far as
18 not allowing them to be portable or fixed on portable
19 things, like barges.

20 MR. FRAZEE: Terry Frazee, State of Washington.
21 You mentioned an inspection frequency that might be on the
22 order of four or five years. That's about the frequency we
23 do with our specific licensees, fixed gauges. We've
24 discovered, unfortunately, that even that's not often enough
25 for specific licensees; lost a gauge because the company

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1 changed hands several times and people disappear and the
2 gauge is gone.

3 I guess with reference to the general license, did
4 you give any thought to doing something similar to --
5 actually, it's Oregon that has a program of inspection by
6 mail, sending out maybe an annual letter to the licensee,
7 general licensee, saying do you still have the gauge.

8 MS. MCBURNEY: I would think that the annual fee
9 will sort of take care of some of that. Not so much on the
10 inventory, but we could include something like an inventory
11 check at that time. But at least we'll have some sort of
12 annual contact with that general licensee through the fee.

13 If they've gotten rid of all of them, they're
14 going to let us know at that time.

15 MR. FRAZEE: Except that depending upon the size
16 of the company, if you're sending the invoice to their
17 billing department, if it's a big enough company, they just
18 pay it and the people that really have the gauge may not
19 know about it.

20 MS. MCBURNEY: That's a good point, too. That's
21 another problem we're having with our fees, is the contact
22 person may or may not be the same person as the person that
23 gets the fee invoice.

24 MR. HILL: Tom Hill, Georgia. Ruth, we spent
25 three or four years off and on, with summer help, cleaning

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1 up and establishing a database for our general licensees.
2 Finally, we got them cleaned up a little bit, but the best
3 cleaned up we got was when that first invoice went out.

4 MS. MCBURNEY: Right.

5 MR. HILL: And the ones that didn't have the
6 material, they said we don't have it, we said where did you
7 transfer it to. Most of them, not all, but most of them
8 could provide us that information.

9 The ones we have trouble with is that ten percent
10 that you have there that you couldn't find. The invoices
11 were returned. Those were the ones that were difficult to
12 track down and try to come up with what was going on.

13 MS. MCBURNEY: Right.

14 MR. LUBINSKI: John Lubinski with NRC. A question
15 about your costing. You had said that you weren't sure as
16 far as an inspection what kind of additional manpower you
17 would need. Do you have any projections on that, as well as
18 projections for maintaining the database, as well as
19 processing the paperwork which will come in for these
20 acknowledgements?

21 MS. MCBURNEY: As far as from the licensing end, I
22 think that we feel that our one full-time person just
23 dealing with the general license program will be enough for
24 that. We have asked for three additional persons in the
25 inspection division to cover all that we have in the state.

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1 MR. LUBINSKI: Also, you had mentioned that the in
2 vitro licenses, there was right now an annual fee of \$80.
3 Is that per general license? Do you plan on applying that
4 per general licensee or would that be per device that the
5 general licensee --

6 MS. MCBURNEY: Per general licensee. If you look
7 at, like, the way we do other specific licenses, most of the
8 cost is in just the licensing and the inspection time and so
9 forth. The number of devices won't make that big a
10 difference. So it would be per location.

11 MR. LUBINSKI: One last question. Do you foresee
12 a breakdown in different costs for people having devices
13 such as exit signs, where someone may only have one or two
14 exit signs and they would be --

15 MS. MCBURNEY: We're not going to do exit signs.

16 MR. LUBINSKI: Not at all?

17 MS. MCBURNEY: No.

18 MR. PARIS: This is Ray Paris from Oregon. Our
19 inspection-by-mail program is very effective and I'd be
20 certainly willing to share our form with anybody who would
21 be interested.

22 MS. MCBURNEY: Yes.

23 MR. PARIS: If you'll give me your business card,
24 we'll send you a copy of the form. It's effective.

25 MS. MCBURNEY: I see Richard taking his card out

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1 now.

2 MR. BAILEY: Right, Ed Bailey from California. We
3 are going to -- we have rules now being proposed and we are
4 going to charge for exit markers, too, but we're going to
5 charge the distributor upfront and we automatically register
6 them when they come in rather than the other way around.

7 We've run into some interesting situations where
8 people are trying to get rid of, like, 200 exit markers at
9 one time and, at 20 curies apiece, that's a considerable
10 amount of tritium, even. We don't intend to inspect them,
11 but to put the money into a fund to be used to dispose of
12 ones that we can't get rid of or that crop up later and that
13 sort of thing.

14 MS. MCBURNEY: That's a good point.

15 MR. ALLEN: One final question. Part of your
16 comments there sounded -- Gerald Allen from Kansas. Part of
17 your comments there sounded to me like a fairly good load on
18 the manufacturer in terms of getting the regulations to
19 their user and getting the application to their user.

20 Have you gotten support from the manufacturers in
21 Texas for that?

22 MS. MCBURNEY: Obviously, we haven't had too much
23 success in them just getting the regulations, as we saw by
24 the survey, but we're really going to make an effort to
25 educate and put a little pressure on them to get that out

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1 for us.

2 MR. ALLEN: Have you talked with them about that
3 so far or is that --

4 MS. MCBURNEY: We have talked with the ones that
5 are in-state.

6 MR. ALLEN: But not out-of-state.

7 MS. MCBURNEY: Right. Anything else?

8 [No response.]

9 MS. MCBURNEY: Thank you.

10 MR. KULIKOWSKI: Thank you, Ruth. That was our
11 penultimate speaker. Our ultimate speaker is John Cook, who
12 was educated in health physics at the University of Michigan
13 and currently works for NRC in NMSS.

14

15

TRANSPORTATION

16

17 MR. COOK: Thank you, Robert.

18 [Slide.]

19 MR. COOK: I have some copies of these visuals in
20 the back of the room in case you find it difficult to take
21 notes, if you feel needed, in the lower light here.

22 [Slide.]

23 MR. COOK: This afternoon, the topics I'd like to
24 cover are transportation regulations, just in a very broad
25 sense, just enough to give you a flavor for the distinction

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1 between NRC and DOT.

2 [Slide.]

3 MR. COOK: Quality assurance programs. There I'd
4 like to look at the question about when NRC registration is
5 required and when an NRC QA program is required for
6 transportation. Then, lastly, some recent Department of
7 Transportation requirements that DOT put out this past
8 summer. These requirements were issued by DOT under their
9 Hazardous Materials Transportation Uniform Safety Act, or
10 HUMTSA, as they like to call it at DOT.

11 We are advising our licensees of these
12 requirements and we thought that you might be interested in
13 them, as well.

14 [Slide.]

15 MR. COOK: Looking at the transportation
16 regulations, first, the transport of radioactive materials
17 is governed at the Federal level -- or as it's governed at
18 the Federal level, is jointly shared between DOT and NRC.

19 DOT has most of this responsibility. They have
20 the carriage, the routing, the driver training, emergency
21 response information requirements, shipping papers, the list
22 kind of goes on and on. The NRC has kind of a small subset
23 of this, and that is the packaging for large quantity
24 radioactive material, the packages.

25 Where you find the rules for the two agencies,

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1 DOT, as it shows there, is in Title 49. Part 173.400 has
2 most of the radioactive material transportation
3 requirements. Our regulations are in 10 CFR Part 71.

4 We impose on our licensees the DOT requirements
5 through a provision in 71.5. That allows us to inspect our
6 licensees against DOT's transportation requirements. It's
7 not that the DOT requirements wouldn't apply. This gives us
8 the capability to inspect our licensees against whether they
9 have complied with DOT rules.

10 With respect to packages, under a memorandum of
11 understanding that we have with DOT, they have the smaller
12 quantity or Type A package designs, while NRC issues the
13 certificates of compliance for the larger quantity or Type B
14 or fissile material package design.

15 So basically this is kind of the split between the
16 two. DOT, if this package is out in carriage and being
17 transported, it's a DOT area. With respect to the design
18 for the larger quantity packaging, that's with us at NRC.

19 [Slide.]

20 MR. COOK: Turning to the states with respect to
21 transportation, the agreement states impose Title 49 through
22 the suggested state regulations for interstate shipments,
23 and interstate shipments are, of course, subject to 49 CFR
24 through that Act itself.

25 Since 49 CFR does not require NRC Part 71 QA

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1 programs, most agreement state licensees are not subject to
2 Part 71 and do not require QA plans. But through Part 49,
3 which does apply to agreement states, they do need to
4 register with us for the use of an NRC certified package.
5 Now, there's no fee required for package registration, but
6 that is a requirement for anyone transporting an NRC-
7 certified package, be you an agreement state, non-agreement
8 state, what have you.

9 In most cases, there is not a requirement for an
10 NRC QA plan for agreement state licensees. The Commission
11 itself has 8,000 licensees and we only have about 400 QA
12 plans. But there are certain specific cases in which a QA
13 plan is required for agreement state licensees, and that's
14 what I'd like to look at next.

15 [Slide.]

16 MR. COOK: In looking at the title there,
17 agreement state licensees transporting -- in the sense of
18 using, as in a radiographer would -- NRC packages under
19 reciprocity, those are the agreement state licensees that
20 need NRC QA plans.

21 If you're transporting to an NRC jurisdiction, 10
22 CFR 150.20 applies. That's reciprocity. You are then
23 treated as if you were an NRC licensee, subject to 71.12,
24 and then you need to have the QA plan, a copy of the
25 certificate of compliance, comply, of course, with the

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1 certificate of compliance, and, also, this is where we
2 require transporters to register with us.

3 Again, there is no fee on the registration, but
4 there is for the QA plan. That's \$250, I believe, to have
5 it initially approved and then about \$1,700 per year
6 thereafter. So these are the instances in which you are
7 required to have a QA plan if you're an agreement state
8 licensee. Again, we're here talking about transporting and
9 using the material in a different jurisdiction, like a
10 r/...ographer would.

11 [Slide.]

12 MR. COOK: I would next like to look at what about
13 if you're only shipping; that is, you're going to ship this
14 thing off of your site. You're never going to see it again.
15 It's going to a distant destination. Take a look at that
16 briefly and then review again where the registration and QA
17 plan requirements are. So if we could look at this table
18 here, I'll try to summarize here.

19 Again, this is for agreement state licensees here.
20 You need to take a look at what's the destination that you
21 have in mind for the package here, an NRC-certified package.
22 You have different cases. You could be shipping intrastate,
23 you could be shipping interstate to another agreement state,
24 or interstate to a non-agreement state, two cases there, and
25 then shipping to an NRC licensed facility.

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1 If you look at the center column on shipping, if
2 that's all you're doing is just shipping this thing -- when
3 I'm saying you, I mean an agreement state licensee -- all
4 that's required is NRC registration. All that is required
5 is the registration.

6 But if you do get into the use, engaged in an
7 activity in an agreement state, for example, in the far
8 righthand column, let's look at that. If you are using that
9 certified package within your agreement state, again, it's
10 just registration. That's the top item in the far right
11 column.

12 If you are making an intrastate shipment to
13 another agreement state, again, NRC registration is the only
14 thing that is required. But if you are shipping to a non-
15 agreement state or to an NRC licensed facility, then
16 registration and the quality assurance program requirements
17 kick in.

18 So this box down there in the lower righthand
19 corner is really saying that's if you're working under
20 reciprocity there. All of the other instances, most cases
21 we've talked about previously, that in most instances, you
22 don't need a QA plan because, in most instances you're not
23 shipping outside of your state. Most people work within
24 their state, not shipping out.

25 [Slide.]

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1 MR. COOK: We have been talking so far about the
2 QA plans, when you're shipping them either intrastate or
3 interstate, for the use of packages only. Just to shift
4 subjects on you slightly. If you are involved not in just
5 using the package, but in fabricating, that is designing
6 them or fabricating them, for that activity, then you need
7 to come to NRC, where we review and approve these package
8 designs, and that process, the design and the fabrication of
9 certified Type B packages must be conducted under a QA plan.

10 This is a different one than the user plan that we
11 were talking about before. The QA plan here has a
12 significant fee associated with it. It's in the \$20,000
13 neighborhood. Again, this is only, though, for design and
14 fabrication, not simply for use.

15 Is there a place that you can go to find out,
16 well, I want to know who the registered users are, what are
17 the certificates of compliance, and who has quality
18 assurance programs, you can. That's NRC's NUREG-0383, and
19 it comes in three volumes and, in fact, it's published
20 annually and it should be available -- this year's edition
21 should be available shortly.

22 Volume 1 gives you a list of registered users by
23 the package type. Volume 2 is a compendium of all the
24 certificates of compliance, including what materials are
25 approved and other conditions for the use of the package.

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1 Then Volume 3 has a listing of the quality assurance
2 programs that have been issued to date.

3 That is the summary for the quality assurance
4 provisions.

5 [Slide.]

6 MR. COOK: The next topic is DOT's new
7 requirements, and just listing here for you what the
8 specific references and the Federal Register, if you want to
9 dig out the full text of the statement of considerations, as
10 well as the requirements of the rules themselves.

11 But both of these rules are in effect now. They
12 are in effect now and we're going to be issuing an
13 information notice, as I mentioned earlier, to summarize
14 these requirements for our licensees.

15 [Slide.]

16 MR. COOK: To look at them individually in a
17 little more detail. The first one requires employers to
18 train HAZMAT employees. This would require companies to
19 establish a program for HAZMAT employees to ensure
20 familiarity with the provisions of Title 49, the ability to
21 recognize the hazards that they're dealing with. This
22 applies to all hazardous materials.

23 What I'm synopsising for you here is that part
24 that pertains to radioactive materials. Knowledge of
25 specific requirements applicable to employee functions. I

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1 guess what that really means is that if you're the person in
2 the company that is responsible for blocking and bracing a
3 shipment so that it won't shift during transport, what this
4 provision requires is that you train that employee to block
5 and brace before he's allowed to perform that function.

6 Also, it would require a knowledge of emergency
7 response information and knowledge of how to protect
8 yourself from the materials that you're handling. Then
9 there are additional provisions in this requirement,
10 including that employees be not only trained, but tested on
11 what they've been trained; that carriers cannot carry
12 hazardous materials unless their employees have been
13 trained; and, of course, there is the usual recordkeeping
14 requirement that applies, as well.

15 You may wish to take a look at that in greater
16 detail.

17 [Slide.]

18 MR. COOK: Lastly, we have another new DOT
19 requirement, also issued this past summer. This is for a
20 shipper/carrier registration. It applies to anybody,
21 looking at the first item, who offers. So if you're a
22 person who is offering the material, you need to have a
23 registration, provided you meet one of the criteria just
24 below here, or if you transport the material.

25 For radioactive, the materials that trigger this

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1 requirement are highway route controlled quantity of
2 radioactive material. I guess that would be the lesser of
3 3,000 times the applicable A-1 or A-2 value or 30,000
4 curies, whichever is least.

5 The second trigger would be placarded shipments of
6 5,000 pounds or more. That probably will not involve too
7 many licensees. We seem to have identified reactors making
8 radioactive waste shipments as probably the most likely
9 candidates falling into that second category there. But
10 there are not many highway route controlled quantity
11 shippers.

12 But if you are subject to this requirement, then
13 you need to have a current DOT certificate on file, a
14 registration. The carrier must also be registered. He's
15 the person who transports the material. They would need to
16 be registered, each paying -- each party paying a \$300 fee
17 to the DOT. This was effective this past summer.

18 We are advising our licensees of this because our
19 licensees are subject to inspection by both DOT and NRC on
20 these points. So we're making this available to them.

21 That's really what I had for this afternoon. If
22 there are any questions, I'd be pleased to try to answer
23 those.

24 MR. KAYSK: George Kaysk, New York State
25 Department of Labor. I'm kind of puzzled about the

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1 rationale behind no quality assurance if it's in-state, but
2 the moment you go outside of the state, you have to have
3 quality assurance on the package.

4 Does it mean that they can bang around the camera
5 like radiography for five years and it's all right, but when
6 they're going to cross the border to a non-agreement state,
7 they have to perform the QA. I have a little difficulty in
8 understanding why they don't have to do it in-state, also.

9 MR. COOK: We have these requirements for
10 licensees that are in non-agreement states. And if someone
11 from an agreement state comes into a non-agreement state,
12 the playing field becomes level at that point. But you're
13 right there is a difference between quality assurance
14 requirements for transportation with respect to whether
15 you're transporting solely within an agreement state or
16 within a non-agreement state.

17 Now, that matter has been transferred to the
18 agreement states with respect to whether they -- what needs
19 that they -- what requirements that they feel that they
20 should impose there.

21 Not suggesting whether it's needed or necessary,
22 there are different options that could be considered. The
23 Department of Transportation could require that everybody
24 have a QA plan. Similarly, agreement states could also
25 require it, if they so felt. But I'm not aware of any

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1 initiatives in those areas to proceed in that direction.
2 That's just the status as it is right now.

3 MR. KAYSK: All right.

4 MS. SCHNEIDER: Kathy Schneider, Office of State
5 Programs. The suggested state regs, Part T, does have a
6 provision in there that has a quality assurance program for
7 the agreement states to administer. It was an area that was
8 overlooked when we talked about compatibility and it's one
9 that's historically been around for a while. John and I
10 have even talked about it. I'd like to see a new change, a
11 new MOU with the Department of Transportation so we could
12 get that closed.

13 But we are suggesting and working with states who
14 are adopting the new Part T and who are now looking at that.
15 So that some of the states do have programs. Whether or not
16 they're implementing them, we're still working with them on
17 that.

18 MR. COOK: Any other questions?

19 [No response.]

20 MR. COOK: Thank you for your attention.

21 MR. KULIKOWSKI: Are there any questions for Ruth,
22 if anyone has thought of anything since -- I'm sorry,
23 Dennis.

24 MR. SOLLENBERGER: If there are no questions, I
25 just want to make an announcement.

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1 MR. KULIKOWSKI: If there are no questions, we'll
2 have Dennis Sollenberger make an announcement.

3 MR. SOLLENBERGER: Vandy asked me to follow up and
4 let you know that if we're done early, maybe we can break
5 until 2:30, assuming the speakers come back and are here by
6 then. We will try to reconvene at that point.

7 MR. KULIKOWSKI: Before we break, it's now just
8 not quite 2:00, for about a half-an-hour, I'd like to give
9 both Ruth and John a nice round.

10 [Applause.]

11 MR. KULIKOWSKI: We'll see you all back here about
12 2:30.

13 [Recess.]

14

15 LOW LEVEL WASTE MANAGEMENT PANEL

16

17 MR. AUTRY: Let's settle down. As soon as you all
18 get settled down and we get finished, you all get out.

19 I'd like to welcome you back to this afternoon's
20 presentation. I'm Virgil Autry with the State of South
21 Carolina, if some of you don't know who I am. Before I
22 introduce our first speaker, I would like to give you a
23 little bit of news about South Carolina, what's going on.

24 I think most of you have heard that we were
25 unsuccessful in getting out of the waste business this year.

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1 Money speaks louder and our Governor saw fit to use this as
2 an occasion to help balance our deficit that we have in the
3 state by using some of this money.

4 So one Presidential candidate is saying right now
5 watch your wallet. If Bush or Clinton gets in, if you send
6 waste to South Carolina, you better not only watch your
7 wallet, you better watch your bank account and your savings
8 account, too, because it's going to cost you a lot of money
9 to bury waste in that state after the first of the year.
10 It's already costing plenty of money.

11 But we will be in business for a little while
12 longer. Some of the issues in the new legislation that was
13 passed, of course, allowed out-of-region waste to be brought
14 into the state up until June of 1994. After that point in
15 time, supposedly only southeast regional waste will be able
16 to be disposed of there, but the legislature can revisit
17 that. They have that option.

18 The Southeast Compact Commission now has
19 responsibility to review the compliance of the states to
20 ensure that they are on track with their siting processes,
21 and I'm sure that a committee will be formed, if not
22 already, to start looking at these out-of-region states and
23 compacts, to review that process to see what's happening.
24 That's out of our hands now. So you can't call me and say,
25 hey, you know, give us a break. We don't do it anymore.

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1 Call those Commissioners.

2 But the agency is prepared to continue with our
3 regulatory process at that site. An additional thing we're
4 going to have to do, of course, is the license is up for
5 renewal the end of this year and we'll be going through that
6 with the licensee, and I predict it will probably be a
7 timely renewal process, run a long time. So we'll see what
8 happens.

9 Anyway, if anybody has any question about it, see
10 me later and we'll surely talk about that. We have a very
11 good panel today. I think they're going to entertain you
12 very well. Some of the things that are going on not only at
13 the NRC, but in the State of Nebraska, and hopefully
14 everything will be very informative to you.

15 Our first speaker today, Bill Brach, who is the
16 Deputy Director, Division of Low Level Waste Management and
17 Decommissioning. He is also serving as the Acting Chief of
18 the Low Level Waste Branch while Paul Lohaus is on special
19 assignment for Research.

20 Bill has over 21 years with the AEC/NRC. He
21 worked four years in Region II and 16 years in NRC
22 headquarters. Bill is going to talk a little bit about
23 title transfer and low level waste storage, extended
24 storage.

25

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1 EXTENDED STORAGE OF LOW LEVEL
2 RADIOACTIVE WASTE
3

4 MR. BRACH: Thank you, Virgil. I got here right
5 as you all broke from the previous session and the first
6 thing Virgil told me is that the session right before us has
7 set the standard and that for early dismissal, we need to
8 talk fast and hurry up.

9 I mentioned to Virgil, I said, well, presentations
10 this afternoon fit that to a T. I'm on the agenda to talk
11 about two topics. One is low level waste storage and the
12 rulemakings that are currently underway. The second topic
13 was on performance assessment.

14 I mentioned to Virgil that when we put that item,
15 the second item on the agenda, there was an anticipation on
16 our part that we would have a draft branch technical
17 position on performance assessment. That would be developed
18 to a point where this afternoon we could talk through with
19 you all the draft branch technical position and some of the
20 issues we're wrestling with.

21 In the spirit of trying to keep the sessions
22 moving, I mentioned to Virgil that we are not there yet with
23 the draft branch technical position. So this afternoon,
24 with regard to performance assessment, we're not yet at a
25 point of being ready to discuss with you all or present or

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1 give even an overview of where we are in the draft.

2 We are working on it. We've got an inhouse draft
3 that has been undergoing review within the division and we
4 are not quite there yet.

5 Let me start first with the presentation on low
6 level waste storage.

7 [Slide.]

8 MR. BRACH: Let me back up. On the back table, I
9 have copies of the overheads, if anybody would like those.
10 The first viewgraph is a basic overview of the presentation
11 I'm about to briefly cover with you this afternoon. I want
12 to talk briefly about the NRC policy position with regard to
13 low level waste disposal.

14 Also, a summary or an overview of the current
15 status of new disposal facilities and, as Virgil has
16 mentioned, some of the difficulties. The second two bullets
17 make reference to the regulatory structure that we have in
18 place with regard to our guidance, regulations and current
19 inspection and overview activities.

20 The next bullet, I wanted to give an overview of
21 the storage situation, storage of low level waste situation
22 in the State of Michigan. You all are aware that they have
23 been denied access for disposal since November of 1990. The
24 last bullet, the last few pages of the overheads, I will be
25 talking about the two rulemakings that are currently

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1 underway within the NRC.

2 [Slide.]

3 MR. BRACH: The NRC policy statement with regard
4 to disposal of low level waste I'm sure a number of you have
5 seen. A couple points I want to stress. One, clearly, NRC
6 does not look favorably upon storage. That storage, from
7 the Commission's perspective, is clearly meant to be the
8 measure of last resort, and preference of the Commission is
9 for disposal, not storage.

10 And also the position being that the disposal of
11 storage is clearly, in the long run, a much safer approach
12 and practice to take to preclude overexposures and other
13 perhaps incidents with regard to disposal and transfers.

14 [Slide.]

15 MR. BRACH: This overhead, if it fits the slide,
16 gives an overview of the current status with regard to
17 compact states and unaffiliated states and the new
18 development of disposal facilities.

19 Notice that California, in July 1994, would be the
20 first scheduled new facility to come on-line. Of course, I
21 think we all are aware of some of the litigation and
22 transfer issues that the state is currently facing.

23 Also, just in the last few days, we have updated
24 this sheet, as well, to show for Illinois the dash marks. I
25 think we are all aware of their recent Siting Commission

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1 decision in the State of Illinois to -- I guess it was a 3-
2 1 vote to reject the Martinsville site as an acceptable site
3 for a future disposal facility.

4 Noting on there that North Carolina and Texas,
5 just simply looking under the operate facility timeframe,
6 would be the next facilities to come on-line based on
7 schedules and data and information as we have today.

8 I guess the point I would make is that -- and you
9 can see, as well, that these are dates that are fairly well
10 off in the future from where we are right now. As Virgil
11 has mentioned, the Barnwell facility, with certain
12 limitations, is open to out-of-compact acceptance of waste
13 through June of 1994.

14 This would point to the potential for storage in a
15 number of states and compacts across the country.

16 [Slide.]

17 MR. BRACH: Moving now to our guidance documents
18 and some of our licensing and regulatory approaches that are
19 currently in place for overview and licensing regulation of
20 low level waste storage.

21 The first two items, the two generic letters, are
22 principally directed toward power reactors. Generic Letter
23 81-38, issued in 1981, first specified the NRC statement of
24 policy and preference for storage to last no longer than
25 five years and that if a reactor site were to plan to have

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1 storage to last longer than five years, they should apply
2 for an application for storage to the NRC under 10 CFR Part
3 30.

4 I believe most of you may be aware that most
5 reactors currently that are storing low level waste on-site
6 are doing that under what's referred to as the 50.59
7 process. That's a regulation under Part 50 for power
8 reactors that allows them to change their operating
9 conditions and certain activities, as long as those
10 conditions, one, do not impact any issue, technical
11 specifications, and do not involve any un-reviewed safety
12 issues.

13 The second two information notices deal both --
14 excuse me. The third item, 89-13, pertains both to reactors
15 and fuel facilities and provides guidance to licensees that
16 have experienced difficulty in disposing of materials and
17 provides some guidance on ways to minimize and reduce low
18 level waste.

19 The last item, Information Notice 90-09, does
20 provide guidance to materials and fuel facilities that are
21 planning storage with regard to how to make an amendment to
22 the NRC, some of the details of information to provide, and
23 also the -- and provide some specifications and guidance,
24 such as the inspections and design considerations.

25 [Slide.]

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1 MR. BRACH: The next slide just provides an
2 overview, much of what I've just covered. I'd point out the
3 last two items. That it's NRC's position that storage
4 capacity and planning should be limited to a five-year
5 timeframe and that in license amendments and issuance of new
6 licenses, we'd be looking at a five-year timeframe for those
7 activities.

8 [Slide.]

9 MR. BRACH: An overview of where we are right now
10 with regard to issuing license amendments and applications.
11 So far, and this is over the last couple of years, there
12 have been only 14 license amendments for low level waste
13 storage received by the Commission to date. I don't have
14 all the specifics on these, but I believe most of these were
15 for possession limit increases to account for the increased
16 material being stored.

17 There have been no applications from anyone to the
18 NRC for a storage license to build a storage facility. As I
19 mentioned, most reactors are currently using the 50.59
20 process to build and construct new storage facilities at
21 their sites.

22 [Slide.]

23 MR. BRACH: Moving now to the Michigan storage
24 experience. As mentioned, they have had access to disposal,
25 limited, since November 11, 1990. They have over 600

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1 licensees, and these are NRC licensees in the State of
2 Michigan. On an annual basis, and the data is through --
3 was current for 1990, the State of Michigan was disposing
4 about 36,000 cubic feet of low level waste per year.

5 Absent disposal capability, that waste or
6 approximately that amount of waste is currently being, on an
7 annual basis, stored at the various generating licensees in
8 the State of Michigan.

9 Based on NRC inspections that we've conducted over
10 about a 13-month period, we've concluded, as noted in the
11 fourth and fifth hash mark or bullet, that storage currently
12 being practiced in the State of Michigan is adequately being
13 and safely being carried out. That's based on inspections
14 at all the power reactors. There are four power reactors in
15 the State of Michigan, and at over 250 materials licensees
16 in the state.

17 The last point was noted to our Region III
18 inspectors by one of the licensees. We don't have the
19 specifics, but it stands to reason that with low level waste
20 disposal being limited and storage being currently the only
21 option in the State of Michigan, that there may be some
22 impact economically and operationally for some of the
23 Michigan facilities.

24 [Slide.]

25 MR. BRACH: I want to move briefly now to two of

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1 our rulemaking activities we have underway. I believe most
2 of you all remember back in the January, February, March
3 timeframe, NRC was soliciting input from the agreement
4 states on what we referred to colloquially as the take title
5 rule. We refer to it now as the on-site storage, and
6 received agreement state comments back in the March
7 timeframe.

8 The Commission paper, with the proposed rule, went
9 forward last May and I think all of you all are familiar
10 with the Supreme Court decision this past summer that struck
11 down the take title provision as it applies to non-compacted
12 states. The Commission has directed the staff and we
13 currently right now are preparing revisions to that
14 rulemaking activity.

15 There is one letter I'd like to draw to your
16 attention. Well, I'm not in a position to explain where we
17 are on the rulemaking with regard to the specifics. That's
18 still under Commission consideration and staff
19 consideration.

20 The Commission did issue a letter to Ms. Dicus in
21 the State of Nebraska for the -- excuse me -- Chairman of
22 the Central Interstate Waste Commission, on September 28. I
23 will note that the Commission, in that letter, did state
24 that the Commission sees no need at this point to take an
25 official position on the legality of the take title

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1 provision of the Act as it applies to compact states.

2 So I'm not in a position to go into where we are
3 with regard to the rulemaking. That is a position
4 commentary that the Commission just offered just recently
5 and I think you will see that reflected in our rulemaking
6 activities.

7 [Slide.]

8 MR. BRACH: The next slide, I just want to draw
9 your attention to the third bullet to give you an overview
10 of the comments that we did receive this past spring on the
11 take title or the on-site storage rule. It showed a fairly
12 wide array of comments from the agreement states.

13 I will note that in the Commission paper, when the
14 paper does go forward and the proposed rule is published for
15 public comment, the supplementary information will contain
16 an analysis of all the comments received from the agreement
17 states.

18 [Slide.]

19 MR. BRACH: The second rule I want to talk briefly
20 about is referred to as the receipt/back rule. If you're
21 familiar, most reactor facilities are not authorized to
22 receive back the low level waste they generate. That is
23 they clearly are authorized to generate that waste, to store
24 it on-site and to ship it off, but they are not authorized
25 to receive it back if perhaps it's been sent to a waste

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1 processor for volume reduction or other treatment.

2 This past year, we recognized that we were either
3 going to be faced with a deluge of license amendments from
4 power reactors to request, on an individual basis,
5 authorization to receive back that waste or to initiate a
6 rulemaking activity. We did the latter and I will note that
7 just this past Thursday, the 21st of October, I think it was
8 Wednesday, that final rule was published in the Federal
9 Register.

10 I have copies on the back table just of the rule.
11 I don't have copies of all the supplementary information
12 that went along with that rule. The rule is effective in 30
13 days, so it will be effective November 20.

14 [Slide.]

15 MR. BRACH: Let me just briefly summarize. What
16 I've tried to present just very briefly this afternoon is an
17 overview of NRC's policy with regard to disposal, and
18 clearly we're looking at storage as a last resort. But, as
19 I've pointed out, new disposal facilities are a good number
20 of years off yet and there clearly are going to be some
21 limitations on states, some states and some compacts with
22 regard to disposal capability in the near term.

23 I also want to stress that while I identified a
24 number of NRC guidance documents and generic letters and
25 information notices and some of the activities we've carried

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1 out to date with regard to licensing or license amendments
2 for storage, we are very much interested in input that the
3 agreement states and others may have with regard to the need
4 for new guidance for storage facilities.

5 Just earlier this week, I read in a news article
6 from the Midwest Compact that the Ohio State University has
7 set aside a significant amount of money to consider the
8 construction of a new on-site storage facility for low level
9 waste. That, being a non-agreement state, would be perhaps
10 a license -- would be a license application to the NRC.

11 So I'd point out that if, on the agreement state
12 side, if you see that there's a need for guidance where NRC
13 could help with regard to storage of low level waste, I'd be
14 interested in your areas you might identify for us.

15 Finally, just a note on the two rulemakings, as I
16 summarized. The one rule, commonly referred to as the
17 receipt/back rule, is now an effective rule -- excuse me --
18 has been published and will be effective November 20. The
19 other rule, the on-site storage rule, will be going to the
20 Commission in the near term for Commission consideration and
21 then publication as a proposed rule for public comment.

22 That's all. Thank you.

23 MR. AUTRY: Any questions for Bill?

24 [No response.]

25 MR. AUTRY: I guess Aubrey doesn't have a

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1 question. I apologize to Ed here. He got kind of
2 shortchanged on this getting up here, but let's try to keep
3 to the schedule. Are you ready?
4

5 ANION RETENTION IN SOIL
6

7 MR. O'DONNELL: Yes. Thank you very much, Virgil.
8 My name is Ed O'Donnell. I represent the Office of Research
9 at the U.S. Nuclear Regulatory Commission. It's a pleasure
10 to be here on the program. It's also a real surprise to
11 find everything is running so early.

12 Dennis Sollenberger is giving a handout of the
13 viewgraphs which I will be talking from. There are 40
14 copies, it looks like there are 49 people sitting here in
15 the audience. A few of you will be shorthanded. If you are
16 shorthanded and you're interested in the subject further,
17 just give me a business card and we'll provide you with the
18 handouts.

19 Kind of as background to the whole thing, I should
20 mention that most soils are very good at binding up cations,
21 and it's the anions that are presenting the problem and
22 there are a few very significant radionuclides which travel
23 in the anionic form, and that's what the whole story is all
24 about.

25 [Slide.]

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1 MR. O'DONNELL: The first viewgraph, of course, is
2 the title, the Anion Retention in Soil, and we're focusing
3 on just looking to see if there would be some way of
4 reducing the migration of buried technetium and iodine.

5 [Slide.]

6 MR. O'DONNELL: Many of you in the room are
7 familiar with the problem, with the story of the modelers
8 doing performance assessments began to realize that there
9 were problems with several of the radionuclides, the long-
10 lived ones, and listed up there are iodine, technetium and
11 carbon-14. The iodine and the technetium will migrate in
12 the anionic form at pHs that you might find typically in
13 groundwaters and natural soil systems.

14 They present a problem in the sense that they're
15 halflife is very, very long. You see almost 16 million
16 years for one, 200,000 years for another one, almost 6,000
17 years for the carbon-14. So they'd be there long after any
18 engineered facility is likely to be present.

19 Also, that third column over there on the right,
20 many of you may recognize the figures, the data. This is
21 inventory information from Hanford, from the Hanford site,
22 of waste which was disposed between 1986 and 1989. It's
23 data which was gathered by Brookhaven National Lab.

24 Those of you who have heard Brookhaven make the
25 presentations at other meetings realize the data is a little

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1 bit shaky and everything else, but the Brookhaven people
2 say, well, that's the numbers we're dealt with. Those are
3 the numbers we have to go with. It's what's reported on the
4 inventories.

5 You also notice that that column over there on the
6 right, it's in unstabilized Class A waste. So it turns out
7 that these radionuclides, these long-lived things which
8 travel in anionic form, they're presence in unstabilized
9 Class A waste, they're usually present in very, very small
10 amounts, which means that they're very difficult to measure
11 and to account for, and all this comes back to the
12 performance assessment.

13 [Slide.]

14 MR. O'DONNELL: Summarizing what I've just said,
15 they have very long halflives. They would be present in low
16 concentrations and, therefore, difficult to measure. They
17 also migrate in the anionic form. Most soils are good at
18 binding up the cations, but not the anions.

19 [Slide.]

20 MR. O'DONNELL: So the question is is there some
21 way to modify the near field environment to bind up the
22 anions. As background for this, we, about a year-and-a-
23 half ago back at NRC headquarters, brought in a bunch of
24 people just amongst ourselves privately to look at the low
25 level waste disposal situation and see is there any way we

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1 can do things better, are there any technologies out there
2 that we haven't looked at. There are big holes in it;
3 brought in about five or six outside people and then a bunch
4 of internal staff, debated it, put it up on flipcharts and
5 the discussion went every which way.

6 The drawing there in the lower right kind of
7 summarizes the outcome. Number seven up there, that says
8 site utilization. The person who suggested that said, well,
9 we could spread the waste disposal units out further and
10 make them further apart. That might be a better way to
11 utilize the site. The type of vegetation was mentioned,
12 cover, concrete, waste solidification, conditioning the
13 waste.

14 Finally, it was one person throughout the question
15 which is up there, could you condition the near field to do
16 some things better. Well, we're familiar with the work of
17 people throwing bentonites and things like that. The
18 bentonites will do very good at binding up the cations, but
19 it was the anions. These are the ones, the forgotten ones.

20 One of the people in the room was at the
21 Department of Soil Science at the University of California-
22 Berkeley, and this person, from their soil experience,
23 recognized there were certain deposits in the western U.S.
24 that the soils belonged to a group called andisols.

25 In this group of andisols, it contains a -- I

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1 don't want to call it a mineral, but something mineral-like
2 called allophane. Allophane is part of the kaolinite
3 family, and what it would be is if you weather a volcanic
4 parent material, get it partially weathered, not yet
5 converted into a clay mineral, that's what allophane is
6 like. It's clay-like and it has the ability to bind up
7 negatively-charged particles.

8 Most clays have a negatively-charged surface.
9 They will bind up the positively-charged. This allophane is
10 the reverse. It's a positively-charged surface which will
11 tend to bind up the anions.

12 [Slide.]

13 MR. O'DONNELL: So we quickly, as a followup to
14 this brainstorming session, the soil scientist from Berkeley
15 said, well, could you please do a quick and dirty literature
16 search, just make a real quick check and find out if these
17 types of materials are common.

18 The column, if you look at the fourth column from
19 the left, which is AEC PH6, that's the anion exchange
20 capacity of PH6. You see a bunch of numbers in there.
21 Generally -- okay. Let's say a value of one or higher is
22 significant.

23 So what it turns up is that there are a bunch of
24 places, the places that you see under the soil types, that
25 came from either Japan or New Zealand or the western United

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1 States. So what is is in a place where you have volcanic
2 parent materials, where you tend to have a fair amount --
3 well, very modest amount of weathering, you don't want a
4 highly leached soil like we have here in the eastern U.S.

5 It's just a modest amount of weathering, retention
6 of many of the elements, and these lead to the formation of
7 andisols and the andisol is rich in allophane. Allophane is
8 kind of a garbage can term and not every allophane has this
9 ability to bind up anions.

10 [Slide.]

11 MR. O'DONNELL: I think this is the very tail-end
12 diagram. This is the actual laboratory results, and I'm
13 going to show you in graph form in a second or two. But
14 what it is is that we then decided to take a real quick
15 check to find out -- the literature said that these things
16 exist. We decided to take a quick check and look and see,
17 indeed, to the extent they did.

18 [Slide.]

19 MR. O'DONNELL: The next diagram is the location.
20 So we quickly looked out in the three sites in the Sierra,
21 Nevada. These were soils which were already existent in the
22 soil library there at Cal-Berkeley, and two of them actually
23 were from volcanic areas, one wasn't.

24 So we did a quick check with these things. The
25 actual laboratory testing was two parts. One was an iodide

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1 test, a quick test to see if there was iodide absorption of
2 the material. If there was iodide absorption, then you'd
3 look further and do an anion exchange using exchange of
4 chloride for nitrate.

5 So we see the three sites.

6 [Slide.]

7 MR. O'DONNELL: These are the actual results of
8 the quick tests of the iodide. The horizontal axis you see
9 is the depth of the soil profile. With those numbers, you
10 can see that there is at least one that's pretty close to
11 that number one up at the top. That was the most promising
12 soil of all.

13 So based on the sampling of about 25 sites, one
14 out of 25 looks very, very promising, at least with this
15 quick check with the iodide.

16 [Slide.]

17 MR. O'DONNELL: And this is using all of the -- is
18 looking at the full anionic exchange, the exchange of
19 chloride for nitrate. Again, you can see several of the
20 samples plot up close to that value of one.

21 So I would say in terms of looking for materials,
22 it looks promising. It looks like we found the glitter out
23 there and very close to finding it.

24 I think in terms of summary, again, what I'm
25 reporting on to you is work that's underway back in our

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1 Office of Research, looking at materials. The question
2 becomes, gee whiz, suppose you find deposits, how do I use
3 it.

4 Well, if a person wanted to engineer their site or
5 condition their site, there are a variety of ways you could
6 use it, one of which could be if you had a concrete
7 engineered structure, it conceivably could be a backfill
8 inside the disposal cells, or it could be outside and
9 underneath. You could figure out a variety of ways to use
10 the material.

11 We've discovered that shipping materials across
12 the country is not an expensive proposition, especially when
13 you're talking about the disposal costs we're talking about
14 these days. That's not a difficult problem.

15 Or, if iodine and technetium is a problem and if
16 there's a way of segregating it, maybe this could only be
17 used around those disposal units which might have iodine and
18 technetium.

19 With that, Virgil.

20 MR. AUTRY: Does anyone have any questions of Ed?
21 I have one. What do you do with the tritium?

22 MR. O'DONNELL: What do you do with tritium? Yes.
23 There's nothing that can stop tritium. Tritium always goes.
24 That's the one. Paul Merges from New York State.

25 MR. MERGES: I do have a question. Would you mix

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1 bentonite with the allophanic soil?

2 MR. O'DONNELL: You could use bentonite. If you
3 realize, the old problem with the bentonite is the expanding
4 and contracting and you'd have to make sure that the
5 bentonite would always stay moist and damp. I would
6 envision it -- you know, you've got bentonite three feet
7 below the earth's surface, it's going to stay damp forever.

8 You could mix them. You could put alternating
9 layers. But you would want that bentonite to be damp
10 always.

11 MR. MERGES: And an observation. Your cryogenic
12 liners are pretty good at tritium.

13 MR. O'DONNELL: There we go. There always is an
14 example of one that will work.

15 MR. AUTRY: All right. Ed, if you will have a
16 seat up here, we have a place for you. Our next presenter
17 is Bill Lahs. Bill is the Senior Program Manager of the Low
18 Level Radioactive Waste Management Division. He's worked on
19 such projects as the uniform manifest rulemaking, which I've
20 been involved with for years and years and years and glad to
21 see it finally come along, hopefully it will come along.

22 He's worked very closely with the conference's E-
23 5 Committee on low level waste management, on the
24 concentration averaging, greater than Class C, which he will
25 be talking about today. It's been a real pleasure to work

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1 with Bill on a lot of these projects. He's included the
2 agreement state and the conference in a lot of these
3 deliberations in developing some of these technical guides
4 which are well needed in the low level waste area as we move
5 forward.

6 So without further ado, Bill.

7
8 GTCC WASTES AND DOE
9

10 MR. LAHS: Thanks, Virgil. On the subject of
11 greater than Class C waste and our interface with DOE, there
12 are really two distinct, but related activities that I'd
13 like to discuss here this afternoon.

14 These two activities have evolved from a series of
15 about a half-a-dozen meetings we've had with the Department
16 of Energy over the last year-and-a-quarter. As you all
17 know, I'm sure you've heard DOE make their presentations,
18 they have a three-phase strategy for greater than Class C
19 waste.

20 It includes an interim storage capability, which
21 was initially planned to come on-line in late 1992, but now
22 predictions are 1994 and I think that's probably very
23 optimistic. They have a dedicated storage facility which
24 follows in 1997 and then with disposal coming about in the
25 year 2010.

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1 Now, the interim storage capability has some
2 specific interests because it's the facility that's designed
3 to take not only abandoned material, but also other material
4 posing a somewhat undefined public health and safety threat,
5 and we're going to be discussing that a little later.

6 Our position in our meetings with DOE is obviously
7 we support this early implementation of their three-point
8 strategy. But in our meetings, we have been trying to
9 emphasize to them that there's also an immediate need to
10 address the disposition of greater than Class C sources or
11 devices that are in the possession of both our licensees and
12 your licensees who are seeking to terminate their licenses,
13 can't transfer or dispose of their sources or devices mainly
14 because they're greater than Class C.

15 They're also judged not to have the capability to
16 continue to exercise proper control over these devices for
17 extended periods of time.

18 Now, DOE didn't want me to bring this up, of
19 course. They say, yes, that's right, we certainly
20 acknowledge the problem, but we really feel that you have to
21 define it better and also to help us carry out your
22 strategy, we'd like you to do two things; first, more
23 clearly estimate the extent of the sealed source problem and
24 then, secondly, to be more active in attempting to establish
25 uniformity in what constitutes greater than Class C waste as

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1 opposed to Class C waste, especially with regard to sealed
2 sources and devices.

3 So what I'd like to do, then, is discuss each of
4 our activities in these two areas separately. We originally
5 made -- well, we've been making a pitch to DOE for some time
6 in this area, but last October, there was a meeting between
7 Bob Bernero, who is the Office Director, and Mr. Leo Duffy,
8 the Assistant Secretary for Environmental Restoration of
9 Waste Management, where we emphasized a need for DOE to take
10 some of these sources on a short-term basis that were other
11 than abandoned material.

12 At that meeting and the subsequent follow-on
13 meetings where DOE came back to us and said, well, define
14 the problem for us and also provide us more information on
15 how you guys are going to define the separation between
16 Class C and greater than Class C.

17 So in a subsequent letter which we sent to Duffy
18 back in January of this year, we estimated that each year
19 there are 300 greater than Class C sources or devices that
20 are placed in the storage mode by small business licensees.
21 That's both your licensees and NRC licensees.

22 And the reason we broke it down that way -- it's
23 that class of licensees that we're probably most concerned
24 with with regard to this ability to maintain adequate long-
25 term control.

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1 We further estimated that there would probably be
2 a one-time surge of some 800 sources or devices that occur
3 because of NRC's implementation of full cost recovery
4 provisions in our regulations.

5 We also used that letter as the vehicle at that
6 time, if you remember, that Amersham had introduced a
7 recycling program. So we pointed that out to DOE and said
8 that certainly we would factor that type of program into our
9 decisions with regard to disposition of greater than Class C
10 sources. In other words, we'd certainly think about recycle
11 before we'd be asking DOE to pick up such sources.

12 We've received a reply from Duffy in April, which
13 acknowledged that DOE may, indeed, be required to take these
14 1,100 sources and then 300 a year thereafter for interim
15 storage, but only if a well-specified public health and
16 safety need was demonstrated to exist.

17 So we really hadn't made too much progress. Just
18 prior to receiving his response, though, and for the reason
19 I just stated, NRC decided to kind of test the waters and
20 submitted a request to DOE for the pickup of three sources
21 from a licensee who was claiming financial hardship, who was
22 seeking to terminate his license, and who we felt posed a
23 fairly high risk with regard to maintaining adequate control
24 for extended periods of time.

25 That request is still pending from April, but in

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1 our latest meeting with DOE, which took place just a few
2 weeks ago, they indicated we should hear back before the end
3 of this month. I haven't begun to hold my breath yet, but I
4 might in another day or so.

5 Our whole idea here is really to try to work with
6 DOE, but still to try to keep some pressure on them to try
7 to come up with a mutually acceptable program for DOE's
8 short-term acceptance of some subset of the greater than
9 Class C sources that pose the greatest loss of control risk
10 prior to the time that DOE's interim or their dedicated
11 storage facility comes on-line.

12 Subsequent to receiving what we're hoping will be
13 this favorable response with regard to accepting the sources
14 we've asked them to take, our plans are to try to finalize a
15 draft procedure which we put together when we made this
16 request to DOE, and that procedure deals with things that we
17 should do before we ask DOE to take such sources.

18 For example, checking to see if recycle is
19 available, checking to make sure that the licensee has made
20 an attempt to transfer his sources to other licensees. The
21 development of these final procedures, I think it's our
22 intent to be heavily coordinated with the agreement states.

23 So now let me switch gears and say a few words
24 about our activities to more clearly define what constitutes
25 greater than Class C waste. As you all know, in our

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1 regulations at Part 61, there are two tables which list
2 specific nuclides and the concentration values which are
3 used to determine the waste classification.

4 This approach of using classification seems fairly
5 straightforward, but to determine the concentrations, one
6 obviously has to define what volume or weight of the waste
7 you're going to divide the activity into. Since the volume
8 or the weight of the waste could be effected by things like
9 the media maybe that you're using to make the waste
10 structurally stable or by the fact that maybe you're mixing
11 various waste streams or waste types, there is obviously
12 need for some additional guidance in this area.

13 So as a starting point, NRC I think recognized
14 this at the time Part 61 was promulgated, and, in May 1983,
15 we issued a technical position on waste classification. It
16 was only, I think, in terms of this issue of what volumes we
17 should be using, I think it was only like a page long, but
18 it gave general type guidance.

19 We have now attempted to expand this position with
20 a proposed change which was noticed in the Federal Register
21 on July 1 and was sent to all of you on July 7. As Virgil
22 kind of indicated, and I want to emphasize to you that in
23 coming up with this position, we had a lot of cooperation
24 from the conference radiation control directors, E-5
25 Committee on low level waste management, and there are

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1 several people in this room that are members of that
2 Committee, as well as Virgil.

3 I think it's fair to say that committee also
4 recognizes the need to develop low level radioactive waste
5 acceptance criteria which would not only define greater than
6 Class C waste, but develop acceptable approaches to
7 concentration averaging.

8 Well, the position has been on the street, like,
9 say, since July. We received about 20 comment letters,
10 principally from utilities and their supporting
11 organizations, but also received letters from both disposal
12 facility operators and a very extensive comment letter from
13 the Department of Energy.

14 If you grouped all those comments, they really
15 fell into maybe five major issues, four of which I think we
16 can deal with by explaining a response on how the position
17 was developed and by making relatively minor changes to the
18 position.

19 There was one comment, though, that I think at
20 least thus far is going to have a significant impact on the
21 position as it was originally proposed. In essence, it
22 comes out of the comment from the commenters which goes like
23 this. It said, look, if you guys are going to go to the
24 trouble of expanding this position on encapsulation and
25 concentration averaging, we feel -- which they generally

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1 supported -- we feel it's incumbent on you to take a look at
2 the existing practices right now and if you judge those
3 practices to be acceptable and those practices are widely
4 used, we feel it's incumbent on you to make an effort to put
5 that specifically in the technical position.

6 Now, even at the meetings we had with the E-5
7 Committee, this has been discussed. How far can you go in
8 trying to get into all the specific possibilities? And for
9 those of you who may have looked at the technical position
10 as it was published, what we had done is we had provided an
alternative provisions paragraph.

11 The idea of that alternative provisions paragraph,
12 it was saying to you that, hey, if you have a question with
13 regard to concentration averaging or encapsulation and it's
14 not answered in the position -- the specifics in the
15 position, then what it said was, well, obviously, go to your
16 local regulator, either the agreement state or NRC, and get
17 an interpretation from them.

18 And if that's judged to be acceptable and this is
19 a practice that we're just going to lead to waste routinely
20 being sent to disposal sites, we encouraged that to be put
21 into the license condition at the disposal facility.

22 Well, when I wrote that in that draft, the
23 alternative provisions section was the last paragraph in the
24 position, and I think its importance wasn't really -- I
25

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1 didn't bring out the importance well enough. Nevertheless,
2 even if I had, I think the comment that we received about
3 trying to document as much as we can the acceptable things
4 that are going on right now is a valid one.

5 So what we've tried to do now is to further expand
6 the position to cover existing practices. For example, how
7 do you treat metals or materials that may be sectioned for
8 operational reasons, such as transportation?

9 Well, the drawback obviously to any expansion is
10 that the in fact, the position now has gotten one from, I
11 think, 12 or 13 pages to 25, is that the position becomes
12 more complex. It's length is increased because we've added
13 several examples. We've got two new tables and also we
14 included a logic diagram to try to lead people through the
15 classification of activated metals.

16 There is quite a discussion in the management
17 chain at NRC on the efficacy of expanding this position and
18 so I think the votes are still out. One of the feedbacks
19 we're going to be getting is we've just recently submitted
20 this revised position to the members of E-5 and we'll be
21 meeting with them at their session in November and
22 essentially see what they think about it.

23 With that, are there any questions?

24 MR. AUTRY: I have a few comments about some of
25 the work that Bill has done and the importance of it. I

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1 don't know if some of you in the agreement states don't get
2 that involved with low level waste, I think you should. But
3 these are some very important positions and guidance that
4 are being developed.

5 We're talking what's going to determine whether
6 these large sources, you will take care of them or whether
7 DOE, under the Federal mandate, they take care of them.

8 The other important thing, we've talked about
9 radium while we were here. Come the end of the year, unless
10 Beatty and Washington does something, where are you going to
11 put the radium? It's not coming to South Carolina. We do
12 not allow radium. Only on certain occasions.

13 Then you're going to have these large sources. We
14 are turning down more and more sealed sources and large
15 components from the Barnwell site because they do not --
16 they're by far in excess of what we would allow for greater
17 than Class C. We do allow a few variances there, but it's
18 becoming increasingly more difficult to get those.

19 So it's very important that you understand this
20 position that's coming up on greater than Class C and also
21 concentration averaging. Get in there and get involved with
22 it because you may be stuck with some of this stuff in your
23 states and some of these storage facilities that are going
24 to have to be developed.

25 Every day, the development of the low level waste

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1 facilities is moving further and further away. Just in
2 Illinois in the past couple of weeks, we thought they were
3 on track, but they had a major setback there.

4 So I can't emphasize that enough. Next, we've got
5 the Harry and Jay show. What we're going to do here, I'm
6 going to introduce both of these fellows at one time and
7 just let them proceed, because they've got some very
8 important information on what they're doing in Nebraska and
9 how these two agencies in this state are working together on
10 developing their low level waste site.

11 Our first speaker will be Harry Borchert.
12 Everybody knows Harry. He's been around a good while. He's
13 Director, Division of Radiological Health with the State of
14 Nebraska. He has a B.S. in Pharmacy. So he knows about
15 drugs. He also has a Master's in Health Physics, both from
16 North Dakota State University.

17 Harry has about 20 years experience, 15 years with
18 the State of Kansas before going to Nebraska.

19 Jay, of course, is the Program Manager, Low Level
20 Radioactive Waste Division with the Nebraska Department of
21 Environmental Control. So they have two agencies in the
22 state that are working on this.

23 Jay has a B.S. in Chemistry and an M.B.A. in Civil
24 Environmental Engineering, and he also has about 20 years
25 experience with water quality, hazardous and solid waste,

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1 uranium mining, and also five years with low level waste.

2 So I think these folks have got plenty experience
3 to deal with low level waste in that state. I'm looking
4 forward to them doing that.

5

6

DEC/DOH WORKING RELATIONSHIP

7

IN THE REVIEW OF A LICENSE APPLICATION

8

9 MR. BORCHEPT: Thank you, Virgil. I need to
10 clarify something. I didn't spend 15 years in Kansas. It
11 only felt like it, Jerry.

12 The Nebraska Low Level Radioactive Waste Disposal
13 Act designates the Nebraska Department of Environmental
14 Quality as the responsible agency which, in order to protect
15 the public health and safety, welfare and the environment,
16 has the authority to license and develop the program for the
17 regulation of commercial disposal of low level radioactive
18 waste.

19 The Nebraska Department of Health has the
20 authority to regulate low level waste management, except the
21 commercial disposal of low level radioactive waste in a
22 disposal facility designated by the Central Interstate
23 Compact.

24 There was an MOU that was signed between the two
25 agencies dated June 29, 1990, which kind of outlines how the

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1 two agencies work together. There are two statutes in the
2 State of Nebraska. Both statutes have some applicable
3 parts. The lawyers are, at this time, working on trying to
4 expand on the parts that are applicable.

5 The Department of Environmental Quality has the
6 power to temporarily or permanently close the facility if
7 they find a potential hazard to public health or safety or
8 the environment. The Department of Health has similar
9 responsibility, can issue a regulatory order or temporarily
10 close the facility, as well, when an emergency exists.

11 The MOU states "Whereas the parties want to ensure
12 that all aspects of the commercial disposal of low level
13 radioactive waste at the Central Interstate Compact disposal
14 facility are completely, thoroughly and exhaustively
15 regulated to protect the public health, safety, welfare and
16 the environment, and also want to ensure that each agency is
17 involved in the low level waste regulatory process in the
18 most efficient and effective manner in order to utilize each
19 agency's areas of expertise in compliance with statutory
20 duties."

21 "Whereas, the parties recognize that the
22 regulation of commercial disposal of low level radioactive
23 waste at the facility to be built in Nebraska by the Central
24 Interstate Compact requires involvement of both agencies."
25 And there are certain things that were specified that both

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1 agencies would do and certain things that each agency would
2 do.

3 Both agencies will cooperate to issue one license,
4 which will encompass both agencies' statutory and regulatory
5 authority and responsibility for activities for this
6 facility. There will be one license application, the
7 processing of which will be done simultaneously.

8 The Department of Environmental Quality is
9 responsible for determining and ensuring compliance with the
10 requirements of Title 194. The Department of Health will be
11 responsible for determining and ensuring compliance with the
12 requirements of the Radiation Control Act and the applicable
13 provisions of the radiation control regulations.

14 In enforcement, there will be a joint enforcement
15 responsibility from the two agencies, and they will be
16 performing in accordance with what is specified in the
17 application and so on.

18 [Slide.]

19 MR. BORCHERT: Pursuant to the MOU and pursuant to
20 the licensing process in the State of Nebraska, there was a
21 licensing program manual that was developed by the
22 Department of Environmental Quality and Department of
23 Health, and this is the title of that particular document.

24 [Slide.]

25 MR. BORCHERT: The next slide has a statement that

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1 has been signed by directors of both agencies, and I'd just
2 like to read the first paragraph. The State of Nebraska Low
3 Level Radioactive Waste disposal facility and license
4 program plan defines the State of Nebraska Low Level
5 Radioactive Waste program for the licensing and regulation
6 of the Central Interstate Compact low level radioactive
7 waste disposal facility.

8 It establishes specific requirements and
9 responsibilities and provides for their implementation by
10 means of a controlled licensing program plan and procedures.
11 All licensing and regulation activities performed by
12 individuals within the Nebraska Department of Environmental
13 Control, now Environmental Quality, Nebraska Department of
14 Health and the licensing review organizations shall be
15 governed by the State of Nebraska LLRW license program plan
16 and its implementing procedures.

17 Compliance with this plan and its implementing
18 procedures is mandatory. So that's the program plan for the
19 licensing review process. There are approximately a hundred
20 technical reviewers involved in the overall review process
21 of the application.

22 The various areas that they are reviewing are site
23 characterization, design and construction, facility
24 operations, financial assurance, general information,
25 performance assessment, quality assurance, and environmental

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1 issues.

2 [Slide.]

3 MR. BORCHERT: The next slide shows the working
4 relationship between the two organizations. As you can see,
5 the NDEC Director and the NDOH Director are both on the top.
6 The Low Level Waste Program Manager and the Health Physics
7 Section Chief. I have a Health Physics Section Chief in the
8 division that is the Program Manager for low level waste in
9 the Division of Radiological Health, and those two people,
10 for the purposes of this license application review, report
11 directly to the director of the departments.

12 That seems a little bit awkward in terms of the
13 way it sets up, because the Program Manager works for me,
14 but reports directly to the director of the department for
15 this particular process.

16 The rest of the things that that person is
17 involved in, they report directly to me on those issues.
18 You can see the rest of the organization, how the rest of
19 the people reporting and so on and so forth.

20 [Slide.]

21 MR. BORCHERT: The next slide shows how all the
22 different entities that are involved in the project review,
23 from HDR Engineering, which is the project manager, there's
24 Geotechnical Services, Collier, Shannon & Scott, PE
25 LaMoreaux & Associates, Applied Power Associates. Ther

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1 there's consulting geologists. The University Geology
2 Department even has a Conservation and Survey Division
3 that's helping. The Nebraska Department of Environmental
4 Quality, Divisions of Air, Land, Water and Support Services.

5 The Nebraska Department of Health, Division of
6 Radiological Health. My staff. Some of my staff are
7 contact people for various sections and work with the review
8 managers and the technical reviewers to supply input from
9 the perspective of the Division of Radiological Health.

10 Then there's other state, Federal and local
11 agencies. One of the prime other state agencies involved is
12 the local Civil Defense Emergency Management Group.

13 [Slide.]

14 MR. BORCHERT: This slide shows the track that the
15 comments take. If you are a left-handed generated comment,
16 you start in the lower righthand section and work your way
17 up to the center. If you're a right-handed comment, you
18 start in the lefthand section and work your way up to the
19 center.

20 Seriously, that's not the way it works. Some
21 people think that's the way it's going, I think. But what
22 this shows is the overall process of where comments are
23 generated from and where they go and how they get up to the
24 overview committee. There is an overview committee that
25 sits and reviews all of these different comments before they

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1 are submitted to the applicant, and I think Jay is going to
2 expand on that overview process a little bit more.

3 You can see toward the top there where the
4 comments could go from the overview back to the commenter to
5 the review manager and kind of go around in a circle there
6 until they become finalized and ready for submission to the
7 applicant.

8 It's a rather lengthy process. I had the
9 misfortune of having to sit in on a few of those when the
10 program section chief was absent and the other person that
11 was assigned to it was not available. So it gets rather
12 arduous and tedious and some days you go through about three
13 comments and other days you go through ten of fifteen. So
14 it's a rather lengthy process.

15 I think that's the last slide. The Department of
16 Environmental Quality and Department of Health Program
17 Manager and Section Chief conduct monthly meetings with the
18 Project Manager. These meetings are designed to resolve
19 differences or issues, if you will, of concern between the
20 two agencies. In previous meetings, they've been going
21 along fairly well.

22 And another area I think Jay is going to expand on
23 a little bit is the two directors of the department are the
24 two individuals that are responsible to resolve any kinds of
25 issues, differences of opinion or whatever, and I think he's

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1 going to expand on that a little bit further.

2 These two people meet routinely. It's been an
3 average of one to two months. They try to meet every month.
4 Sometimes their schedules dictate it and sometimes they
5 don't. Overall, I think the process is working. There are
6 some concerns, I think, from some of the people that are on
7 the outside looking in that the process is probably arduous,
8 but I think we have a responsibility of protecting the
9 health and safety of the public, and, for that matter, I
10 think we are doing the best of our ability to do that sort
11 of thing.

12 Jay?

13 MR. RINGENBERG: Thanks, Harry. For the record,
14 I agree with everything Harry said. So the relationship is
15 doing fine. I would comment and start out that the title is
16 a working relationship and that implies two things. One is
17 you have a relationship with another agency that is a
18 somewhat hand-in-hand, and, two, it involves working to day-
19 to-day, but implies also that you have to work at it to make
20 that relationship successful.

21 I think that is indeed the case. When you look at
22 the memorandum of understanding that Harry talked about,
23 that is an agreement that is somewhat of an arranged
24 marriage that comes from the legislature, as well as from
25 the directors. As Program Managers, we're tasked to make it

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1 work and it is working.

2 I think if you think about it as yourself in the
3 individual states and you think about the agency that I
4 represent, which is the environmental side of the house, it
5 is a very difficult time many times, particularly in many of
6 the rad programs because they come from the Department of
7 Health. Those are many times different from the state EPA
8 type agency. It has not had a long history of relationships
9 and working together on issues.

10 In fact, in many areas of environmental
11 protection, from wellhead protection to groundwater,
12 whatever, many times the agencies are at odds. If you think
13 about it in your own states, I think many of you would have
14 to agree that that is the case.

15 In this case, with the low level waste review, we
16 were tasked to put together that arrangement, to put
17 together a working day-to-day agreement that would come up
18 with ultimately a licensing decision on an application that
19 is both technically sound, one that at least two agencies,
20 if not many agencies, could agree on the technical positions
21 that are taken, and, in particular, that the process comes
22 to some closure and some final decision.

23 Many times, one of the regulator's biggest
24 problems is ever making a decision. When you have more than
25 one agency, there always is that possibility, I suppose.

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1 The process is process-oriented. It is management-driven.
2 As you see, the directors of both agencies have signed the
3 MOU. They take a very active interest and a very active
4 role, which is one of the reasons why it does work.

5 People tend to pay attention to what the boss pays
6 attention to. In this case, both directors have a very high
7 interest in the process and the outcome. It is designed to
8 raise differences of opinion between the agencies, to raise
9 it at the highest level, to a director's level, and to
10 resolve them as soon as possible and not let items of
11 disagreement between the agencies drag on for a period of
12 time.

13 It all starts with the MOU and Harry showed you
14 the MOU policy statement and talked about it. It does lay
15 out the authorities and responsibilities for the agencies.
16 It has a dispute resolution process in it. Initially, it
17 had a matrix to go with it. Lloyd, if you'd show me this
18 one slide here, I kind of went back to five years ago and
19 dug this thing out.

20 [Slide.]

21 MR. RINGENBERG: This will remind Harry of some
22 things from days past, but we originally, when we started
23 working on this MOU, went through and looked at all types of
24 licensing issues that were involved, tried to identify the
25 agencies who had primary responsibility or review

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1 responsibility or just consultation.

2 This not only covered the Department of Health and
3 Environmental Quality, but it covered lots of other state
4 agencies. We originally -- the intent of Harry and I
5 initially was to put this with the MOU, but in the end
6 result, we decided it was too rigid in the fact that it did
7 not allow you, as you got into the process, to make some
8 adjustments between agencies on who they really thought had
9 the final decision.

10 Also, the numbering system on here shows ones and
11 twos and things. Ones mean that's a final approval or
12 decisionmaking authority. As you can see, there's quite a
13 few of them that have ones in both the column for DEQ and
14 DOH. So when we started working on them, it was obvious
15 that this would not resolve it, other than that we have
16 followed this on many cases.

17 This process was very good to identify other
18 agencies who had a role in the review. And when we say
19 working relationship, that also means that we have to go out
20 and solicit input, as well as cooperation from other
21 agencies. Harry mentioned the Department of Civil Defense.
22 That's one of them the Department of Health has had a
23 traditional working relationship with. So they take the
24 lead with that agency in resolving those issues.

25 The Department of Game and Parks, Water Resources,

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1 other agencies that DEQ has had a working relationship with.
2 We tend to take a lead on resolving comments and questions
3 from them.

4 I put this relationship in two general broad
5 areas. One is the day-to-day activities. How do we manage
6 what we do on the day-to-day and, two, how do we do the
7 technical side. Harry talked about the technical. I'd like
8 to touch on the day-to-day things that I think are important
9 because they set up a framework that allows the agencies to
10 communicate on a continuous basis.

11 One is the low level waste people are housed in
12 the Department of Health and their offices are with the
13 Department of Environmental Quality. We provide them space
14 and secretarial support and all the office type functions.

15 They're in our offices on a continuing basis every
16 day. So that does foster a one-on-one relationship on a
17 continuous basis. In fact, our agency is moving to new
18 office space further away yet and the Department of Health
19 will be moving with us, as well as additional personnel.

20 We, the Department of Environmental Quality, fund
21 the positions in the Department of Health and we provide the
22 funds to them through a fee system where we bill the
23 application who, in turn, bills the Compact Commission for
24 the cost of the regulatory review.

25 So we are funding positions in both agencies.

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1 Department of Health has like three full-time employees.
2 DEQ has like the equivalent of about six, and then the
3 additional consultants, as Harry mentioned.

4 DEQ is tasked with the contract administration for
5 all the health. All of the contractors that you see and
6 were mentioned, DEQ, we do do all the contracting with them
7 and all the fund management for the project. We do task-
8 oriented orders when the Department of Health needs
9 additional expertise, such as we're going to be out looking
10 for additional health physics support for them.

11 We will then -- DEQ will go out and do the
12 contracting, provide those contractors to DOH. DOH develops
13 the scope of work, what kind of work they want done, what
14 it's going to do. We tend to do the administration and the
15 schedule and the pricing and the cost of that work.

16 We do have a process where we have at least every
17 other week and most of the time weekly meetings between
18 Department of Health's Program Manager and myself, as well
19 as our lead consultant. We tend to hammer out the day-to-
20 day issues. It is very important. If you don't do that,
21 they tend to drag on for some period of time.

22 Secondly, I think when we get into the technical
23 side of the house, then we tend to change hats. We tend to
24 change from a day-to-day issue to a technical review,
25 looking at the agencies' particular areas of expertise.

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1 Harry showed the process. We have a licensing plan. The
2 licensing plan isn't shown here. It was required. Both
3 agencies signed the plan and agree in principal that that's
4 how it would be done.

5 Changes to the plan really require the signature
6 of both Harry and myself to change those particular plans.
7 So we laid out a process up front and it has kept
8 particularly our staffs in what I'd call the straight and
9 narrow. When they want to get original on how we're going
10 to do something, the first question is what does the plan
11 say how you're supposed to do it, how are we doing it, if
12 you don't like it, we'll change the plan.

13 But that is an arduous process and it tends to
14 force the agencies and the staff to indeed do it as designed
15 versus how they may think on any particular day.

16 We also have a quality assurance plan for -- in
17 the same type of concept for both agencies. It involves
18 internal and external audits of both Department of Health
19 and DEQ, as well as all our contractors, as well as external
20 on the applicant, U.S. Ecology, and their contractor is
21 Bechtel National, and their multitude of subcontractors.

22 The other area I think that has worked very well
23 is what we call the overview committee. Harry alluded to
24 it. He got stuck working in there one day and it is a very
25 difficult task and we have five individuals that man that

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1 overview committee.

2 That is the Section Chief for Health Physics from
3 the Department of Health, the Environmental Engineer from
4 our staff, a licensing and environmental specialist from our
5 staff, and two consultants, one that is responsible to write
6 the safety evaluation report and the other one who is
7 responsible to write the environmental impact analysis.

8 Those five individuals compose the overview
9 committee, plus additional technical people may be in there
10 on a day-to-day basis. It is arduous in the fact that when
11 they start working, they tend to work eight hours a day and
12 they work at least four days a week, sometimes five, in the
13 overview committee, and that's all they do; review comments,
14 resolve comments, take out duplicate comments, and, indeed,
15 they even write some of their own as a committee if they
16 feel that the technical team has not raised some issues.

17 This is the first round comment period. They
18 generated as a group in the neighborhood of -- it started
19 with about 700 comments. Overview boiled that down to about
20 500 that ultimately went to the applicant. Second round was
21 about 500, with about 300 going to the applicant. It has
22 worked very well.

23 That process, the agencies get in there and roll
24 up their sleeves and they tend to get down to the real
25 issues and resolve them on a day-to-day technical basis.

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1 The only time that the management gets involved really with
2 the overview is if they cannot resolve something or they
3 identify something that they need a policy decision or
4 policy direction on. Those are there referred to in the
5 chart as a policy determination group, which is really Harry
6 and myself and the directors to resolve of those cannot be
7 done, and it has worked very well.

8 I think the other thing it involves is we do have
9 directors meetings on a periodic basis, as Harry mentioned.
10 We try to do that at least monthly. Those particular
11 meetings have agendas laid out in advance so the directors
12 know what the subjects are going to be. They take a very
13 active interest. They are designed for resolution of issues
14 and program guidance for both staffs.

15 So we have a uniform guidance for both staffs.
16 Secondly, I think it has set a process that has our
17 directors actively involved in the technical review from the
18 very start. I see many agencies that have the review and
19 the directors, who are the decision-makers, don't get
20 involved until the very end, and then they get this mountain
21 of material to look at and try to dissect.

22 Our directors are actively involved and it will be
23 on a continuous basis. In addition to the monthly meetings,
24 we do have technical briefings for the directors by our
25 review managers, by our lead review managers in a particular

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1 area. Those we do in between the monthly meetings.

2 I think, in conclusion, that it is -- the key
3 point is that it does work. It can work. I think we have a
4 good working relationship. I think we will end up with a
5 technically defensible decision, whatever that is, in a time
6 yet to be determined. We expect to see the second round
7 comments from U.S. Ecology here the first part of November.
8 As soon as those go out, they will go back to the technical
9 review and we'll be into third round review, really, and
10 into the overview committee again.

11 With that, I do appreciate the opportunity and I'd
12 be glad to answer any questions.

13 MR. AUTRY: Any questions for Harry or Jay?

14 MR. TOPPAN: Clough Toppan from Maine. Was this a
15 politically-motivated decision to join the two departments
16 in this review? The reason I ask is if you were to have,
17 say, a shopping mall in your state, then the Environmental
18 agency, you'd think, would do the review and DOT would
19 provide all the expertise for traffic flow and all that.

20 I'm just wondering why your agency, Jay, didn't do
21 the permitting, for example, for, say, the site permit or
22 whatever and then the Health Department would provide the
23 expertise. I'm just wondering why they went together like
24 that. It seems like a power play of some sort.

25 MR. RINGENBERG: That is a good question. I think

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1 the legislature set it up this way and the fact that I
2 suppose they had a couple choices. One is give it to either
3 agency in total, with the other one being in an advisory
4 role or whatever, or -- what some states have done is
5 created a separate state agency that does the review and
6 marries all those pieces together.

7 This is the way it's laid out. We do have the
8 process of memorandums of understanding agreement, we do
9 have with other agencies on various things and it is a
10 process, it is used in Nebraska for these type of processes
11 where you have a multi-agency review.

12 MR. BORCHERT: The legal people really put this
13 together after the legislature passed the two acts. It was
14 hammered out primarily between the legal counsels of the two
15 agencies and they felt that working together, that that was
16 the best of all the different possibilities and so on.

17 MR. AUTRY: Any further questions?

18 [No response.]

19 MR. AUTRY: I'm glad to see these two agencies
20 working together. I know there are other states in here
21 that work real close with their sister agencies, as well. I
22 won't mention any names.

23 MR. MILLER: Mr. Chair, this is Vandy Miller. I
24 feel obligated to make some comment on that last session
25 there with Nebraska, because Nebraska is one of the few

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1 states that I've had to visit twice. Some states I haven't
2 even been to yet.

3 But the first time I went was to encourage them to
4 get on down the road with an MOU that would be workable. I
5 must tell you that within no time at all, after I had
6 returned back, that they put together a very good MOU. This
7 is a document that they really tried to pull us in on and
8 this is not something that our program wanted to really get
9 involved in.

10 But they did put together a good MOU which really
11 became a very effective document, and then they worked
12 together as a team to really get the program going.

13 Then in about a year-and-a-half, I had an
14 opportunity to visit Nebraska a second time, but this time
15 when I went, I wanted to impress on the state that we were
16 treating these two departments as one. In other words, one
17 can't say that they're getting everything done right and the
18 other one is not doing so well.

19 They have to work as a team because when the
20 agreement state officer performed the assessment, they only
21 -- he prepared a report that reflected a report for the
22 state, not for DEQ on one side and the Health Department on
23 the other. They received one report.

24 And I said to the two program managers, the Health
25 officer and the DEQ Director, just suppose that you have a

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1 problem and the problem happened to be in the medical side,
2 say that they're short of staff, for an example, and,
3 therefore, they can't keep up with their inspections or they
4 get behind in their inspection.

5 Those people who are opposed to a low level waste
6 site being in their state could pick that up and run with
7 it, and that would cause DEQ all kinds of problems. So you
8 can see why they had to work together.

9 I was just recently there and I certainly got some
10 very good commitments that the problems that they were
11 experiencing in one side, that both sides were going to help
12 out, and I do feel that, working as a team, they have solved
13 some problems that they could still be arguing about.

14 I want to commend Nebraska and I'm one of the ones
15 that wanted this topic on this schedule, so that they could
16 share their experiences with the other states who might be
17 going in that direction, to show you that two major
18 departments can work together for a common cause.

19 Thank you.

20 MR. AUTRY: Like NRC and EPA.

21 [Applause.]

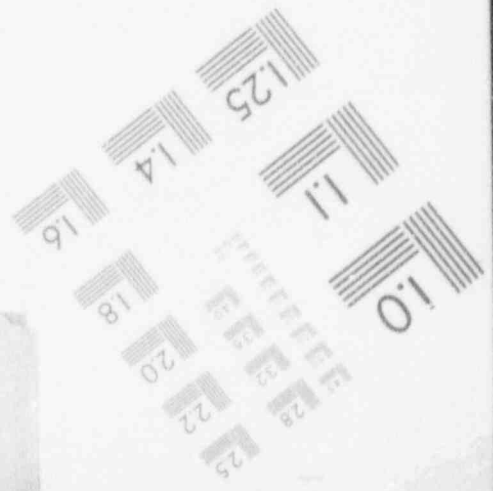
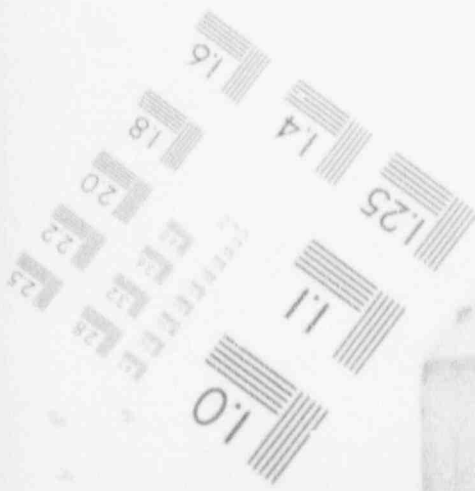
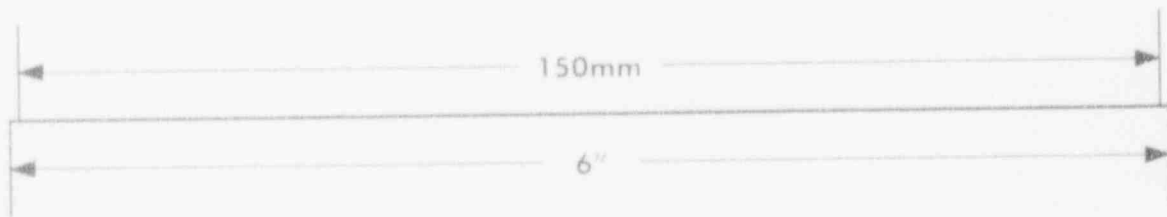
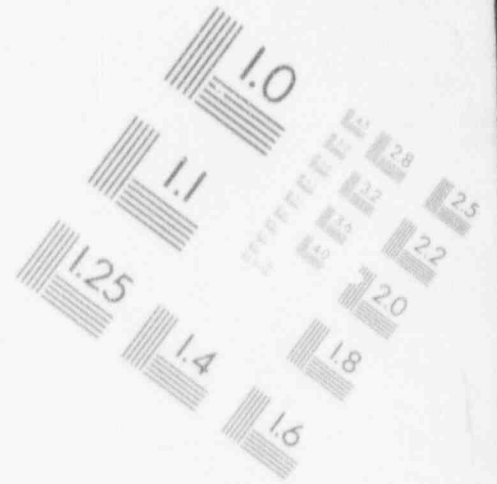
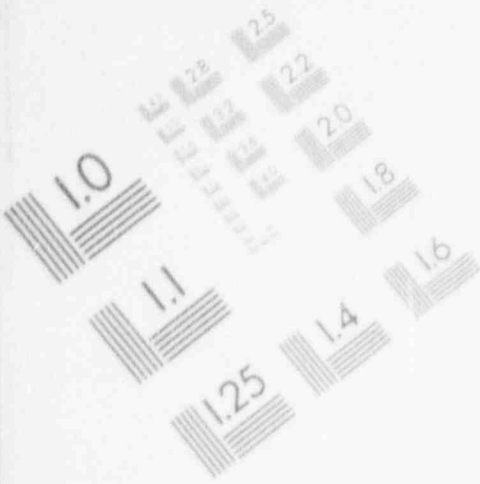
22 MR. AUTRY: Since Ed did a good job, we're going
23 to have him for an encore. He's going to speak with us. Ed
24 is the last speaker this afternoon, so I'm sure he will get
25 through this.

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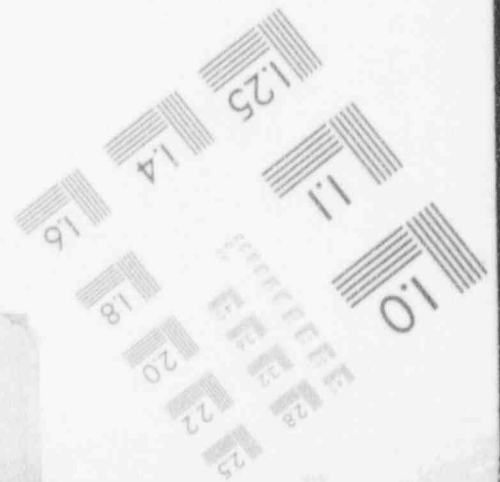
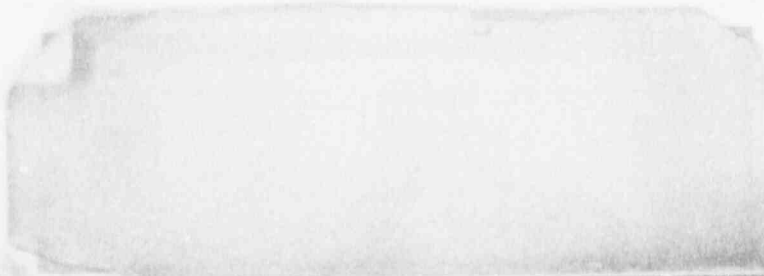
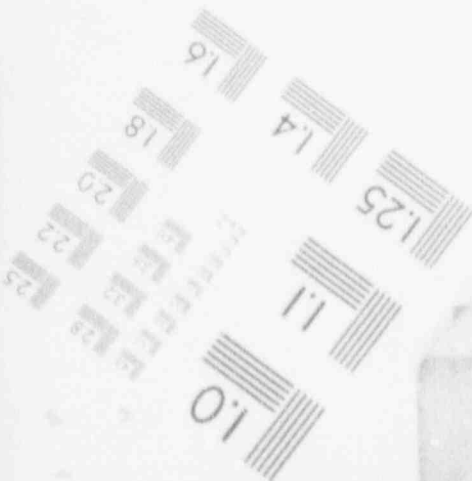
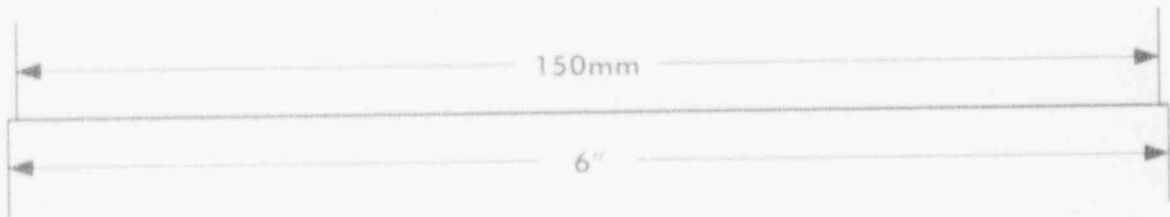
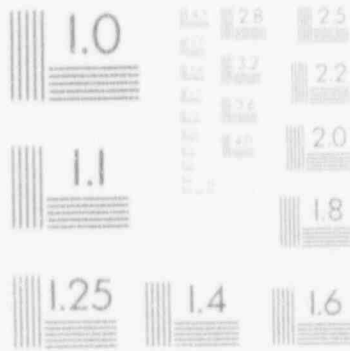
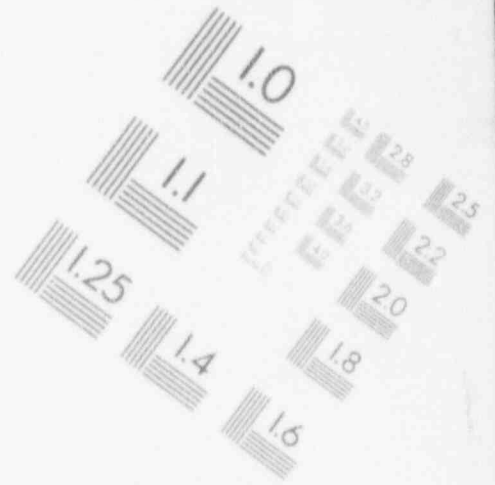
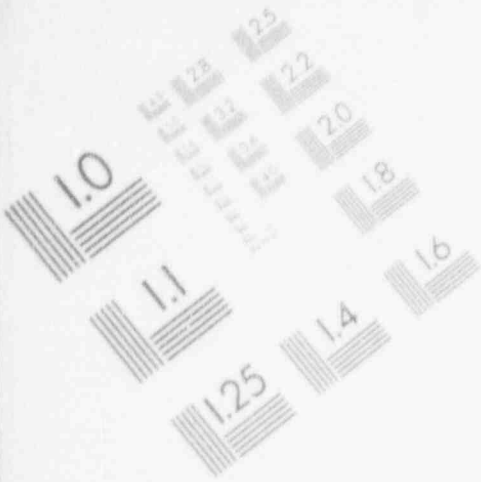
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IMAGE EVALUATION TEST TARGET (MT-3)



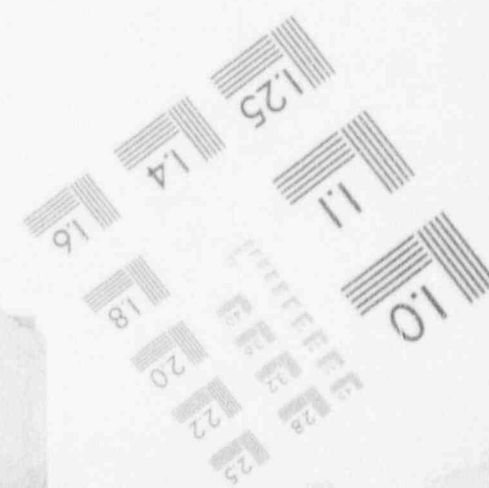
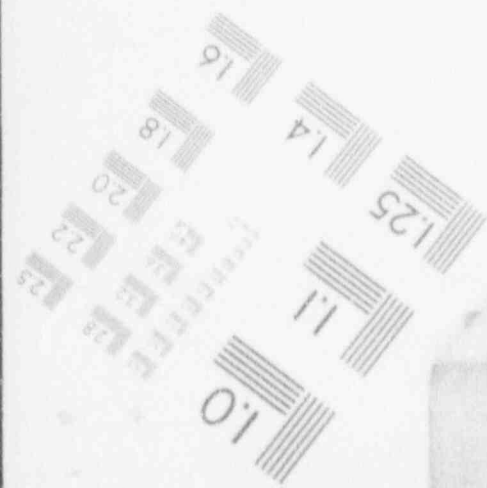
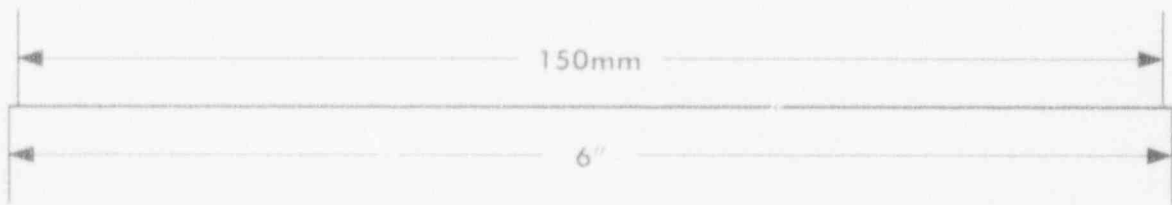
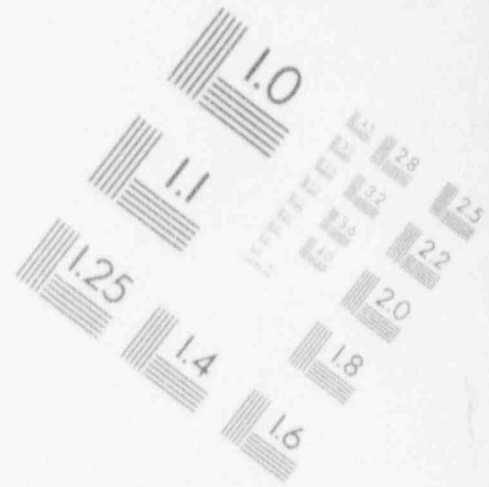
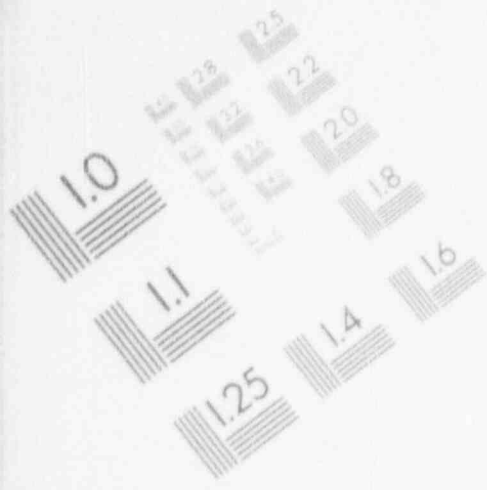
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IMAGE EVALUATION TEST TARGET (MT-3)



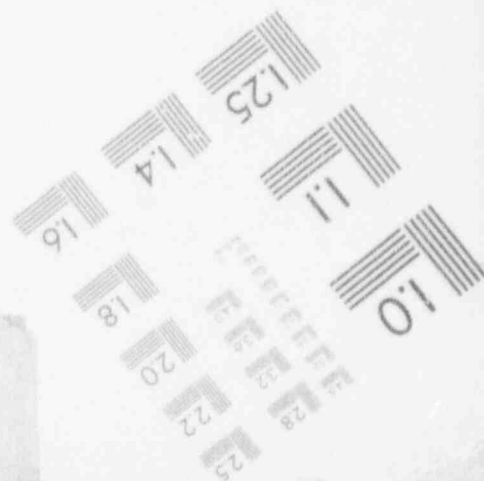
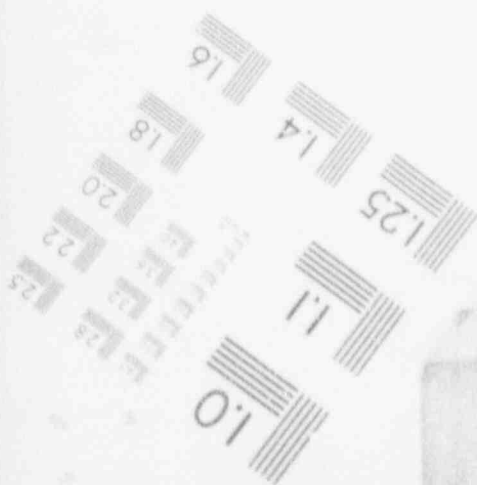
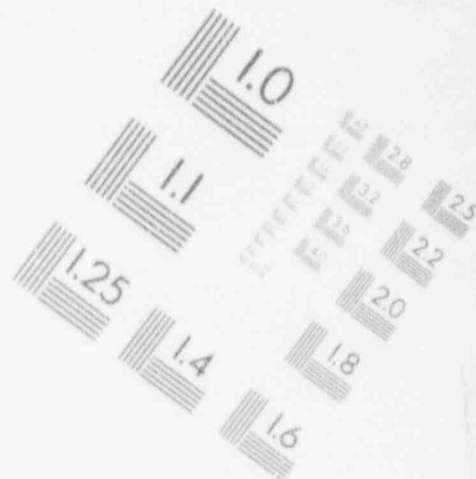
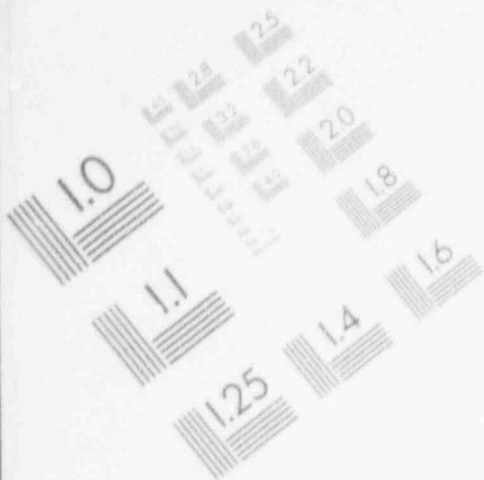
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IMAGE EVALUATION TEST TARGET (MT-3)



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IMAGE EVALUATION TEST TARGET (MT-3)



1 TRENCH COVERS - BIOENGINEERING

2
3 MR. O'DONNELL: Thanks very much, Virgil. It's
4 always a pleasure to be the last speaker of the day. I've
5 noticed that nobody has slipped out, which is very, very
6 remarkable. Dennis Sollenberger is again giving you a
7 handout. It's going to be on covers, basically. That will
8 be the story.

9 In addition, there will be another handout on the
10 back table which Dennis won't hand out. The second handout,
11 which I will not talk about, but it's called the Summary of
12 the Low Level Waste Research Program. I've been starting to
13 do this. We appeared at some of the state meetings and
14 everything else, which the various projects that our branch,
15 the Waste Management Branch in the Office of Research, is
16 sponsoring; for example, long-term service lives of concrete
17 will be listed, the NRC Project Manager, with his telephone
18 number, and the principal investigators, with their
19 telephone numbers, maybe just a one-liner telling you what
20 the project is about.

21 That will be on the back table. That would be
22 worthwhile picking up. There are 40 copies back there and
23 you'll have to get it at the tail-end of the day.

24 What I'm going to do with the covers, we're going
25 to do some slides, then we'll to the handout that Dennis is

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1 passing out.

2 [Slide.]

3 MR. O'DONNELL: What I wanted to do really was get
4 to the bottom line, the direction we're going toward. This
5 is an above-ground structure and there's some kind of a
6 multiple-layered cover in that.

7 [Slide.]

8 MR. O'DONNELL: The principals that we're going to
9 be talking about apply to both above-ground and below-ground
10 structures.

11 [Slide.]

12 MR. O'DONNELL: What we actually have is a field
13 project, an actual site. It's about a half-hour drive from
14 here at Beltsville, Maryland. It's by the USDA agricultural
15 field site down there. You can see some plots of ground and
16 everything else, rather complicated plumbing and hardware
17 that you can't see a lot of stuff is there.

18 Those devices, those plots are called lysimeters.
19 If you look in the dictionary to see what a lysimeter is,
20 two definitions. One, it's a device to give you percolation
21 data, or to give you a water balance. These things are to
22 give us a complete water balance. We start with the amount
23 of moisture coming out of the sky, surface runoff, how much
24 percolates through the cover.

25 I should mention that water is the universal

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1 solvent. Keep water from waste, problems go away. Problems
2 solved, right?

3 [Slide.]

4 MR. O'DONNELL: So the cover performance is being
5 assessed in large scale lysimeters.

6 [Slide.]

7 MR. O'DONNELL: A planned view of it. There are
8 six of them out there. There are actually five different
9 types being tested. Two of them are very, very promising.

10 [Slide.]

11 MR. O'DONNELL: To give you an idea of the --
12 okay. We don't have a sense of the scale. To give you a
13 sense of the scale, if you could just imagine the dimensions
14 of this room, that would be about the length, half the room
15 is the width, depth about twelve foot, about where my hand
16 is. So we're talking about a swimming pool size. So it's
17 almost a realistic scale for a field test.

18 I might also mention there are very few of these
19 field tests of covers going on around the world. We
20 interviewed, we talked to people to find out what was going
21 on. We found out very, very little. A lot of fluff, a lot
22 of feathers, but very little in terms of what was actually
23 being done.

24 [Slide.]

25 MR. O'DONNELL: You can see some human beings and

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1 that will give you an idea. They're putting liners in. NRC
2 does not like liners, but to get a complete water balance,
3 we had to put liners underneath it to account for any water
4 getting into the system.

5 [Slide.]

6 MR. O'DONNELL: I have to remind you this is just
7 a field experiment and there were some simulated barrels put
8 at the bottom of one of the -- two of the lysimeters.

9 [Slide.]

10 MR. O'DONNELL: Three of the types of covers being
11 investigated. We've got three different kinds. One is
12 called a resistive layer barrier, something that resists
13 percolation of water. If you just think about your old-
14 fashioned compacted earthen cover, in other words, clay,
15 that would be a good example of it. Or if you had an
16 impermeable membrane of some kind or other, one of your
17 geomembranes or something, that also would be a resistive
18 layer, resists percolation.

19 Conductive layer, that will take a little more
20 explaining. It's something that will conduct water away
21 from waste, and I'll have to go into a little more detail on
22 that, and something else called bioengineering.

23 [Slide.]

24 MR. O'DONNELL: So the resistive layer in this
25 drawing shows clay as the resistive layer, directs water

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1 away, functions just like a roof.

2 [Slide.]

3 MR. O'DONNELL: This drawing shows a bunch of
4 layers and that's pretty much of a cartoon of one of the
5 lysimeters out through there.

6 [Slide.]

7 MR. O'DONNELL: I think this is a place to stop.
8 Why don't we just work now from the handouts. This handout
9 which I've given, this is a reprint of a paper presented at
10 Waste Management '92 in Tucson in the springtime. The
11 principal investigator for the project, his name is listed
12 here at the bottom of the project, Dr. Robert K. Schulz,
13 Department of Soil Science, Cal-Berkeley.

14 I think perhaps Figure 8 is the most important
15 diagram of all in this. I'm sorry to those of you in the
16 back of the room that don't have copies of this. But if
17 you're really interested, either you can look on or give me
18 your business card later on and I'll get you a copy.

19 Figure 8 is the most important one because it
20 shows results. The way that diagram, you read it, the axis
21 along the bottom, there's time, and you see some curves that
22 start up here. This is water depth in one of these --
23 actually, two different curves, they're two different
24 lysimeters.

25 One would start with one meter of water, another

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1 one starts with almost two meters of water at the bottom of
2 this thing. There was already water in there when the cover
3 was put on. And you see those curves, they go down to zero
4 and they have stayed at zero for the last several years.

5 In contrast, there's a diagram towards the upper
6 right, that's Figure 7, and you see time and you see the
7 water levels have gone up in these other two lysimeters.

8 The one at the bottom of the page is this
9 bioengineering type of cover. If you flip back one page --
10 actually, let's flip back two pages and look at Figure 3.
11 This is a drawing of this cover. This was one that turned
12 out to be very, very promising. It's a surface cover which,
13 at this particular site, about 92 percent of the surface is
14 covered with some impermeable panels.

15 The idea of the impermeable panels was to just
16 limit water going through the cover, promote runoff. It's
17 very, very expensive to make a leak-proof roof. Almost
18 every roof, every engineered structure leaks, and I invite
19 you to look at the concrete parking garage out here and
20 you'll see all sorts of cracks in the concrete.

21 Metro tunnels that you see, you'll see cracks in
22 concrete. So water tends to go through most of the
23 engineered things. This is one which -- well, a little bit
24 of water is going to go through it. The water that gets
25 through it is picked up by some vegetation. Vegetation acts

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1 as a solar-powered pump to pump out the water that gets to
2 that cover.

3 This cover was conceived of as a remedial action
4 cover for actually Maxey Flats, Kentucky. Maxey Flats is a
5 low level waste site, that waste was put in and all sorts of
6 different types of containers. It's underlaid by very
7 impermeable shale. Put water in the trenches at Maxey
8 Flats, water just doesn't get out of them.

9 Since the waste is in all sorts of different kinds
10 of containers, it's a site which will experience subsidence
11 for a long time into the future.

12 So at a major program review meeting that had a
13 whole bunch of people in it, people from the state and other
14 agencies and everything else, discussed how could you close
15 Maxey. A variety of thoughts were thrown out on the floor
16 and one person argued for dynamic compaction, followed by a
17 concrete cover, and somebody else for something else, and
18 somebody else for something else, and somebody else for
19 vegetation.

20 Finally, a couple of the ideas clicked and the
21 ideas that clicked were the idea of a surface cover. So
22 what you would do is you would manage the subsidence, just
23 accept that there will be subsidence. We will treat it like
24 a graveyard. We'll just keep putting dirt on top, but what
25 we want to do is, first of all, enhance runoff, build up the

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1 cover a little bit, enhance the runoff, get as much runoff
2 as you can, and, for the small amounts that might leak
3 through the cover, get something, some kind of vegetation
4 that would suck it out.

5 This is how this concept of bioengineering came
6 about, a surface cover, easy to see, fix if there's a
7 problem or whatever. It could be applied to other sites
8 where you don't have subsidence, but this would be best for
9 a site -- it certainly was designed with a site with
10 subsidence in mind.

11 I would call that probably the most important
12 diagram of all, this Figure 8, because rarely in these
13 reports do you get actual results. If you are a soil
14 scientist and you're interested further, there is another
15 diagram, which happens to be Figure 11. This would be
16 paired with that Figure 8 because what it shows is that not
17 only did it de-water it, the soil got drier and drier with
18 time.

19 The way you would read that, the axis going
20 across, the horizontal axis shows soil moisture. I think
21 it's in grams per cubic centimeter. You can convert that to
22 percent. The 0.35 grams per cubic centimeter would be 35
23 percent moisture, which would be saturation for that soil.

24 So what it was is if you -- each of those curves
25 represented a different year. The one furthest to the right

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1 is 1987, 1988, 1989, 1990, 1991, 1992. So the soil got
2 progressively drier and it showed what happened with it.

3 I think probably we ought to jump to the -- I
4 think it's Figure 25. I think that would be another good
5 figure to jump towards.

6 About ten years ago, there was this term much in
7 vogue called capillary breaks, capillary barriers, and a
8 variety of people were advocating these types of things.
9 What a capillary barrier represented, you had some sort of
10 fine grain material overlaying something with a bunch of
11 voids. The idea was as long as you had unsaturated
12 conditions in the fine grain material, moisture in there
13 will be held under tension.

14 It would be impossible for it to break through
15 into the voids. This diagram here at the bottom shows an
16 above-ground type of structure, multiple-layered type of
17 thing. I should point out that these kinds of structures
18 will be very difficult to construct. You're going to have
19 to have very, very good quality control, very good quality
20 assurance on them.

21 This particular thing, if you were to start at the
22 surface, there was vegetation of some kind or other, a
23 little bit of soil for the vegetation to grow in, some sort
24 of a drainage layer. Get rid of as much water as possible
25 as fast as you can.

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1 The first barrier you come to is a clay. While
2 clays are a compacted earth material, they are permeable.
3 Waters do pass through clays. You can say, well, I can put
4 a geomembrane in, plus a clay, well, yeah, okay, the
5 geomembrane might function very well, but, again, some water
6 will probably pass through some imperfections in the
7 geomembrane.

8 Below that clay there is a second barrier and that
9 second barrier is, in this particular drawing, we're calling
10 it a conductive layer, plus a capillary break. To
11 understand how this -- okay. The way this would function is
12 this conductive layer, which would be some kind of a very
13 fine grain material, would wick away the very small amounts
14 of moisture which would normally leak past through a clay.

15 As long as this capillary break is present, it's
16 physically impossible for water to get to the waste. Now,
17 to understand the theory, we can back up a few drawings and
18 the drawing that we want happens to be Figure No. 16. This
19 conductive layer, what we're looking at is something which
20 will transmit significant amounts of water in the
21 unsaturated condition.

22 Gravel is not what we wanted. Gravels pass lots
23 of water when they're saturated, but when they're dry, they
24 pass very little water. A very fine silt, think of
25 something like a Bounty towel, will pass a lot of water even

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1 though it can be quite unsaturated.

2 Now, imagine what you've got in this drawing here
3 at the upper left, an inclined plane. We pack in some fine
4 grain materials, a silt or something very fine grain. You
5 can introduce water at the upper left. The water could
6 actually move through here and bring it down vertically. It
7 could actually exit towards the right.

8 You could puncture holes in the bottom in the
9 bottom of this inclined plane. As long as it was
10 unsaturated, no moisture would leak out. The drawing
11 towards the right just shows that those voids would be
12 provided maybe by a gravel or large cobbles or something.
13 Again, as long as it's unsaturated flow.

14 Flip over to the following page. Somebody asked
15 us at one of these meetings, well, what happens if you have
16 a sag in it. That's what this drawing here at the upper
17 left. If there's a small sag, as long as you have
18 unsaturated conditions, it's physically impossible for
19 moisture to leak out.

20 To test this -- actually, we wanted to test this
21 out in the field and before we went out in the field, we
22 actually developed a device, which this photograph towards
23 the lower left shows an actual soil beam which is
24 constructed. We conducted a series of tests. The results
25 of the test of one of the favorable materials, which turned

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1 out to be diatomaceous earth, is shown here at the lower
2 right. The way you would read that is we were looking for
3 tension, a certain amount of tension, about minus to 15 to
4 20 centimeters of suction on it.

5 Here at the top where it says one, that's
6 atmospheric pressure. Anything above one is saturation.
7 What we were looking for was a curve which would go across
8 the page more or less horizontally which would decline with
9 distance.

10 That indicated that you could maintain unsaturated
11 conditions indefinitely or if it got declined with distance,
12 it meant you were getting drier and drier with distance. So
13 that was considered to be a favorable material.

14 As a construction convenience, we settled on a
15 diatomaceous earth. There are those types of deposits here
16 in Maryland. We actually located a site where it could be
17 shipped in very cheaply from actually the State of Nevada.
18 It has very low bulk density. It's very cheap to ship.

19 So kind of in summary, then, what this paper here
20 is about three different kinds of covers. We have some
21 reports on a resistive layer barrier, this bioengineering,
22 and this combination of a conductive -- it should be a
23 resistive layer over a conductive layer barrier.

24 We believe if you want to go the multiple layer
25 route, the combination of resistive with the conductive

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1 backing it up. it should be a very, very effective system.
2 If you use geologic materials of known stability, we stuck
3 our necks out in the abstract and said it should function
4 for millennia. And as a geologist, I feel fairly
5 comfortable.

6 We know the stability of diatomaceous earth. We
7 know the stability of quartz and those kaolinite clays.
8 They're end products of weathering. So those types of
9 materials would last a very long time.

10 I would like to extend an invitation to any of you
11 who are interested further in covers, cover design, who
12 would like to go out to visit our site at Beltsville, feel
13 free to contact me. The phone number, I guess, is on the
14 cover of the handouts. Just feel free to call me or contact
15 me.

16 In conjunction with this meeting or at the end of
17 the week or something, feel free to call me and I'd be
18 delighted to take anyone out to the site.

19 Virgil?

20 MR. AUTRY: Thank you. Any questions of Ed?

21 [No response.]

22 MR. AUTRY: I'd like to acknowledge the work that
23 they've done. We, of course, at the Barnwell site, are
24 going through some closure. We also have actually closed 18
25 acres of that site. And the work that they have done has

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1 been very important to us, very useful in some of the
2 information that is being done there.

3 Does anyone have any more questions of anyone on
4 the panel this afternoon?

5 [No response.]

6 MR. AUTRY: I think we had a good panel and I
7 think they're well deserving of a lot of applause here.

8 [Applause.]

9 MR. AUTRY: I will now turn it over -- nobody
10 wants to take it. We're gone. We're out of here. Thank
11 you.

12 [Whereupon, at 4:05 p.m., the meeting was
13 concluded.]

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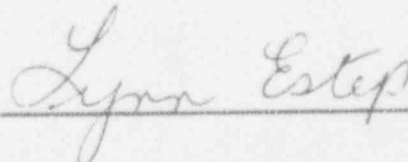
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DOCKET NUMBER:

PLACE OF PROCEEDING: Towson, Maryland

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