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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON NUCLEAR WASTE (ACNW)

174th MEETING

FOURTH DAY

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THURSDAY,

NOVEMBER 16, 2006

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ROCKVILLE, MARYLAND

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The Advisory Committee met at the Nuclear
Regulatory Commission, Two White Flint North,
Room T-2B3, 11545 Rockville Pike, Rockville, Maryland,
at 8:30 a.m., Michael T. Ryan, Chairman, presiding.

COMMITTEE MEMBERS PRESENT:

- | | |
|------------------|---------------|
| MICHAEL T. RYAN | Chairman |
| ALLEN G. CROFF | Vice Chairman |
| JAMES H. CLARKE | Member |
| WILLIAM J. HINZE | Member |
| RUTH F. WEINER | Member |

1 ACNW STAFF PRESENT:

2 JOHN T. LARKINS, Executive Director, ACRS/ACNW

3 CHRISTOPHER BROWN

4 ANTONIO DIAS, Designated Federal Official

5 NEIL M. COLEMAN

6 DEREK WIDMAYER

7 MIKE SNODDERLY

8

9 SPEAKERS:

10 STEPHANIE BUSH-GODDARD, NRR

11 WILLIAM OTT, NRR

12

13 ALSO PRESENT:

14 JEAN-CLAUDE DEHMEL, NRR

15 STEVE GARRY, NRR

16 HARRIET KARAGIANNIS, RES

17 DAVID McCURDY (via telephone), NRR

18 BOBBY ABU-EID, FSME

19 ERIC DAROIS, RSCS

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I-N-D-E-X

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P-R-O-C-E-E-D-I-N-G-S

(8:32 a.m.)

CHAIRMAN RYAN: Okay. If I could ask everybody to come to order, please.

This is the fourth day of the 174th meeting of the Advisory Committee on Nuclear Waste. During today's meeting, the Committee will consider the following: proposed revision to Reg. Guide 1.112, Calculation of Releases of Radioactive Materials in Gaseous and Liquid Effluents from Light-Water Reactor -- Light-Water-Cooled Reactors, excuse me, the proposed revision to Reg. Guide 4.15, Quality Assurance for Radiological Monitoring Programs (Inception Through Normal Operations to License Termination) -- Effluent Streams and the Environment.

We will have a discussion of potential ACNW letters and ACNW reports and other miscellaneous items as may come before us.

This meeting is being conducted in accordance with the provisions of the Federal Advisory Committee Act. Mike Lee is the Designated Federal Official -- is Mike Lee here? Antonio Dias will be the Designated Federal Official for today's initial session.

We have received no written comments or

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1 requests for time to make oral statements from members
2 of the public regarding today's sessions. Should
3 anyone wish to address the Committee, please make your
4 wishes known to one of the Committee staff.

5 It is requested that speakers use one of
6 the microphones, identify themselves, and speak with
7 sufficient clarity and volume so they can be readily
8 heard. It is also requested that if you have cell
9 phones or pagers that you kindly turn them off.

10 Thank you very much.

11 And without further delay, let me turn
12 over our first presentation to Dr. Stephanie Bush-
13 Goddard. Stephanie, welcome back.

14 DR. BUSH-GODDARD: Thank you very much --

15 CHAIRMAN RYAN: Nice to see you.

16 DR. BUSH-GODDARD: -- Chairman Ryan. As
17 Chairman Ryan said, my name is Stephanie Bush-Goddard,
18 and I am --

19 CHAIRMAN RYAN: I'm sorry. You either
20 need to sit and use the microphone or get --

21 DR. BUSH-GODDARD: Oh, oh, sit.

22 CHAIRMAN RYAN: -- or get -- either way.
23 If you want to stay up, you can use that one. It's up
24 to you.

25 DR. BUSH-GODDARD: Let me stand up.

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1 CHAIRMAN RYAN: Okay.

2 DR. BUSH-GODDARD: I have to sit hours a
3 day.

4 CHAIRMAN RYAN: You've got to be
5 comfortable. That's fine.

6 DR. BUSH-GODDARD: Thank you. And I am
7 here to give an update and status on Reg. Guide 1.112.
8 It's a long title, but basically it's a reg. guide to
9 show calculations of releases of radioactive materials
10 for PWRs and BWRs.

11 So I have two main points of the
12 presentation. I'm going to talk about why we decided
13 to update the regulatory guide now, but I'm going to
14 spend the majority of my time on the next steps of
15 this revision and -- which is to update the computer
16 GALE code and the associated NUREG.

17 Now, a reason why we decided to go ahead
18 and do minor and administrative changes, as you know,
19 is because we did want to incorporate the most recent
20 ANSI standard. In looking at deciding what we were
21 going to do to meet the March deadline -- you know,
22 the high priority guides have a March deadline -- we
23 knew that updating the computer code and the NUREG
24 would take a long time. We're gueestimating about a
25 year and a half to two years.

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1 So we kind of juggled, you know, do we
2 wait for a year and a half, two years, to just do the
3 guide, or do we kind of just do some of the
4 administrative changes up front? And so we kind of
5 struggled with that. What we decided to do was do the
6 administrative changes, insert the ANSI standards,
7 because applicants are currently using that standard,
8 ask for a waiver of review, because we didn't realize
9 the changes were administrative in nature, and just to
10 continue the process. And we got all that
11 successfully done except the waiver of review, because
12 I'm here telling you about it.

13 So, basically, the purpose of the
14 regulatory guide is to comply with these regulations.
15 I won't necessarily go over them, but they are Part 20
16 and 50. One of the minor reasons for going ahead and
17 updating it is because the guide was published in
18 1977, and that was pre the new Part 20. So all the
19 references for Part 2 did not mesh, and it was kind of
20 difficult reading, "You must comply with 20.106," and
21 there is no 20.106. So that was kind of a minor
22 reason to -- to just go ahead on and update the
23 current Part 20.

24 Some of the supporting materials in the
25 reg. guides -- of course, I mentioned the two NUREGs,

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1 NUREG 17 and 16 -- they both describe how to calculate
2 PWRs and BWRs, so we are in the process of getting
3 ready to modify those. And then, the last two bullets
4 are the standards that we reference, the last bullet
5 being the current standard that we decided to go ahead
6 and put in.

7 So make a long story short, this is a
8 summary of interim changes. We included the most
9 recent standards, because applicants are currently
10 using those standards, and we just made it easy to
11 read. So let me spend the bulk of my presentation
12 talking about what the next steps are for this reg.
13 guide.

14 Well, back in April when I did the program
15 overview for the Health Physics Branch and the Office
16 of Research, I talked about a lot of things. And one
17 thing I talked about was this big effort to update
18 these regulatory guides. We were going to focus on
19 Division 8 guides, but spend the time on those type of
20 guides that fit into our section.

21 I spent a couple of minutes talking about
22 Regulatory Guide 1.109 and our efforts to review that.
23 We were going to send a SECY paper, which is now being
24 developed. And within that SECY paper we do mention
25 that Reg. Guide 1.112 is one of the guides associated

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1 with that. However, if we fast-forward to November,
2 we know that based on changes that we were looking at
3 a lot of high priority guides, and this was a guide
4 that was pulled out to look at in depth.

5 So where are we now? Well, you know, the
6 administrative changes that I talked about, we're
7 going to do that -- complete that in March. We're
8 trying to update the GALE computer code by late 2007
9 and then update the NUREG after that. Finally, we're
10 going to publish a new regulatory guide that
11 incorporates all of the changes.

12 I want to -- what we've -- this is very
13 preliminary, but since, you know, I am presenting the
14 ACNW -- and I wanted to talk about some of the
15 limitations of the GALE code, some of the things
16 technically that we are looking at. And I also have
17 NRR here, who are the technical expertise. So you can
18 ask me all the hard questions, and I will give it to
19 them.

20 The GALE basically stands for Gaseous and
21 Liquid Effluents, and the main thing that it does is
22 it calculates the annual gaseous -- liquid and gaseous
23 source terms. This is the curies per year that the
24 licensees are to submit to NRR, and, in fact, we put
25 it in a database. The Office of Research puts these

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1 numbers in the database.

2 I was surprised to find that some things
3 are hard-wired into the code, some things aren't. For
4 example, the radionuclide concentration in the reactor
5 coolant is actually hard-wired in the code, but things
6 like the mass of the water in the reactor vessel you
7 have to input. But basically the NUREG provides the
8 technical basis for all the defined parameters. It
9 describes the format, the sample problems, data and
10 source terms, and things like that.

11 So this is kind of a slide on what we see
12 as the limitations of the GALE code, kind of the
13 technical limitations, and the things that we're
14 looking at. First, we're going to review all the
15 parameters -- review and update all the parameters
16 reflecting present fueling reactor design. The 1977
17 code referred to only zircalloy cladding, and at that
18 time it was to differentiate between stainless steel
19 cladding that was currently as part of some of the
20 cladding designs back then.

21 We're going to make our parameters
22 accessible to users. As I explained, some of the
23 parameters are hard-wired to make it -- the code a
24 little bit more flexible. Another limitation, it does
25 not provide the capability to consider its new

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1 processes and new treatment technologies, and it does
2 not recognize improvements in fuel cladding. You
3 know, we have zircalloy, but I also heard that there
4 is this N3 type of cladding. It does not recognize
5 high burn up, pellet design performance.

6 The PWR code NUREG was actually last
7 published in '85, so that's 20-something years ago.
8 And then, the BWR is even older than that. That's
9 about 30 years old.

10 And then, to add insult to injury, or
11 injury to insult, it operates in FORTRAN, and it
12 doesn't even have a Windows interface. So we are
13 looking at the technical capabilities of what do we
14 need to upgrade to reflect present fuel and reactor
15 design as well as doing some GUI interface.

16 So our immediate next steps, we're going
17 to get all of the high priority reg. guides out of the
18 way, and then we're going to develop this
19 multidisciplinary working group, identify all the
20 limitations -- I'm here just to give you some things
21 that we've identified, you know, very quickly -- but
22 then, identify the limitations and propose the
23 revisions for the fuel cladding and burn up. We have
24 source term experts, HP reactor people, just a lot of
25 people to kind of look at what our limitations are and

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1 to propose revisions.

2 Another thing that we're also going to do
3 is to analyze the regulatory structure for the reg.
4 guide. You know, we're in this loop, in that we have
5 a stand-alone reg. guide, but it's really not stand
6 alone. You update the reg. guides, you have to update
7 the GALE code, and you have to update the NUREGs. And
8 we have -- we're struggling to say, "Why should we
9 even update the reg. guide at this time when we have
10 so many other things associated with that to update?"

11 So we're maybe trying to figure out if we
12 can take some things out of the reg. guide, which are
13 like the appendices. The appendices go directly into
14 the GALE code, and have a stand-alone reg. guide,
15 since at present moment, well, reg. guides take a
16 little bit longer to get out, although these high
17 priority guides are an exception. So we're even
18 looking at the regulatory structure of the reg.
19 guides.

20 And, finally, we're going to identify the
21 pros and cons of using FORTRAN. We might even think
22 about putting a GUI face on it, or just revamp it and
23 use some type of up-to-date computer code. So there
24 are a lot of different issues that's going on, you
25 know, from the technical issues to the regulatory

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1 structure and some of the computer issues.

2 So that's all I have. Any questions?

3 CHAIRMAN RYAN: A bunch.

4 DR. BUSH-GODDARD: Okay.

5 CHAIRMAN RYAN: Let me get you to turn to
6 I guess it's -- slide 3 is probably the best place to
7 go.

8 DR. BUSH-GODDARD: Okay.

9 CHAIRMAN RYAN: This may seem like the
10 dumb guy question, but it sounds like you're going at
11 it backwards.

12 DR. BUSH-GODDARD: Okay.

13 CHAIRMAN RYAN: I'm a little nervous that
14 you're updating references to new regulations when the
15 foundation of what people will be calculating isn't --
16 in no way reflects any of that. So why aren't you
17 doing the code first, and just -- I mean, if you go,
18 let's say, to a later slide, I'd go just exactly the
19 opposite of what you've outlined. I mean, if you
20 don't know the GALE code is up and running and
21 working, why update the reg. guide references?

22 DR. BUSH-GODDARD: I hear you loud and
23 clearly.

24 CHAIRMAN RYAN: Okay.

25 DR. BUSH-GODDARD: And we --

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1 CHAIRMAN RYAN: So it's not a dumb guy
2 question?

3 DR. BUSH-GODDARD: No.

4 CHAIRMAN RYAN: It's okay?

5 DR. BUSH-GODDARD: And we've discussed
6 this over and over and over again.

7 CHAIRMAN RYAN: Oh. Well, tell me why my
8 approach is wrong.

9 DR. BUSH-GODDARD: Okay. The main reason
10 why we decided to go ahead and do an interim
11 publication was to include the reference to the ANSI
12 standard, the 1999 standard, because we knew that
13 applicants were currently using that standard. So the
14 focus in considering what's the right thing to do,
15 which would be to update the computer code as you
16 suggested, we knew that the administrative contracts,
17 looking for people to do it, would take maybe a year,
18 year and a half.

19 CHAIRMAN RYAN: That's okay.

20 DR. BUSH-GODDARD: Okay.

21 CHAIRMAN RYAN: But that timing is not the
22 reason to do it out of order.

23 DR. BUSH-GODDARD: Well --

24 CHAIRMAN RYAN: In my view.

25 DR. BUSH-GODDARD: Okay. Okay. And --

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1 CHAIRMAN RYAN: I just don't think that
2 makes sense to me, because if I'm trying to use this
3 -- I mean, to me it would be better to publish the
4 schedule, publish the parts and pieces, do the
5 important foundation pieces first, and then tell
6 people, you know, if you want to use an ANSI standard
7 or some other part of a regulation, write us a letter,
8 we'll say okay.

9 But to give the impression that this is an
10 updated reg. guide on these points only doesn't seem
11 right to me.

12 DR. BUSH-GODDARD: Okay. And point well
13 taken, and maybe -- the reg. guide is out for public
14 comment, and I'm sure we will probably get a comment
15 like that.

16 CHAIRMAN RYAN: You will from us.

17 DR. BUSH-GODDARD: Okay. And, you know,
18 our -- basically, our answer will -- you know,
19 satisfactory or not, but we did struggle with this
20 question to go ahead and put the ANSI standard in
21 there and to continue.

22 When we identified the reg. guides, kind
23 of give you a -- what was going on at the time, we
24 were at a very short time to identify all of these
25 reg. guides and put on the high priority list that was

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1 sent to the Commission.

2 Once this reg. guide got on the list, it's
3 very difficult -- it's much easier to do the work than
4 to give a reasoning why we should take it off. And we
5 also knew that some of the changes that we wanted to
6 make would make it read better, you know. But, you
7 know, we just decided to make that decision.

8 CHAIRMAN RYAN: Well, but it doesn't seem
9 right to me. I mean, I -- you haven't convinced me
10 that I'm wrong.

11 DR. BUSH-GODDARD: Okay.

12 CHAIRMAN RYAN: So --

13 DR. BUSH-GODDARD: Well, and I don't think
14 you're wrong.

15 CHAIRMAN RYAN: Okay. Well, there you go.

16 (Laughter.)

17 What's next?

18 (Laughter.)

19 And I appreciate your good humor about it,
20 Stephanie. Thank you.

21 DR. BUSH-GODDARD: Yes.

22 CHAIRMAN RYAN: Let me -- point well made
23 on this one, okay?

24 DR. BUSH-GODDARD: Okay.

25 CHAIRMAN RYAN: Let's move on, so we

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1 can --

2 DR. BUSH-GODDARD: Okay.

3 CHAIRMAN RYAN: The GALE code -- you know,
4 I recall in 1976 that my computer had a 16K processor
5 as opposed to a 2 gigabyte processor. That's just one
6 major change from that interval of time. And I'm a
7 little nervous that we've got a FORTRAN code. God
8 knows how to run FORTRAN anymore. I mean, I'd be
9 hard-pressed to rerun FORTRAN, boxes of cards, you
10 know, fabulous.

11 But I'm a little nervous that without a
12 fundamental review of the basics that the code was
13 written from, there's missed opportunity there. I
14 mean, I'm sure as all FORTRAN codes of that vintage
15 were, they were written with shorthand and with
16 intermediate calculations, with hard-wired stuff,
17 which you mentioned, because the processors couldn't
18 handle it. Now we can calculate anything.

19 So if you had a clean sheet of paper and
20 all the time in the world, would you take the GALE
21 code and modify it, or would you start from scratch?
22 I'm not asking you to answer that necessarily today,
23 but --

24 DR. BUSH-GODDARD: Okay.

25 CHAIRMAN RYAN: -- I mean, that -- I'm

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1 trying to understand why you would take an old code
2 and even worry about, do we put something on the front
3 end of a FORTRAN code?

4 DR. BUSH-GODDARD: Okay.

5 CHAIRMAN RYAN: Or not?

6 DR. BUSH-GODDARD: Maybe because of cost
7 would be the leading factor, cost and maybe time.
8 Okay. But, again, I agree with you.

9 CHAIRMAN RYAN: Well, it's better to get
10 it right than get it early.

11 DR. BUSH-GODDARD: We're going to look
12 into that.

13 CHAIRMAN RYAN: Okay.

14 DR. BUSH-GODDARD: Actually, we haven't
15 delved into that. We've been really just working on
16 the administrative changes and things like that, but
17 that is something that we're going to --

18 CHAIRMAN RYAN: Okay.

19 DR. BUSH-GODDARD: -- look into in --

20 CHAIRMAN RYAN: I would say that's a
21 higher priority than the administrative changes. My
22 own view.

23 DR. BUSH-GODDARD: Okay.

24 CHAIRMAN RYAN: Because that's the
25 technical meat of the guide.

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1 The third thing that strikes me is -- and
2 you mentioned this -- that reactor operating
3 characteristics are dramatically different from '76 to
4 now, particularly with regard to coolant water
5 cleanliness. I mean, that's an INPO measurable, and,
6 you know, everybody knows that cooling water isn't as
7 troublesome as it perhaps was in the '70s.

8 Finally, how is this going to be risk-
9 informed? This is a deterministic code. How are you
10 going to use principles of risk-informed PRA or other
11 kinds of approaches that are more up to date with the
12 way we think about things now?

13 DR. BUSH-GODDARD: Okay. Well, one thing
14 that we were thinking about, since we're going to
15 change it to have a lot of user inputs, you know, take
16 out the things that are hard-wired, one thing we are
17 thinking about is maybe putting some probabilistic
18 functions to some of our inputs.

19 Another thing is, you know, when we talk
20 about risk-informed, the fact that we are -- will be
21 considering current operating experience, and when we
22 update the code we'll be applying new -- the new
23 technologies, the cladding, and things like that. So
24 at kind of the higher level, I think in deciding how
25 we're going to do that, in the back of our head

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1 because we know it has to be risk-informed, we're
2 going to be thinking about those things.

3 CHAIRMAN RYAN: I guess, kind of in
4 summarizing all of those points, it would seem to me
5 that it would be worth the exercise -- and I don't
6 think it's a huge, long one -- to say, "If we did have
7 a clean sheet of paper to do this reg. guide, what
8 would we do today with nothing in hand?" versus, "How
9 are we going to patchwork this one together and cobble
10 it together over three years?"

11 DR. BUSH-GODDARD: I like that approach.

12 CHAIRMAN RYAN: Because I think, frankly,
13 from what you've said and what you've presented, I
14 think it would be a lot different.

15 DR. BUSH-GODDARD: I like that approach.

16 CHAIRMAN RYAN: Maybe that's just me, but
17 I -- those are some thoughts.

18 Ruth?

19 MEMBER WEINER: At the risk of disagreeing
20 with the Chairman, I just want to talk a little bit
21 about your FORTRAN code and just to give you some of
22 our experience. First of all, there is a
23 FORTRAN 2003. This is not something that --

24 CHAIRMAN RYAN: Not this one.

25 MEMBER WEINER: No, not this one, but, in

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1 fact, ours is '95. But it is an upgraded code.

2 One of the biggest advantages -- I want to
3 talk a little bit about FORTRAN and then a little bit
4 about user input. One of the biggest advantages of --

5 DR. BUSH-GODDARD: I'm going to sit if you
6 all don't mind.

7 MEMBER WEINER: Please do.

8 CHAIRMAN RYAN: Please do, yes. Please.

9 DR. BUSH-GODDARD: I want to write some
10 notes.

11 MEMBER WEINER: Yes. Of FORTRAN is that
12 you can read it. And that's not really true for C++
13 or any of the more modern codes. And it makes it very
14 easy for somebody who uses the code but isn't a
15 programmer to figure out what's going on. You can
16 always look back and see exactly what your code did,
17 and it -- another advantage is it runs very quickly.

18 A third advantage to speak to what the
19 Chairman just said is that there are a number of
20 programs that allow you to distribute your inputs in
21 FORTRAN and run a probabilistic -- get probabilistic
22 output, get an output that incorporates the
23 uncertainty in your inputs. And they run fast, run on
24 a PC.

25 I think this is a really major advantage

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1 for any code, if you can get it so that you don't need
2 a big -- a lot of electronics to run it, if you can
3 just run it on a PC.

4 The other -- I would encourage you to make
5 it as flexible as far as user input is concerned as
6 possible. I was listening to your discussion of fuel
7 cladding, and instead of, you know, putting in hard
8 wiring in the parameters for all different kinds of
9 cladding, let the user do it. It makes it harder on
10 the user. I mean, it means that the work of making
11 the calculation is in figuring out what to put in, but
12 it also means that the user has a much better feel for
13 what is being done with the code.

14 And I'd be happy to talk to you offline
15 about some of our experiences.

16 Finally, when you come up against a user
17 -- a GUI question, how to make it user friendly,
18 either Java or Visual Basic work very well. Java has
19 a major advantage in that its platform independent,
20 although your program is not platform independent.
21 There is a real problem with starting coding from a
22 clean sheet of paper, and that is that you may want to
23 look at how important it is to be backwards compatible
24 with people who now use the GALE code, and whether
25 that -- any of those inputs can be incorporated.

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1 That's the pro for sticking with a code
2 that you can get backwards compatible. The con is
3 just what Mike pointed out, that you may be able to do
4 these calculations much more efficiently with a modern
5 code. You can get rid of all kinds of jump that has
6 crept in, spaghetti programming and things of that
7 sort.

8 But I would encourage you just to look at
9 all sides of that. And I would, finally, really
10 encourage you to look very carefully at the -- at
11 incorporating uncertainty and making it risk-informed.
12 This -- I think the more that we do that with these
13 calculations the more it becomes clear to the people
14 who use it that you really do have uncertainty in
15 these parameters. You really can't just pinpoint a
16 value.

17 DR. BUSH-GODDARD: Okay.

18 MEMBER WEINER: That's it.

19 DR. BUSH-GODDARD: Okay.

20 CHAIRMAN RYAN: Just for reference, Ruth,
21 I'd challenge you to go to the appendix here -- 3, I
22 think it is -- and follow some of this FORTRAN, tell
23 me what's happening.

24 MEMBER WEINER: Yes, I'll do that. I do
25 it all the time with my codes.

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1 CHAIRMAN RYAN: I think you'd be hard
2 pressed to -- I mean, if you pick out a note like
3 Bateman equations or an LTM-361, you get a hint what's
4 happening there. But it's not readable. Sorry.

5 The other part that, just to talk about
6 this code another minute, is a lot has changed in
7 terms of how people think about radionuclide
8 inventories. In those days and times, predicting the
9 upper bound of the liquid effluent was the right
10 answer, because if you underpredict an effluent, oh my
11 God, you know? The NRC will come in and find you at
12 fault, because you underpredicted an effluent. It's
13 kind of like waste disposed. Waste disposed, my God,
14 you want to give an overestimate.

15 So little things like instead of using the
16 actual measured value in an effluent, we do a
17 measurement and declare that the detection limit is
18 what is actually there, and that's wrong. That's
19 particularly wrong for tech-99 and I-129, two
20 important environmental radionuclides.

21 You know, Gene Vance did a study in the
22 '80s of particularly resin effluents and found that
23 technetium and iodine were overestimated by orders of
24 magnitude in resins.

25 DR. BUSH-GODDARD: Okay.

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1 CHAIRMAN RYAN: So just accepting some of
2 these older codes accepts inherently, perhaps, some of
3 those issues. And I think you need to run those kinds
4 of questions to the ground.

5 DR. BUSH-GODDARD: Okay.

6 CHAIRMAN RYAN: And there's a lot of them
7 there that raises the question in my mind: is it
8 better to start over, or is it easier to fix this?
9 And the answer is: I don't know, but, boy, I'd sure
10 want to think hard about that.

11 DR. BUSH-GODDARD: Okay.

12 CHAIRMAN RYAN: And then, simple things
13 like running Bateman to K equations. I mean, there
14 are little routines. You can use three lines in
15 modern code and get it done. In fact, you can do it
16 on a hand calculator now.

17 DR. BUSH-GODDARD: Okay.

18 CHAIRMAN RYAN: So there's lots of things
19 to think about in terms of just accepting this code
20 and reworking it as a FORTRAN code without really
21 looking at a lot of details.

22 DR. BUSH-GODDARD: Okay.

23 CHAIRMAN RYAN: So I'm a little concerned,
24 and I think my view is that you're really taking care
25 of the administrative stuff first, because you can do

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1 that quickly, is the wrong view. You ought to tackle
2 the hardest part and get that right, and then the
3 other stuff flows more smoothly from there.

4 DR. BUSH-GODDARD: I hear you loud and
5 clearly.

6 CHAIRMAN RYAN: Jim?

7 MEMBER CLARKE: I guess this comes under
8 the "for what it's worth" category. I did the
9 calculations for my dissertation using FORTRAN 4. I
10 don't know what FORTRAN is up to now, but I'm looking
11 at this code here and I'd like to say it brings back
12 fond memories, but it doesn't.

13 (Laughter.)

14 And it -- three boxes of punch cards on an
15 IBM-360, I just don't even want to think about that.
16 So, I mean, I'm not really supporting either Mike or
17 Ruth, but just under the "for what's it worth"
18 category. And I don't think it's very readable now,
19 and I didn't think it was very readable then, so --

20 CHAIRMAN RYAN: Professor Hinze.

21 MEMBER HINZE: Tangential to these
22 conversations, what are your plans for verifying and
23 validating your codes?

24 DR. BUSH-GODDARD: Well, this is very
25 preliminary. For example, we don't know if we will

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1 use FORTRAN or just where we will go with this.

2 MEMBER HINZE: But you still have to
3 validate, you still have to verify.

4 DR. BUSH-GODDARD: To verify, yes. Can
5 you maybe add a little bit of light on that, Jean-
6 Claude?

7 MR. DEHMEL: Yes, I will try. Jean-Claude
8 Dehmel, NRR, Health Physics Branch. Yes, obviously,
9 every time you modify a computer code, or you generate
10 a new code, you have to go through this V&V process,
11 absolutely. The question is, you know, what are the
12 procedures to develop a program? I believe that there
13 are some reg. guides from the NRC as well as IEEE
14 standards that actually address this process. Very,
15 very complex, very, very time-consuming, and requires
16 a lot of upfront time investment.

17 And we would have to look at this and
18 figure out whether or not we would -- we would, you
19 know, apply, you know, all of the elements that are
20 identified in the reg. guides as well as the IEEE
21 standards and figure out whether or not some of this
22 information is extraneous and need not to be factored
23 into a V&V code -- the V&V of a new code.

24 So these are kind of administrative and
25 technical decisions that have to be made. But that's

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1 all I can say at this point.

2 MEMBER HINZE: Well, in my past life,
3 whenever I had a contract -- research contract with
4 NRC I had to go through a great deal of time, money,
5 resources, and validating and verifying the codes that
6 I was using and developing. And it seems to me that
7 before you get too far down this pike you'd better
8 have a plan in mind and where the resources are for
9 both making certain that the code is doing what you
10 think it is and that the model is correct.

11 DR. BUSH-GODDARD: All right.

12 CHAIRMAN RYAN: Just if you look at
13 page 225, there's a Table 2-10, Summary of
14 Radionuclides' Primary Coolant Concentrations in PWRs.
15 Two things strike me. One is the radionuclides that
16 are listed here don't include all the radionuclides
17 you need to do Table 1 and Table 2 calculations for
18 waste in 10 CFR 61, because 61 came after this reg.
19 guide I think. All right?

20 Certainly, it's contemporaneous with --
21 you know, there's a disconnect with what radionuclides
22 are important, and, of course, at this day and time we
23 think about I-129, tech-99, not 99M but 99, and other
24 issues -- you know, other radionuclides from an
25 environmental standpoint that may or may not have been

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1 important here. So --

2 DR. BUSH-GODDARD: Okay.

3 CHAIRMAN RYAN: -- relying on this older
4 operational data as examples in foundation, I'm
5 wondering if we're missing an opportunity to better
6 align what people look at in these effluent issues,
7 not only with environmental releases in the air, and
8 so forth, but also in waste management questions.

9 And, again, I come back to the idea that
10 what people do in terms of clean coolant water these
11 days -- I mean, it's the reason we have short outages
12 and we have lower doses, and, you know, there's lots
13 of issues there that would also be part of this
14 effluent management question that I think we're --
15 it's not clear to me that that's going to be a
16 transparent shift from where you are now to the
17 outline you've presented us with.

18 And, again, this isn't really intended to
19 be criticisms of what you're thinking about today, but
20 just some food for thought, and maybe to switch the
21 order, because if you get the GALE code redone and
22 right, the rest of it is easy.

23 DR. BUSH-GODDARD: What we might think
24 about doing is when we develop this multidisciplinary
25 team to kind of look -- comb through these two NUREGs

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1 is maybe come back to the ACNW with, you know, this is
2 our work plan, we've come through the NUREG, we've
3 looked at the pros and cons of FORTRAN, we've
4 considered what we're going to do with V&V, and maybe
5 give you a status of where we are to kind of answer
6 some of these questions before we even start actually
7 doing what we need to do.

8 CHAIRMAN RYAN: Bill?

9 MEMBER HINZE: Could I just ask a
10 question? I don't know of the GALE code at all, but
11 are meteorological conditions and climatic conditions
12 in this code at all? Does that -- it would seem to me
13 that that would have an impact upon effluent.

14 DR. BUSH-GODDARD: Well, this calculates
15 the source term from the liquid -- the effluent, so
16 it's the --

17 MEMBER HINZE: Okay. So it's not --

18 DR. BUSH-GODDARD: -- not to the
19 environment yet. It hasn't gotten to the environment
20 yet. It's the curies per year from the waste stream.

21 MEMBER HINZE: Okay.

22 CHAIRMAN RYAN: One last point on the code
23 part of this. One of the authors of ORIGEN is on this
24 Committee, Allen Croff, he's unfortunately at another
25 meeting this morning, but we've commented time and

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1 again that in the early days -- early days being the
2 timeframe of this run -- that ORIGEN was designed to
3 accurately predict fission of uranium.

4 It really didn't matter if it created any
5 one of a half dozen or two dozen or 100 fission
6 products. That wasn't the issue. But when you talk
7 about waste and effluents, we really care which
8 fission product and which, you know, was created. So
9 the cross-sections, which have been updated many, many
10 times in the intervening years, do a better job of
11 creating -- of calculating and estimating fission
12 products and activation products.

13 So, again, I'd just ask another question.
14 What ORIGEN set, what cross-section set, creates these
15 -- is used in the code? Probably an older one? I
16 don't know. It's just -- that's a minor point, but --

17 DR. BUSH-GODDARD: Okay. Because the
18 radionuclide concentrations are actually hard-wired.
19 But what we were also thinking about doing is putting
20 something like ORIGEN ARP, which is the new --

21 CHAIRMAN RYAN: Right, right.

22 DR. BUSH-GODDARD: -- put a little of
23 different -- you know, thermal power level and things
24 like that.

25 CHAIRMAN RYAN: Yes, it's under operator

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1 control, then.

2 DR. BUSH-GODDARD: Exactly.

3 CHAIRMAN RYAN: Okay.

4 DR. BUSH-GODDARD: Maybe putting something
5 like that computer program into the new update of the
6 code.

7 CHAIRMAN RYAN: Okay.

8 MEMBER WEINER: If I could make a comment.
9 With new codes, you can often have -- and we do this
10 -- have automatic electronic input. In other words,
11 you run your ORIGEN R, and it will automatically feed
12 -- you can program it to automatically feed into the
13 right place.

14 DR. BUSH-GODDARD: Exactly.

15 MEMBER WEINER: Which makes it much easier
16 for the user.

17 DR. BUSH-GODDARD: And you can put in for
18 high burn up and a lot of that stuff.

19 MR. SNODDERLY: Excuse me, Mike.

20 CHAIRMAN RYAN: Any other questions?

21 Comments? Yes, Mike.

22 MR. SNODDERLY: Yes, I just had two
23 questions. Mike Snodderly, ACNW staff. Stephanie, on
24 Monday we heard a very interesting presentation from
25 the Lessons Learned Task Force, the Tritium Lessons

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1 Learned Task Force, and in particular we discussed the
2 importance of the planned release at Braidwood. Could
3 you tell us about what changes you've either made or
4 you plan to make to the reg. guide as a result of that
5 Lessons Learned Task Force?

6 DR. BUSH-GODDARD: Well, we have
7 identified the reg. guides. I think 1.21 and some
8 Division 4 environmental siting reg. guides are ones
9 that we're looking at. To be honest, we are actually
10 having that kind of kickoff meeting next week.

11 MR. SNODDERLY: Okay. Now, that's for
12 unplanned releases, correct? 1.21, unplanned
13 releases?

14 DR. BUSH-GODDARD: For unplanned releases.

15 MR. SNODDERLY: It is.

16 DR. BUSH-GODDARD: Yes, it's not -- yes,
17 yes.

18 MR. SNODDERLY: Okay. So, but the
19 Braidwood event was a planned release, and I think
20 some of the insights I thought that we heard was that
21 it did call into question or brought up the need for
22 the ability to monitor planned releases for the
23 condensed condensation and where -- then, tritium
24 showed up in surface groundwater offsite or near
25 onsite.

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1 So I didn't see where there were any
2 changes made to the reg. guide to address that type of
3 release. And I think that's an important finding, so
4 my question is: have you made any changes right now?
5 Or is that something that's going to be looked at as
6 part of the multi-task -- the multi-task force group
7 that is being put together?

8 DR. BUSH-GODDARD: The first answer is,
9 no, we haven't made any changes.

10 MR. SNODDERLY: Okay.

11 DR. BUSH-GODDARD: And the
12 multidisciplinary task group is going to look at a
13 number of issues. The first priority is to make sure
14 that we've captured things that didn't necessarily get
15 into the push to complete the high priority reg.
16 guides. That's kind of like our top priority at the
17 moment, things like identifying the issues with the
18 GALE code and doing it the right way, looking at the
19 GALE code.

20 And then, looking at the Tritium Task
21 Force recommendations and seeing if we can incorporate
22 some of those into it. And we know we can, because we
23 have this series of what I call environmental
24 monitoring and effluent guides that we're going to
25 kind of look at at a whole. So it's the 1.21, the

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1 1.109 series, which is 1.112, and just to look at what
2 those recommendations from the task force entail, what
3 we need to do for the new reactors, and combine all of
4 those. And it is in a very early planning stage.

5 MR. SNODDERLY: Okay.

6 DR. BUSH-GODDARD: We haven't met -- I
7 might be missing something that we're going to talk
8 about. This is just what I'm going to bring to the
9 table next week.

10 MR. SNODDERLY: Okay. Thank you. Just
11 one follow-up, and this next question -- my second
12 question is a follow-up to that, and it's really
13 directed more to NRR. So now that we've established
14 that clearly Reg. Guide 1.112 and, you know, the GALE
15 code needs to be updated, needs to reflect the Lessons
16 Learned Task Force.

17 And the way the rule is written in Part 52
18 is that those people that are preparing COL
19 applications for the September timeframe, which is a
20 number of proposed applicants, only have to use that
21 guidance that will be in place six months before,
22 which is why there is this big push for the March 2007
23 deadline.

24 So my question is: considering this
25 revised reg. guide, which doesn't have the benefit of

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1 the insights of the Lessons Learned Task Force, and
2 references the old GALE code, how does -- what is the
3 expectation from NRR of what will be submitted? And
4 what are you guys -- what does NRR plan to do to
5 address this deficiency for these --

6 MR. DEHMEL: Jean-Claude Dehmel, NRR, the
7 Health Physics Group. This is -- what I'm about to
8 say is information at my own level that does not
9 reflect the position of management ultimately in how
10 NRR will ultimately decide on how -- on what to do
11 with this. But at this point, for example, I'm
12 working on a revision of SRP Sections 11.2, 3, and 4,
13 which addresses liquid and gaseous effluents and
14 radioactive waste.

15 We are, at this point, addressing issues
16 associated with unplanned and unmonitored releases,
17 essentially. So we are flagging those as tell-tale
18 indicators in the SRP without the benefit of a fully
19 revised and final reg. guide that would address
20 essentially the lessons learned on the tritium, the
21 Tritium Task Force.

22 And so the development of additional
23 guidance is being worked on as a parallel effort.
24 Ultimately, NRR is going to have to make a decision as
25 to how will this parallel effort be folded into, for

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1 example, the new reg. guides -- for example, DG-1146
2 or -- that essentially is -- that replaces Reg. Guide
3 1.70 for Part 52 application and COL application, as
4 well as additional guidance that would be inserted
5 into those revised sections of the SRP. So I can't
6 speak to what NRR will ultimately do.

7 MR. SNODDERLY: Well, that -- I'm sorry,
8 but before you follow up -- okay. So, to summarize,
9 you had planned to address that as part of the updates
10 to SRP Section 11.2 and 11 -- the Chapter 11 series,
11 which we planned to review, I believe, in December.
12 So we'll see you next month, and we'll be looking
13 forward to hearing how you guys address that. Derek?

14 MR. WIDMAYER: Yes. For the Committee's
15 benefit, and also Jean-Claude, Steve Connick was with
16 us on Tuesday, and he told me that 11.2 would probably
17 be ready to support the December meeting, and that
18 11.5 would not. So that's his current thinking right
19 now.

20 MR. DEHMEL: Right. 11.2, 11.3, 11.4
21 should be ready for the December meeting. 11.5 is
22 focusing on the radiation monitoring equipment. The
23 offsite dose calculation manual, the radiological
24 environmental monitoring program, that is being worked
25 upon and is due to Steve at the end of December,

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1 unfortunately.

2 MR. GARRY: This is Steve Garry. I'd just
3 like to clarify, too, on Reg. Guide 1.21 and the
4 Braidwood issue, it's important to recognize that the
5 Braidwood issue, the source term, the amount of
6 activity and the type of activity is activity that was
7 expected. The key thing there is that it didn't go
8 where it was supposed to go. It was being discharged.
9 It had been monitored, sampled, analyzed, and
10 everything.

11 It was supposed to make it to the
12 discharge point, but it didn't. It came out a vacuum
13 breaker along the way. So the amount of radioactivity
14 released would have been reported under Reg. Guide
15 1.21. It's just that it didn't make it to where it
16 was supposed to go, and the environmental monitoring
17 Reg. Guide 4.1, we're going to be revising that as
18 well to improve not only the offsite environmental
19 monitoring but to add onsite environmental monitoring.
20 But as far as the characteristics of the release, it
21 was as anticipated and as sampled.

22 MR. SNODDERLY: I appreciate that, and I
23 think that's an incredibly valuable insight. My
24 concern is that, how does one make sure that the
25 plants that are going to be licensed and approved here

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1 in September are going to have the benefit of that
2 revised guidance? And hopefully it can be done
3 through the SRP, but I think that's a -- that's the
4 concern.

5 CHAIRMAN RYAN: Okay. Any other comments,
6 questions? Yes, please. Chris Brown.

7 MR. BROWN: Chris Brown, ACNW staff.
8 Stephanie, maybe Jean-Claude can help you out with
9 this response. I was wondering if there is -- is
10 there another code out there that actually does the
11 same calculation? And is there a PC-based version of
12 this code?

13 DR. BUSH-GODDARD: I'm going to refer that
14 to NRR.

15 MR. DEHMEL: Not that I know of. I know
16 that the applicants have -- in the application package
17 have indicated that they have conceptually used the
18 models of the GALE code and developed their own
19 computer codes. And beyond that, that's all I can
20 say.

21 So the applications we're receiving
22 sometimes will say straightforwardly that we have used
23 the GALE code, you know, and it will give us a table
24 with all of the parameters. In other instances,
25 they'll say they conceptually -- used the conceptual

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1 models of the GALE code but not the GALE code itself.

2 MR. BROWN: And just one other follow-up.
3 I know just to caution you that I saw a few
4 disconnects. For example, zirconium alloys is
5 mentioned in the revision, but the GALE code talks
6 about zircalloy. And they totally are different, and
7 zirconium allows is another whole family, and they
8 perform differently in the reactors.

9 DR. BUSH-GODDARD: Okay.

10 MR. BROWN: And you also mentioned that
11 the reg. guide was out for public comment. Do you
12 know when that public comment period closes?

13 DR. BUSH-GODDARD: Let me ask the PM. Do
14 you know?

15 MS. KARAGIANNIS: It is supposed to be in
16 -- Harriet Karagiannis, the Office of Research, the HP
17 Group. It will be completed -- public comment -- by
18 the end of November.

19 MR. BROWN: Thank you.

20 CHAIRMAN RYAN: Okay. Well, thank you
21 very much, Dr. Bush-Goddard. We appreciate seeing
22 you, and it sounds like you've got this easy one in
23 front of you, and probably a tougher one later on.

24 (Laughter.)

25 So we really appreciate your -- an early

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1 view of it. It's helpful for us, and hopefully we'll
2 be helpful to you. So --

3 DR. BUSH-GODDARD: Okay. Thank you very
4 much.

5 CHAIRMAN RYAN: -- thanks very much.
6 Okay.

7 Let's see. It's -- we're well within our
8 appointed hour, so I'm going to suggest that we move
9 to Reg. Guide 4.15. Can we do that now, or should we
10 take a 15-minute break and come back at 9:30?

11 Theron, maybe we can check and see if the
12 person who is going to call in at 10:00 could call in
13 at 9:30, or we could call him?

14 MR. DIAS: Mike, we shouldn't -- you know,
15 according to FACA, we shouldn't move things ahead.

16 CHAIRMAN RYAN: Yes, we have some
17 flexibility, but I don't want to sit here for 45
18 minutes and do nothing. So we can take a short break
19 now until 9:30, see if we can arrange our caller to
20 call in, and then we can resume at 9:30 or a few
21 minutes thereafter. Is that possible?

22 MR. SNODDERLY: No, we can't start the
23 Reg. Guide 4.15 until 10:15. Now, we could -- for
24 that 45 minutes we could start something else.
25 Because of FACA, we -- it has been --

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1 CHAIRMAN RYAN: Well, that's not true. We
2 can adjust the schedule. We just -- I just don't --
3 I mean, we can't move things from one day to the next,
4 but we do have the flexibility to adjust the schedule.
5 We do it all the time.

6 MR. SNODDERLY: Okay. Well --

7 CHAIRMAN RYAN: As far as I know.

8 MR. SNODDERLY: -- let's see if we can get
9 in touch with the person that is going to start at
10 10:00.

11 CHAIRMAN RYAN: Yes. I mean, there's some
12 flexibility. I just --

13 MR. SNODDERLY: Okay.

14 CHAIRMAN RYAN: I just don't want, you
15 know, to get started on something else and not be
16 done. Let's see if we can move it up a little bit.

17 MR. SNODDERLY: All right. We'll do our
18 best.

19 CHAIRMAN RYAN: We'll take a 15-minute
20 break. Come back at 9:35.

21 (Whereupon, the proceedings in the
22 foregoing matter went off the record at
23 9:18 a.m. and went back on the record at
24 10:13 a.m.)

25 CHAIRMAN RYAN: If I could get everybody

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1 to take their seats, please, we'll reconvene the
2 meeting.

3 We have one participant on the telephone.
4 I'm going to ask that you identify yourself for
5 everybody else, please.

6 MR. McCURDY: Okay. This is David
7 McCurdy, and I'm filling in for Dr. Powers. He asked
8 me to be available for any questions. I was one of
9 four who provided some writing and development of the
10 revised reg. guide.

11 CHAIRMAN RYAN: Dave, welcome, and we
12 appreciate your being with us on the telephone. Thank
13 you very much.

14 MR. McCURDY: Okay.

15 CHAIRMAN RYAN: The presentation will be
16 by William Ott, Chief of the Waste Research Branch.
17 And without further ado, Bill, we'll turn over the
18 presentation to you. Thank you for being with us.

19 MR. OTT: Okay. Just a few little
20 background remarks with regard to this particular reg.
21 guide.

22 CHAIRMAN RYAN: Just one second, Bill. If
23 I could ask you, Dave, if you wouldn't mind putting
24 your phone on mute. That would be helpful.

25 MR. McCURDY: I will do.

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1 CHAIRMAN RYAN: All right.

2 MR. OTT: This is one part of this huge
3 effort that NRR has asked the Office of Research to
4 undertake to update a lot of regulatory guides in
5 anticipation of new reactor applications coming in.
6 When it first came in, there was one on the list, and
7 I asked one of the staff to look at it.

8 And we looked at it in light of the fact
9 that, one, it was published in 1979; and, two, there
10 has been a lot going on in -- since 1979, and in
11 particular in the last 10 years, with multi-agency
12 efforts such as MARSSIM and MARLAP, which have made
13 major advances in at least the federal community
14 coming together and agreeing on procedures and
15 processes for doing radiological measurements.

16 So we concluded that that, in and of
17 itself, plus the fact that Part 20 is no longer the
18 Part 20 referenced in the original guide, made it sort
19 of a requirement that we go ahead and do this
20 regulatory guide and update it. And the primary basis
21 for the changes are both MARLAP and the new Part 20,
22 but you also see extensive reference to a couple of
23 other ANSI standards in there that are more recent
24 than the old guide.

25 When we went to do this, essentially what

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1 Powers did was go back to the interagency team that
2 had worked on MARLAP and actually brought forward --
3 oops, I guess it was -- get rid of that. I did this
4 right the first time, and the slide didn't come up, so
5 I hit it again and it passed the slide, went to the
6 next one.

7 This is basically the group that George
8 Powers put together to work on this particular reg.
9 guide, and these were all principals in MARLAP. And
10 all of these people were involved in the development
11 of multiple chapters, many of which they authored.
12 And we thought it was an extremely good group to go
13 to.

14 We brought them in here for a week. As a
15 matter of fact, in this very room, and they went
16 through this guide section by section, line by line,
17 and applied all of their expertise to try and update
18 all these references and make this guide current. And
19 we were actually very pleased with the results of this
20 process.

21 The objectives of the update -- one of the
22 things they wanted to do was try and keep the
23 structure similar to the old 4.15, so it wouldn't
24 suddenly look like a totally new and different kind of
25 beast. I mean, the topics and things that are

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1 addressed are the same. It's just that we're updating
2 and trying to improve the process.

3 We wanted to look at all of the old
4 references, check their availability and purpose, see
5 whether they're still relevant, or have been -- there
6 are more recent references that could be put in. And
7 in many cases, a lot of the old references just aren't
8 even available or aren't readily available.

9 We wanted to incorporate advances and
10 updates of regulatory framework, primarily Part 20,
11 and the QA/QC improvements into the regulatory guide.
12 We wanted to standardize the nomenclature. And one of
13 the things that MARLAP does is it has an extensive
14 index of defined terms, and what we've attempted to do
15 here is adopt, whenever possible, those definitions as
16 they occur in MARLAP.

17 As you go through the guide, you'll see a
18 number of terms that appear in all caps the first time
19 that they're used, and that is an indication that that
20 term is later on in the back of the guide defined.
21 And in most cases, those definitions are straight out
22 of MARLAP. We actually ran into a couple of minor
23 problems where it was inconsistent with an NRC
24 definition, and we elected to stay with the MARLAP
25 definition in most of those.

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1 We wanted to standardize the nomenclature
2 to be consistent with national and industry
3 terminology, and those two industry standards and
4 MARLAP are the ones that we wanted to standardize with
5 respect to.

6 And in addition, the way this guide was
7 originally written it was defined as QA/QC for
8 operating -- for operational programs, and we didn't
9 see a lot of difference between QA and QC as a concept
10 for measurement programs at any time in a facility's
11 life, whether it's operating or not, whether you're
12 out taking background information prior to operational
13 startup or whether you're post-operation and doing
14 measurements on the facility prior to decommissioning
15 or during decommissioning. So the scope of the
16 guidance can change to include full range of a
17 facility's life.

18 If you look through the -- through MARLAP
19 and through the guide itself, you'll see data quality
20 objectives and measurement quality objectives
21 referenced. A question has been raised: is the guide
22 risk-based or risk-informed? The QA/QC process is
23 performance-based. It's not risk-based.

24 But the data quality objectives which are
25 implemented by the QA/QC program, the measurement

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1 quality objectives, those should be based on risk
2 concepts. So in that context, you would consider the
3 guide to be risk-informed, because it is based on
4 risk-informed or risk-based quantities.

5 It facilitates consistent environmental
6 monitoring program development, updatable
7 implementation, and it covers a really broad spectrum
8 of regulatory and licensing needs. It shifts the
9 effort from measurement for measurement's sake to
10 measurement with a purpose. A lot of things from the
11 early '70s and '80s were "I've got to go out and
12 measure something," not necessarily knowing why.

13 And if you apply the processes in this
14 revised Reg. Guide 4.15, you measure a quantity for a
15 reason, and you measure it at a given precision for a
16 reason. So all of that should be addressed in the
17 development of your QA/QC program.

18 This is basically an outline of what's in
19 the regulatory guide, and this outline follows what
20 was in the old 4.15. There's an organizational
21 structure and responsibilities of operational
22 personnel, specifications of qualifications of
23 personnel, operating procedures, records, QA/QC for
24 environmental sampling in a radiological laboratory
25 for effluent monitoring systems, verification and

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1 validation, assessments and audits, and preventive and
2 corrective actions. I think you'll recognize that all
3 these things are parts of a good QA/QC program.

4 Now, the next set of slides just go into
5 each one of the sections. And if you'll notice at the
6 bottom of each slide there is a reference to either
7 MARLAP or an ANSI standard, and these are the primary
8 reference for that section in the regulatory guide.
9 And you'll find these references actually in the
10 regulatory guide itself.

11 And I should say there is -- in the back,
12 in addition to the copy of the viewgraphs, I have also
13 provided copies of the draft guide for anybody that's
14 interested. And there is a set of supplemental
15 viewgraphs back there that actually describes MARLAP.
16 Those are part of this presentation, but I don't
17 intend to go into them unless somebody has questions.
18 Okay. I intend to stick primarily to the regulatory
19 guide.

20 In terms of the organizational structure
21 and responsibilities, the guide has information which
22 would require you to define and document management
23 structure, including the function and policies related
24 to QA, establish the authorities, duties, and
25 responsibilities within an organization down to first-

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1 line supervision, responsibilities for review and
2 approval procedures, an evaluation of data and
3 reports.

4 There's a provision in there which talks
5 about QA functions having sufficient authority to
6 identify, initiate, and recommend. I don't think
7 "authority" is the proper word. I think what we
8 really mean here is priority. These QA functions have
9 to have sufficient priority to initiate, recommend,
10 and provide solutions. In other words, they have to
11 take precedence in situations where there's an
12 indication that there's some -- there's a problem that
13 has to be addressed.

14 Reporting is at a management level that's
15 independent of activity performance. They are trying
16 to divorce or eliminate what you might call a conflict
17 of interest within the organization and make certain
18 that QA/QC matters are dealt with at a level above
19 where the initial responsibility might lie.

20 The section on specifications and
21 qualifications of personnel defines -- it says you
22 have to define and document qualifications of
23 individuals, and you have to have some kind of a
24 training program and provisions for retraining,
25 reexamination, recertifying, and performance reviews.

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1 It says -- basically, it says we don't
2 want a QA program being carried out by people that
3 don't really understand QA or the measurement program.

4 There are written procedures for all
5 activities that generate data, and this basically
6 lists all those -- dose calculations, measurements,
7 sample analysis, sample collection, chain of custody,
8 final sample disposal.

9 There are written procedures for all these
10 provided for in the QA/QC manual for a given facility.
11 There are written procedures for supporting functions
12 and for ancillary functions. And I don't want to just
13 go through and read all these things, so if you have
14 any questions, you know, please interrupt. And at the
15 bottom here you'll see that there are three primary
16 references here. There's MARLAP, there's this IOC/IEC
17 document, and the ANSI ASQC-1994.

18 Essentially, under the QA/QC program, you
19 have to document everything, and you have to document
20 every change. You have to maintain records, you have
21 to maintain records of training, analytical results,
22 audits, corrective actions, data reduction. All these
23 things have to be available, they have to be easily
24 retrievable, and they have to protect it against
25 damage or loss.

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1 In the environmental sampling, the guide
2 brings out a number of things that are of concern,
3 sampling of solids, liquids, and gases, includes
4 knowledge of masses, flow rates, volumes. The guide
5 addresses concepts such as accuracy, precision,
6 uncertainties, and reproducibility, either directly or
7 through reference to MARLAP and the other -- and the
8 ANSI standards.

9 It talks about minimal detectable
10 concentrations for individual samples, and the minimum
11 quantifiable concentrations for a series of
12 measurements.

13 In the laboratory section, we talk about
14 calibration and QC of instruments, measuring devices,
15 and test equipment. This would apply not only to
16 quality control of the laboratory itself, but quality
17 control of any outside laboratory that is used by the
18 facility, though if a reactor or a fuel cycle facility
19 does not have its own real analytical laboratory and
20 farms these samples out, that particular laboratory
21 where they send these samples to would have to meet
22 these QA requirements.

23 Internal quality control samples and
24 analysis -- addresses performance evaluation program,
25 interlaboratory comparison.

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1 For the effluent monitoring systems, it
2 talks about the effluent process monitors, the flow
3 monitoring instrumentation, again going back to the
4 slide on knowing rates and volumes of effluents. It
5 talks about grab sampling of effluent process streams
6 and general quality controls considerations.

7 Verification and validation -- and these
8 terms are defined very specifically in MARLAP, and
9 we're talking about something that's a very -- very
10 real and very doable process in terms of verification
11 and validation, even though in some parts of the
12 organization "validation" is not a good word to use.

13 Basically, the definition here is that
14 demonstration -- this is demonstration that a method
15 using performance-based method selection is capable to
16 provide results that meet the MQOs or other
17 requirements.

18 MR. WIDMAYER: I'm sorry, Bill. What's an
19 MQO?

20 MR. OTT: That's a measurement quality
21 objective. And here we're again referring to MARLAP
22 Chapters 6 and 8, an ANSI standard, and this ISOE --
23 ISO/IEC document.

24 Assessments and audits -- the point is
25 made here that assessments and audits are designed to

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1 independently assess the QA/QC program. And as such,
2 they are independent day-to-day operations. They are
3 not necessarily announced. They are not -- you don't
4 give a clue to somebody that they're going to have a
5 QA/QC audit the next day. You just appear and you do
6 the QA/QC audit.

7 They're performed routinely. They include
8 management surveillance, peer review --

9 MEMBER HINZE: Could I interrupt you for
10 a second, Bill?

11 MR. OTT: Yes.

12 MEMBER HINZE: Are you talking about
13 internal or NRC audits? Or are you talking about --

14 MR. OTT: These are internal.

15 MEMBER HINZE: Internal. Thank you.

16 MR. OTT: This is a guide for use by
17 applicants.

18 MEMBER HINZE: Thank you.

19 MR. OTT: Okay. And provision for all
20 this stuff is included in the QA plan for the
21 facility. Okay? And these audits have to be
22 performed by qualified QA staff. I mean, you can't
23 have somebody going in and doing an audit that doesn't
24 really understand the purpose of the audit or the
25 purpose of the measurements that are being made. So

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1 these people have to be familiar with the QA plan and
2 the purpose of the QA plan.

3 The section on preventive and corrective
4 actions -- they are designed to improve the program
5 and eliminate deficiencies to identify something
6 through an audit, or even to identify a problem
7 through the QA plan itself, and provisions in there
8 for you to go back in and change it, fix it, identify
9 the root causes of problems.

10 For adverse conditions that are adverse to
11 quality, it includes these elements -- identification
12 and documentation, classification, cause analysis,
13 corrections, follow-up.

14 Okay. The next two slides are nothing
15 more than a list of regulations that are cited in the
16 reg. guide as either affected by or requiring QA/QC.
17 It's basically a compendium of authorities under which
18 the reg. guide might be cited or used.

19 And, basically, it's defining a whole list
20 of -- it relates to a whole bunch of different
21 facilities -- waste management facilities, reactors,
22 materials facilities, and the regulations that guide
23 those in which there might be environmental
24 measurement programs. Those environmental measurement
25 programs would have QA/QC requirements. This would be

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1 the guide that you would use to implement those QA/QC
2 requirements.

3 Summary and projections -- I made the
4 point at the beginning that we have moved from a
5 prescriptive to a performance-based guide. We put in
6 the latest references. There is even a reference in
7 here to an ANSI standards which has not yet been
8 promulgated. We anticipate that that standard will be
9 promulgated before this guide goes final. If it not,
10 then we will fix that reference to an existing
11 standard or guide.

12 So we're aware of the fact that we have a
13 guide referenced in there that is not yet current, but
14 are expecting it to be current before this guide goes
15 public, or before it becomes final.

16 MR. BROWN: Excuse me, Bill.

17 MR. OTT: Yes.

18 MR. BROWN: You said ANSI or ASTM?

19 MR. OTT: I'm not certain which one it is.

20 MR. BROWN: Okay.

21 MR. OTT: One of the standards that's in
22 there is one that has not been issued yet.

23 MR. BROWN: Okay. We identified that.

24 MR. OTT: Okay. And we're fully aware of
25 that, and we're expecting it to be coming out before

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1 this does. If it doesn't, then we'll go back to the
2 previous standard.

3 MR. BROWN: Unless somebody votes a
4 negative on it. It's in ballot now.

5 MR. OTT: Oh, it is? Okay.

6 This last bullet in here is somewhat
7 problematic. It doesn't really refer to approval of
8 this particular guide, but what it's saying is that
9 once we've updated this one we might want to take a
10 look at some others. And, in particular, the changes
11 to Part 20 affect a number of regulatory guides that
12 probably ought to be fixed.

13 But the question is, what basis to use to
14 fix them, so -- and that decision is being -- under
15 review right now by the internal offices in the NRC.

16 I think this is the last slide of this
17 group. Yes. And that essentially goes into the
18 backup slides on MARLAP, which I don't intend to go
19 into unless you guys actually want to talk about it.

20 CHAIRMAN RYAN: Bill, I guess as a general
21 comment, it seems like you are well a long the way
22 here. I don't -- I mean, I don't know what's left to
23 do. I notice on the draft reg. guide you have a date
24 of September 2006, so we're pretty current with where
25 you are. So what's left?

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1 MR. OTT: The only thing that's left is
2 the guidance is out for public comment right now. As
3 soon as the public comment period ends, then we will
4 address those comments. The revised guide will then
5 be published final by March of '07. So we will
6 consider ACNW comments along with any public comments
7 that we get, if you have specific observations to make
8 on the reg. guide.

9 CHAIRMAN RYAN: Okay. Jim, any comments?

10 MEMBER CLARKE: Thanks, Bill. I agree
11 with Mike. I think you're in awfully good shape for
12 this. I did have a couple of questions. You
13 mentioned that some facilities will use outside
14 laboratories. They don't have their own, they will
15 send samples out. What are the requirements for those
16 labs? Are there certification programs that they must
17 meet? And do you encourage audits of the outside
18 laboratories as well?

19 MR. OTT: Basically, they'd have to meet
20 the provisions of the guide in terms of a QA program.
21 Whether those measurements are made internally or at
22 an external facility, they'd have to have a QA program
23 that met those requirements.

24 MEMBER CLARKE: Right. And would you
25 encourage the facility to, from time to time, audit or

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1 have someone audit that facility?

2 MR. OTT: Oh, of course.

3 MEMBER CLARKE: The outside lab as well?

4 MR. OTT: Yes.

5 MEMBER CLARKE: So those provisions are in
6 here?

7 MR. OTT: My impression is that they are.
8 Dave, do you have any observation on that?

9 MR. McCURDY: Yes. We have a section
10 under -- let me take a look. There is one section
11 that deals with internal quality control assessments,
12 and internal quality control itself, the program, and
13 then we have a section -- subsection on external
14 performance evaluation programs and assessments.

15 MEMBER CLARKE: Okay. Great.

16 CHAIRMAN RYAN: Dave, just for your
17 information, Bobby Eid is here in the room, and he
18 has, of course, been a principal involved in MARLAP.
19 And I'd offer that, Bobby, any comment you might want
20 to make.

21 MR. ABU-EID: Yes. Good morning. My name
22 is Bobby Eid. I was the lead staff to -- for NRC to
23 develop MARLAP, and I would like to thank everybody
24 who participated in MARLAP, from NRC Tim Mo, and
25 George Powers was mentioned. Jim Kotem from Region I

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1 participated in that activity. Of course, Dave, he
2 was an active participant as consultant.

3 I would like to recognize all the federal
4 organizations who participated in MARLAP -- EPA, DOE,
5 the U.S. Department of the Army, DoD. We have also
6 NIST, as well as USGS and FDA. John Greg, who was the
7 Chairman, I would like to recognize him for MARLAP.
8 It is about half a foot thick -- that comment, and
9 that's why it's good to extract information to see how
10 it can be applied.

11 The comments regarding the -- to respond
12 to your answer directly, Section 18 or Chapter 18 of
13 MARLAP is -- laboratory quality control is the chapter
14 for -- to address the issue of quality control.
15 However, as you know, for accreditation there is NELEK
16 program, which is mostly organized by the states, and
17 this program can be used.

18 However, from NRC point of view, what we
19 said for the labs, they must have traceability to
20 NIST. That's one of the issues we said about the
21 laboratories. So the labs, we prefer that in their
22 analysis they participate in a program and to have
23 traceability to NIST. That's really the major issue
24 with respect to NRC regarding the laboratories.

25 MEMBER CLARKE: Thanks, Bobby. That

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1 helps.

2 Just one more comment, if I could, Bill.
3 The terms "QA" and "QC" are often found together with
4 a slash between them, and at least my experience has
5 been not so much in the rad arena but in the chemical
6 arena that those terms get used synonymously. And I
7 notice you've made a distinction between them, and
8 that's good, and MARLAP has a glossary with
9 definitions. And you've also tackled verification and
10 validation, and that's good, too, so -- and other
11 terms tend to either get used synonymously or
12 inversely. So, thank you.

13 MR. OTT: Yes. There's a discussion in
14 the first paragraph of Section B which talks about
15 QA/QC and how QA is considered to be a part of QC, or
16 QC is a part of QA. And they'll use them
17 interchangeably in this guide throughout after that.
18 They weren't going to make any distinction.

19 CHAIRMAN RYAN: Bobby?

20 MR. ABU-EID: Yes. I would like to
21 mention that, assuming that for Reg. Guide 4.15 -- and
22 this is update -- this issue is updated for 4.15, and
23 this is regarding QA/QC. When we developed MARLAP, we
24 have in mind that we did not look at the specific
25 program.

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1 And we need to keep in mind there are
2 certain programs that are very small, and they cannot
3 afford having all of these aspects that -- you know,
4 in the organization aspect does not mean that they
5 need to have, you know, a representative or single
6 individuals. Actually, in each of those aspects that
7 was mentioned here.

8 There are some small programs. They
9 cannot afford to have all of these organizations
10 listed. So this is just to pay attention to that.

11 I gave a presentation at an EPRI meeting
12 about I extracted some information, how it can be
13 applied to reactors. Not every information in MARLAP
14 that can be applied. Even in the presentation that is
15 in this reg. guide, I would like to emphasize that
16 maybe certain small licensees, when they see all of
17 this huge organization for the QA/QC, they may not be
18 actually practical to apply it.

19 CHAIRMAN RYAN: No, I understand.

20 MR. ABU-EID: So we'd like to leave it to
21 the licensees as much as they can to extract from the
22 reg. guide and from MARLAP whatever they can in order
23 to apply it. Otherwise, it will be cumbersome for
24 them to apply everything that is mentioned in the
25 reg. guide.

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1 MR. WIDMAYER: Mike?

2 CHAIRMAN RYAN: Yes.

3 MR. WIDMAYER: If I could, that actually
4 was a question I had for Bill. Does the reg. guide
5 have enough discussion about I guess applying it on a
6 graded approach? Because you've got a number of
7 regulations listed here, some of which might be a
8 facility that operates for eight years and something
9 that might last for a lot longer than that. So --

10 MR. OTT: Well, I think the answer is in
11 the MQOs and the DQOs, the data quality objectives and
12 the measurement quality objectives. If you're dealing
13 with a very, very small licensee, you probably have
14 also a limited inventory and well-defined inventory.
15 Your measurement program -- supporting measurement
16 program probably is much smaller.

17 So my guess is that the answer is yes.
18 It's addressed through the use of the data quality
19 objectives and the measurement quality objectives.
20 The intention is that your program be appropriate to
21 the potential hazard.

22 Now, if you don't have a lot of things, if
23 you're a very small licensee, then you measure
24 appropriate to what you have.

25 MR. WIDMAYER: Okay. I just wondered if

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1 there was enough discussion in the reg. guide. When
2 I read it, I kind of got scared about how much was
3 going to be required for some -- like Bobby said, a
4 small licensee.

5 MR. OTT: But that might be a subject
6 that's worthy of us calling out in a little bit more
7 specific detail.

8 MR. WIDMAYER: Thanks.

9 CHAIRMAN RYAN: Ruth?

10 MEMBER WEINER: Are you ISO compliant?

11 MR. OTT: Dave?

12 MR. McCURDY: Oh. We are referencing
13 ISO 1702.5 for most of the measurement effects, a lot
14 of reference to that, and MARLAP also is very
15 consistent with the ISO concepts. And this guide is
16 very consistent with the ISO concepts on QA. It
17 doesn't get into an ISO 2001 type quality assurance
18 program, which really it doesn't -- ISO 2001, the
19 latest version of that does not get into process
20 control, and it doesn't require certification or
21 accreditation type of things.

22 And we didn't think that, you know, all
23 these facilities should go through a
24 certification/accreditation process. That's why we're
25 not looking at an ISO 2001 type of implementation.

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1 MEMBER WEINER: Thanks for that
2 explanation. That's very helpful.

3 Just out of curiosity, Bill, why isn't
4 Part 71 included in the regulations that this applies
5 to?

6 MR. OTT: I don't know. Maybe it should
7 be listed. My suspicion is that when George was
8 listing all the regulations he started at the --
9 started with the ones that were listed in the old reg.
10 guide, and he may not have just looked at it. I'll
11 take a note to have him take a look at --

12 MEMBER WEINER: I would appreciate that,
13 because there are certainly activities that you do
14 under Part 71 which -- where QC and QA are very -- are
15 fairly critical.

16 MR. OTT: It doesn't surprise me that we
17 missed one.

18 (Laughter.)

19 MEMBER WEINER: Okay.

20 MR. OTT: This was -- unlike most of the
21 guides that are being redone for NRR for this go-
22 round, this one was totally rewritten. I mean, this
23 is just like a brand-new guide. And I have to say
24 thanks not necessarily to all of MARLAP but to the
25 five guys that worked on this -- this team for doing,

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1 I thought, an extraordinary job of bringing all those
2 references -- Part 20 and MARLAP and the current ANSI
3 standards and everything. I thought it was a
4 remarkably good job.

5 MEMBER WEINER: Yes, I think it is, too.
6 I was just curious, since that's the part that I refer
7 to often, that it was missing.

8 MR. OTT: Well, again, I'm not surprised
9 that we missed something, considering how massive the
10 changes were.

11 MEMBER WEINER: When you say "validation,"
12 what do you mean? I mean, under the essentially basic
13 definition, is -- does this conform to the real world?
14 And I'd just like you to expand a little bit on what
15 is meant by "validation" in the various applications.

16 MR. OTT: I'm going to let Dave address
17 that one as well, since he was the author of the --
18 one of the authors of the document.

19 MR. McCURDY: Okay. Well, first off, we
20 distinguished between verification and validation.
21 Verification is just ensuring something has been done
22 but not ensuring that it's -- the proper application
23 has been performed. It may have -- you know, have a
24 number on a result that has been submitted or
25 recorded, and, yes, you verify that the analysis has

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1 been done.

2 But has it been done with the right
3 procedure? Has the procedure been validated from the
4 standpoint of being able to analyze like a Part 61
5 hard-to-detect analysis, and can it handle all of the
6 other interferences that are in that sample from
7 resins or primary coolant?

8 Well, that method has developed -- has to
9 be validated that it can do that. So that's a proper
10 application of that method. So that's a validation.
11 We get into validation of V&V with software as a
12 separate issue, with recommendations that is currently
13 out there in various guides.

14 But "validation" to us means, are you
15 applying the proper process, method, protocol, for
16 software?

17 MR. ABU-EID: Can I add to this? I would
18 like to read from MARLAP exactly the wording for
19 meaningful validations.

20 MR. OTT: Just a second, Bobby.

21 Are the definitions that are in the back
22 of the guide the ones from MARLAP, Dave?

23 MR. ABU-EID: Exactly. That's what I'm
24 using.

25 MR. OTT: Yes. They're on the last page

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1 of the guide.

2 MR. ABU-EID: It's the evaluation of data
3 to determine the presence or absence of an anilide and
4 establish the uncertainty of the measurement process
5 for contamination of concern. Data validation
6 qualifies the usability of each datum after
7 interpretation of the impacts of exception identified
8 during data verification.

9 By comparing the data produced with the
10 measurement quality objectives, and any other
11 analytical process requirements contained in the
12 analytical protocol specification developed in the
13 planning process.

14 MEMBER WEINER: Thank you for the
15 clarification. Finally, who does your audits? Do you
16 have an internal audit team, or do you use an external
17 -- external auditors? Who does your QA audits? I
18 don't mean the people. I mean --

19 MR. McCURDY: Well, essentially, every
20 operating facility has their own -- well, within the
21 management structure, they're going to have a quality
22 assurance officer. That's the one that will actually
23 come up and have qualified staff, if it's a large
24 program, or they'll bring in technical experts to do
25 the technical aspects. But these technical experts

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1 have to be qualified also to audit a certain section.

2 Most of the big facilities and lab
3 facilities have a quality assurance plan, which they
4 have an audit schedule and a quality control sample
5 schedule, as well as an external performance
6 evaluation schedule which is set up. But the quality
7 assurance officer is the one that sets that up, and
8 that's really defined in the quality system manual of
9 any processing facility.

10 It will be a graded approach. I mean,
11 very small programs don't have such things like that.
12 The licensee is expected to tier down the requirements
13 of this particular reg. guide. It's normally done.
14 NUPIK, which is the auditing arm of the nuclear power
15 industry, normally goes out and audits against a reg.
16 guide, or in some cases against an ANSI document, an
17 ISO document, or they come up with quality assurance
18 plates or audit plates, and they key in on things to
19 determine what is a deficiency recommendation,
20 observation, what have you.

21 So it's really -- the organization does
22 the QA assessments. I hope that answers your
23 question.

24 MEMBER WEINER: Yes, it does. I was
25 really -- what I was looking for was the independence

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1 of the auditors, and I noticed you mention that in
2 your -- in the presentation, Bill. But apparently,
3 you've guaranteed that there is a wall between the
4 people who are doing the stuff and the people who are
5 auditing.

6 Thank you very much.

7 MR. McCURDY: Yes, that's correct.

8 CHAIRMAN RYAN: Bill?

9 MEMBER HINZE: Bill, you mentioned that
10 this is essentially a new document. Is there any
11 change in the discussion of the philosophy and the
12 overall objectives of quality assurance?

13 MR. OTT: I couldn't tell you if there's
14 any change. I mean, everything was examined for its
15 applicability. And if it was considered to be
16 current, then it was retrained. So some of the
17 language in here may be repeated. All I can tell you
18 is that if you do a redline strikeout on this document
19 and the old one, you'll come up with all redline and
20 all strikeout.

21 (Laughter.)

22 MEMBER HINZE: Well, I guess -- so it's a
23 new one.

24 MR. OTT: It's a new document.

25 MEMBER HINZE: It's pretty new.

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1 MR. OTT: But the topic is probably -- is
2 most likely discussed, yes.

3 MEMBER HINZE: What's the greatest
4 improvement in this document over the old?

5 MR. OTT: Well, I'd say there are two.
6 One is bringing in MARLAP and the related ANSI
7 standards, and the second one is updating in regard to
8 Part 20. And that was badly needed.

9 MEMBER HINZE: I note that, you know,
10 Part 61 is in here, and we have site characterization
11 all the way from site characterization to
12 decommissioning. It seems to me that there are
13 aspects of MARSSIM that are also involved in the site
14 characterization or could be carried over to site
15 characterization. Did you involve the MARSSIM people
16 in this at all?

17 The MARLAP people, as I understand it, do
18 not include the field activities that would be
19 associated with site characterization, so I'm
20 wondering how you brought those in.

21 MR. OTT: Well, MARSSIM and MARLAP are all
22 part of the same interagency effort. And MARSSIM was
23 the beginning and MARLAP was the second of the
24 documents to come out. That group is still working on
25 MARSAME, which is essentially procedures for measuring

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1 equipment and materials. And after they finish with
2 MARSAME, they're supposed to go on to what is
3 currently called MARSASS.

4 (Laughter.)

5 MR. McCURDY: Can I add a comment there?

6 MR. OTT: Well, just let me finish this
7 one before I leave it. Ed would really like it to be
8 changed to MARSUB, because that's supposed to deal
9 with subsurface and volumetric contamination, which is
10 relevant to something that came up on Tuesday.

11 But go ahead, Dave.

12 MR. McCURDY: Okay. Well, the basic
13 introduction or preface is the same in terms of how we
14 address quality assurance between the two -- the old
15 and the new reg. guide. What George wanted to do on
16 this one is to sort of have a cradle-to-grave type of
17 concept here, because the quality assurance programs
18 apply across the board, not just for what 4.15 was
19 established to do, and that was for normal operations
20 of nuclear powerplants.

21 So it's important because MARSSIM brought
22 in mainly on the DQO -- data quality objective
23 process. In other words, just set that up if you --
24 for example, on releases from nuclear powerplants, if
25 you have tech spec limits, how good do the

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1 measurements have to be to see if you exceeded those
2 tech spec limits?

3 So you set up data quality objectives, and
4 then from that we established a measurement quality
5 objective to say, "Well, how good do results have to
6 be as you're approaching that effluent limit?" And so
7 they are tied together, so the data quality objective
8 issue was brought in up front just to point that out,
9 that not only you can do this for a MARSSIM
10 application, you can do it for any application, as the
11 DQO and the MQO process.

12 MR. ABU-EID: I would like to add to that
13 also MARSSIM and MARLAP, they share similar
14 methodology in accounting for the decision error
15 rates. For example, in Appendix B of Volume 3, the
16 discussion about the decision error in the analysis,
17 at MARSSIM they are quite similar, and the same
18 principles are used in the DQO process. And this is
19 very important.

20 There's only one concern that we need to
21 make that MARSSIM more or less is becoming like
22 regulation, which is this reg. guide, because people
23 they like it, they apply it. For MARLAP, we need to
24 emphasize that it is not a regulation, it is still
25 guidance, because it depends on the specific case.

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1 For the decision error, to have it valid, you need to
2 have enough number of samplings.

3 Sometimes in the environmental analysis
4 you may not have enough number of sampling, and this
5 is a cushion that I would like to advocate that when
6 you apply the process you need to think about the
7 number of sampling in environmental monitoring.

8 MR. OTT: But in terms of the specific
9 question with regard to MARSSIM, I think what Dave is
10 implying here is that if you -- you can use MARSSIM to
11 establish your DQO, your data quality objectives and
12 measurement quality objectives. But you could do it
13 some other way, too, as long as you do -- you do some
14 -- have some systematic approach to establishing those
15 data quality objectives and measurement quality
16 objectives. This guide deals with the QA/QC of those
17 things after they're established.

18 MR. ABU-EID: I would like to add that,
19 just for your information, as you know that software
20 has been developed for MARSSIM, and currently John
21 Greg and his group at EPA, they are developing
22 software actually for applying that decision error and
23 application of MARSSIM using environmental data.

24 That would be good to pull up on that, to
25 see how it can be applied. I assume that it's

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1 friendly use software and is being developed.
2 Unfortunately, because of the lack of resources, NRC
3 could not participate in that exercise, but it is
4 something that it is good to pay attention to the
5 software is being developed for application of MARLAP.

6 MEMBER HINZE: One of the leading lights
7 in the agency today is lessons learned, and it should
8 be. Where have you brought lessons learned into the
9 preparation of this document?

10 MR. OTT: Into the preparation of this
11 guide?

12 MEMBER HINZE: Of this guide, yes.

13 MR. OTT: I think through the five people
14 that we've brought in from MARLAP, if you look at the
15 qualifications of those people, and I have --

16 MEMBER HINZE: I was thinking more, Bill,
17 you know, my -- my experience with this goes back to
18 a decade and a half ago with the quality
19 control/quality assurance problems involved in Yucca
20 Mountain. And there were problems I think with the
21 application of quality assurance, perhaps by the
22 auditors, and also there were very definite problems
23 on the part of the scientists and engineers that were
24 doing the work, in terms of their ego, and in terms of
25 their thought processes and scientific logic.

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1 I'm wondering if you have brought in the
2 experience of auditors and the people that are
3 actually doing the work and being audited, and their
4 experience with quality assurance.

5 MR. OTT: The only way I can answer that
6 is the way I started to answer it in terms of the
7 people that we had on this panel represented somewhere
8 on the order of probably 150 years' experience in this
9 field. And that experience is current. These are
10 still practitioners in the art.

11 With regard to what you observed at DOE
12 audits and things like that, one of the very prime
13 parts of this reg. guide is a requirement for
14 certification and recertification and training of
15 auditors. So that, to my mind, what's really
16 important is, does the QA/QC guide require that kind
17 of experience? And it does. It requires it through
18 qualification and training.

19 MEMBER HINZE: Certainly, bringing that in
20 is very helpful, and I'm sure is part of the lessons
21 learned. I note on your slide 7 on the specifications
22 of quality -- of qualifications of personnel that
23 there is nothing about the technological expertise of
24 the personnel. And in my experience, in terms of
25 audits, you certainly get a much better audit if you

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1 have a person who has some depth of knowledge in the
2 technology that they are reviewing. And they are not
3 just -- they are not just experts on quality
4 assurance.

5 MR. OTT: Well, the QA/QC program will
6 define the qualifications required of the individual
7 staff. Okay?

8 MEMBER HINZE: Okay. I just didn't see
9 that here.

10 MR. OTT: Well, if you look in -- if you
11 review the guide itself, you'll see in the details of
12 the discussion that you have to define the
13 qualification or the -- the qualifications required of
14 the personnel are defined in the QA program, in the
15 personnel part of it.

16 And these requirements for training and
17 reexamination and certification are very specific to
18 the process that is being implemented, to the
19 radiological measurements, to equipment, to all that
20 kind of stuff. Your QA/QC plan has to have -- has to
21 contain all those requirements within it.

22 CHAIRMAN RYAN: Bill, I think it's fair to
23 say that the qualifications, retraining, and currency
24 for those individuals is pretty specific. It's not a
25 "one size fits all" hat that if you've got a QA hat

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1 you can do anything. It's very specific and skill-
2 based.

3 MEMBER HINZE: I think that's very
4 appropriate. In the past, we haven't seen that at all
5 times, and that's what I'm getting at here.

6 MR. McCURDY: Well, under Section 9 in the
7 standard -- in the reg. guide, the second paragraph,
8 first sentence says, "Only qualified QA staff" -- and
9 we see Section C-2 as a reference -- "supported as
10 needed by experts in the technical area under
11 evaluation should conduct assessments, audits, and
12 surveillances."

13 MEMBER HINZE: That's great.

14 MR. McCURDY: So we have that in there.

15 MEMBER HINZE: That's great, Dave. Thank
16 you very much.

17 You know, Bill, I think it's really great,
18 and it must have been a challenge to you, to build in
19 the flexibility to handle this range of -- from site
20 characterization to decommissioning while still
21 maintaining specificity that you need in a regulatory
22 guide.

23 Do you see any problems with that as you
24 -- as you prepared this document?

25 MR. OTT: I think you'll find most of the

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1 specificity in MARLAP. That's where you'll find most
2 of the detail. But with regard to the difference
3 between site characterization and operations and
4 decommissioning, the problem there is in the data
5 quality objectives and the measurement quality
6 objectives. And once you have defined those, the
7 process just follows through.

8 And that's why I don't think it was really
9 that much of a challenge to extend the scope of this
10 guide, because that's where the real challenge is.
11 That's --

12 MR. ABU-EID: Yes. I would like to add
13 that I agree with Bill. I think the data quality
14 objective is a very important concept to use. Certain
15 licensees, they may start with good data quality,
16 foresight characterization, in order to use it for the
17 final status survey. And if they can't do that, it's
18 a good practice. But they need to assess the cost, of
19 course, and they need to assess the quality of the
20 data they generate.

21 So there is nothing wrong with that, so it
22 may be -- regarding the Commission and site
23 characterization, the DQO process is so good that it
24 could enable you, without using data just only for the
25 purpose of characterization or to use it for other

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1 purpose. If it's used for other purpose, for example,
2 as final surveys becoming so important that you need
3 to understand that quality should be of higher level
4 than the quality just to understand what is going on
5 in terms of contamination.

6 That's why if you apply the DQO process,
7 as just -- you know, it leads you to the answer that
8 this will answer your question regarding the quality
9 and the QA/QC of the data.

10 MEMBER HINZE: Thank you.

11 CHAIRMAN RYAN: Okay. Any other questions
12 from staff?

13 MR. WIDMAYER: I just had one more.
14 Bobby, when I got -- when I was first introduced to
15 the DQO process, it sounded great, but there was no
16 experience with it. Do you think there is enough
17 experience with it now and enough guidance? You guys
18 have referred to it several times as --

19 MR. ABU-EID: Well, now you triggered --
20 that's something I have to say, and I wish I did not
21 want to say that. The implementation of the guide is
22 -- that really is an issue. The training and
23 implementation is an issue.

24 I mentioned one issue which is that big
25 size that fits all, and this seems to me to propose

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1 this big size. The question is to the smaller
2 licensees, and I reiterated my concern about this, and
3 the question is the implementation of the process as
4 a whole is still -- it needs to be understood.

5 And my concern is the implementation and
6 the training and the software. Fortunately, software
7 -- that's the reason I mentioned software as being
8 developed could facilitate actually implementation of
9 MARLAP.

10 MR. McCURDY: Can I answer -- I mean, make
11 one statement there? Right now, we are -- EPA has
12 conducted five different MARLAP training courses,
13 three-day training courses, in different cities of the
14 country, mainly for EPA -- well, the NRC is invited,
15 for any of the regions they're in -- you know,
16 Atlanta, Sacramento, Chicago, New York, Denver -- and
17 the thing is that during that training we go over the
18 DQO process.

19 We have examples and exercises, direct
20 exercises, wherein we have a -- for example, a
21 contaminated site with americium. The samples have to
22 be collected. This is the limit for contamination in
23 the groundwater. Okay. And then, you come up with
24 DQO process, we come up with measurement quality
25 objectives, the laboratory submits methods and the

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1 validation of the methods, and see which ones apply,
2 and then we do the analysis of the data and look at
3 whether or not the site could be released or not, how
4 to interpret the data, how to apply qualifiers for
5 someone who is going to review the data.

6 All that is being done, and we're hoping
7 to have one in Washington, D.C. and get the
8 sponsorship of the NRC also to get the word out to
9 have people come to these, because this is really
10 where the education comes from is actually going
11 through the training and having the application and
12 exercises. And, hopefully, Washington, D.C. will be
13 in 2007.

14 CHAIRMAN RYAN: Thank you, Dave.

15 Jim Clarke had a question, and then Chris
16 Brown.

17 MEMBER CLARKE: Just a quick one, and it
18 may not happen enough to warrant consideration. The
19 specifications or qualifications of personnel would
20 clearly apply, I would think, to in-house people who
21 had assumed the Office of Quality Assurance officer
22 would be performing audits and things of that nature.

23 If the facility chooses to use a
24 consultant to do that, would you expect them to meet
25 these standards? Is there these qualifications as

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1 well? And do you have any way of checking that?

2 MR. OTT: I would. I would expect them to
3 meet those qualifications, and I would -- I expect
4 that the way this is written, but I'd have to ask Dave
5 to speak specifically to it, because I'm not as
6 familiar with the details as he is.

7 MR. McCURDY: Yes. In any -- well, any
8 statement of work or contract that the consultant has,
9 that information -- that specification has to be in
10 there, because it's a tiered-down specification of the
11 reg. guide.

12 MEMBER CLARKE: Good. That's a good way
13 to do it.

14 MR. McCURDY: So very similar to -- you
15 have your own plant chemistry laboratory. They don't
16 analyze for Part 61 environmental samples, so they
17 contract those out. But the QA requirements of the
18 reg. guide has to tier down to these outside
19 laboratories as well.

20 MEMBER CLARKE: Good. You've got it
21 covered. Thank you.

22 CHAIRMAN RYAN: Dave, correct me if I'm
23 wrong. This is Mike Ryan. Not only does that
24 requirement flow down in the contract, but the
25 licensee still has an obligation to do verification

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1 and their own review of those -- of that work,
2 correct?

3 MR. McCURDY: That is correct. And one of
4 the things that we have indicated in the MARLAP, that
5 most laboratories have general concepts, internal QA
6 programs where they want to maintain their own
7 operational QA overall, because they are handling a
8 lot of different sponsors or different clients.

9 But if a utility has its own requirements
10 for a measurement uncertainty next to this effluent
11 release limit, you know, that's what they have to
12 apply to. They have to make sure that that's being
13 done, so their own internal QC has to make sure --
14 quality assurance program has to make sure that that's
15 being done, too, and that should be part of the
16 statement of work.

17 That's the whole thing is, how good do the
18 data have to be? We've never discussed that before.
19 They would always say, "Well, let's have a minimum
20 detectable concentration limit." Well, how does that
21 relate to what the effluent limit is? It didn't. You
22 know, it just said, well, this is how good they can do
23 it.

24 Well, that doesn't really -- you know,
25 you're wasting resources and money doing that type of

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1 thing. You want good data right when you have the
2 effluent or clean-up sites, you know, for release and
3 stuff like that. So that's what this whole thing is
4 tiered down to, and the QA program has to go to that
5 laboratory as well.

6 CHAIRMAN RYAN: Great. Thanks, Dave.

7 Chris, you had a question?

8 MR. BROWN: Yes. This is related to what
9 Ruth and Derek has asked you. With the number of
10 regulations cited, did you give any thought to having
11 FSME and NMSS take a look at the document?

12 MR. OTT: FSME has looked at it, NRR has
13 looked at it, NRO has looked at it. Everybody --
14 every place we could think of in the agency that might
15 be affected has looked at it.

16 MR. BROWN: Okay. I'm surprised that NMSS
17 didn't catch Part 71.

18 MR. OTT: So am I.

19 (Laughter.)

20 MR. BROWN: Very interesting. And one
21 last followup question. What about international
22 working groups? Have you looked at, has there been
23 any work in the international communities with respect
24 to this, like IAEA?

25 MR. OTT: Well, I'm certain there has been

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1 work on quality assurance and quality control, and I'm
2 also certain that the five people who are on this
3 panel are thoroughly aware of them. But also, I mean,
4 there will -- in fact, there is -- no, I don't know if
5 there is a reference to any international standards in
6 there or not. Is there Dave?

7 MR. McCURDY: Well, ISO is international.

8 MR. OTT: I was thinking they might be.
9 Okay.

10 MR. McCURDY: Yes.

11 CHAIRMAN RYAN: Okay. Any comments or
12 questions? Yes, one question. Please tell us who you
13 are, who you're with, and have at it.

14 MR. DAROIS: Hi. This is Eric Darois.
15 The backfit analysis that's in the draft reg. guides
16 basically says you can use the old reg. guide or the
17 new reg. guide.

18 And I've got a couple of comments in that
19 regard. One is: where is the incentive for an
20 existing -- say, an existing operating nuclear plant?
21 Where is his incentive -- their incentive to use this,
22 first of all? Second of all, if they do apply this in
23 total, I think there will be a little bit of a larger
24 impact on their programs than what's implied here.

25 And I'll give you just one case in point,

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1 but I can imagine several others. In the event, say,
2 of an onsite spill, you know, a radioactive spill
3 onsite, a facility today goes out, collects a few
4 scoops of soil, and what not, and determines whether
5 they're going to remediate and do some degree of
6 characterization.

7 That's currently done as they normally
8 would a regular, say, health physics survey. There
9 isn't a DQO process or an MQO process behind it. And
10 I'm not saying there shouldn't be, and I understand
11 the whole process, having used it in the
12 decommissioning world, and maybe they should.

13 But that type of thing will certainly have
14 an impact on programs, procedures, training, etcetera,
15 but I guess the larger question is: was there really
16 a robust look to see what the impact would be if they
17 in total used the new reg. guide? And what's the
18 incentive to use it?

19 MR. OTT: In terms of trying to quantify
20 in terms of dollars, we didn't -- we didn't forth a
21 major effort in that area. It was clear from the fact
22 that it was woefully inadequate with regard to the new
23 Part 20, and with regard to basically the state of the
24 art, as evidenced in MARLAP and the other ANSI
25 standards, that it needed to be changed.

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1 With regard to allowing it to be continue
2 to be used by existing facilities, there is a
3 discussion there that says basically, you know, all
4 the references to Part 20 are no longer pertinent.
5 Some of the references may not be available. If an
6 individual facility has the documentation to back up
7 the program they've got, the principles behind the
8 QA/QC programs, as they originally were developed, are
9 not necessarily flawed. They're just not up to the
10 state of the art.

11 So it says you can -- if you're using the
12 old ones, you can continue to use the old ones,
13 because we don't anticipate that to be a problem.
14 Where you're going to run into the biggest problems is
15 when you have, say, a new reactor proposed at an old
16 reactor site, because it's going to be inconvenient
17 for an applicant or a licensee to maintain two
18 different QA/QC programs.

19 And the new facility will be expected to
20 comply with the new guidelines. So I imagine that
21 would mean that they'll probably bring up -- bring the
22 old ones up to speed as well.

23 CHAIRMAN RYAN: Any other questions or
24 comments?

25 MR. McCURDY: A comment on that was that

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1 the -- under the introduction/discussion on the QA
2 plan, the facility's QA program --

3 CHAIRMAN RYAN: Yes.

4 MR. McCURDY: -- the graded approach would
5 apply, and having a specific situation such as
6 contamination, if it's specified in the QA plan that,
7 you know, you would actually -- how you would actually
8 address them from a quality control or quality
9 assurance point of view, you can address it. It
10 doesn't mean that every aspect of this thing has to go
11 into that.

12 It's really, say, when your QA plan is
13 established, the QA program, and it's for the
14 operation of the total facility, you may just want to
15 say -- you know, you just define what it applies to,
16 and this may not be one of them.

17 And I agree with the situation where we do
18 not look at implementation in a staggered effect or
19 by, you know, like five years going into it. But I
20 think people have to look at their own QA program in
21 existence under the Reg. Guide 4.15, and see --
22 really, we'll find that you're not really doing that
23 much different other than you're defining it a little
24 bit better. That's about it.

25 CHAIRMAN RYAN: All right. Thanks.

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1 Any other comments? Questions?

2 Bill, thank you very much for your time.

3 It has been an excellent discussion, and you are well
4 along the way. We'll look forward to see what kind of
5 public comments you get.

6 Thank you. And with that, we are
7 adjourned for our schedule until 1:00, and we'll take
8 up some letter-writing discussions and activities at
9 that time. Also, we'll be preparing or finalizing our
10 slides for our Commission briefing next month.

11 So you're all welcome back, but we
12 understand if you're happy with concluding here.

13 This will conclude our formal record for
14 the meeting, so we'll close the transcript at this
15 point.

16 Thank you very much.

17 (Whereupon, at 11:16 a.m., the
18 proceedings in the foregoing matter went
19 off the record.)

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