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UNITED STATES NUCLEAR REGULATORY COMMISSION'S

ADVISORY COMMITTEE ON NUCLEAR WASTE

November 16, 2006

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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

ACNW STAFF PRESENT:

JOHN T. LARKINS, Executive Director, ACRS/ACNW

CHRISTOPHER BROWN

ANTONIO DIAS, Designated Federal Official

NEIL M. COLEMAN

DEREK WIDMAYER

MIKE SNODDERLY

SPEAKERS:

STEPHANIE BUSH-GODDARD, NRR

WILLIAM OTT, NRR

ALSO PRESENT:

JEAN-CLAUDE DEHMEL, NRR

STEVE GARRY, NRR

HARRIET KARAGIANNIS, RES

DAVID McCURDY (via telephone), NRR

BOBBY ABU-EID, FSME

ERIC DAROIS, RSCS

I-N-D-E-X

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

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

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

Thank you very much.

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

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

CHAIRMAN RYAN: Nice to see you.

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

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

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

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

DR. BUSH-GODDARD: Let me stand up.

CHAIRMAN RYAN: Okay.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

numbers in the database.

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

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

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

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

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

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

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

to propose revisions.

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

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

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

structure and some of the computer issues.

So that's all I have. Any questions?

CHAIRMAN RYAN: A bunch.

DR. BUSH-GODDARD: Okay.

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

DR. BUSH-GODDARD: Okay.

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

DR. BUSH-GODDARD: Okay.

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

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

CHAIRMAN RYAN: Okay.

DR. BUSH-GODDARD: And we --

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

DR. BUSH-GODDARD: No.

CHAIRMAN RYAN: It's okay?

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

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

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

CHAIRMAN RYAN: That's okay.

DR. BUSH-GODDARD: Okay.

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

DR. BUSH-GODDARD: Well --

CHAIRMAN RYAN: In my view.

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

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

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

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

CHAIRMAN RYAN: You will from us.

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

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

sent to the Commission.

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

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

DR. BUSH-GODDARD: Okay.

CHAIRMAN RYAN: So --

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

CHAIRMAN RYAN: Okay. Well, there you go.

(Laughter.)

What's next?

(Laughter.)

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

DR. BUSH-GODDARD: Yes.

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

DR. BUSH-GODDARD: Okay.

CHAIRMAN RYAN: Let's move on, so we

can --

DR. BUSH-GODDARD: Okay.

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

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

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

DR. BUSH-GODDARD: Okay.

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

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

DR. BUSH-GODDARD: Okay.

CHAIRMAN RYAN: Or not?

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

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

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

CHAIRMAN RYAN: Okay.

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

CHAIRMAN RYAN: Okay.

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

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

DR. BUSH-GODDARD: Okay.

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

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

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

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

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

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

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

DR. BUSH-GODDARD: I like that approach.

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

DR. BUSH-GODDARD: I like that approach.

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

Ruth?

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

CHAIRMAN RYAN: Not this one.

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

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

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

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

MEMBER WEINER: Please do.

CHAIRMAN RYAN: Please do, yes. Please.

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

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

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

I think this is a really major advantage

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

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

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

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

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

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

DR. BUSH-GODDARD: Okay.

MEMBER WEINER: That's it.

DR. BUSH-GODDARD: Okay.

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

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

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

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

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

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

DR. BUSH-GODDARD: Okay.

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

DR. BUSH-GODDARD: Okay.

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

DR. BUSH-GODDARD: Okay.

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

DR. BUSH-GODDARD: Okay.

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

DR. BUSH-GODDARD: Okay.

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

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

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

CHAIRMAN RYAN: Jim?

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

(Laughter.)

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

CHAIRMAN RYAN: Professor Hinze.

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

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

use FORTRAN or just where we will go with this.

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

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

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

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

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

all I can say at this point.

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

DR. BUSH-GODDARD: All right.

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

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

important here. So --

DR. BUSH-GODDARD: Okay.

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

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

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

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

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

CHAIRMAN RYAN: Bill?

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

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

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

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

MEMBER HINZE: Okay.

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

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

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

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

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

CHAIRMAN RYAN: Right, right.

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

CHAIRMAN RYAN: Yes, it's under operator

control, then.

DR. BUSH-GODDARD: Exactly.

CHAIRMAN RYAN: Okay.

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

CHAIRMAN RYAN: Okay.

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

DR. BUSH-GODDARD: Exactly.

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

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

MR. SNODDERLY: Excuse me, Mike.

CHAIRMAN RYAN: Any other questions? Comments? Yes, Mike.

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

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

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

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

DR. BUSH-GODDARD: For unplanned releases.

MR. SNODDERLY: It is.

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

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

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

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

MR. SNODDERLY: Okay.

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

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

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

MR. SNODDERLY: Okay.

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

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

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

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

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

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

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

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

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

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

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

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

unfortunately.

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

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

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

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

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

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

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

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

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

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

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

DR. BUSH-GODDARD: Okay.

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

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

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

MR. BROWN: Thank you.

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

(Laughter.)

So we really appreciate your -- an early

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

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

CHAIRMAN RYAN: -- thanks very much. Okay.

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

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

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

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

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

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

MR. SNODDERLY: Okay. Well --

CHAIRMAN RYAN: As far as I know.

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

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

MR. SNODDERLY: Okay.

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

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

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

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

CHAIRMAN RYAN: If I could get everybody

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

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

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

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

MR. McCURDY: Okay.

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

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

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

MR. McCURDY: I will do.

CHAIRMAN RYAN: All right.

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

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

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

When we went to do this, essentially what

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. OTT: Yes.

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

MR. OTT: These are internal.

MEMBER HINZE: Internal. Thank you.

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

MEMBER HINZE: Thank you.

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

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

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

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

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

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

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

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

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

MR. BROWN: Excuse me, Bill.

MR. OTT: Yes.

MR. BROWN: You said ANSI or ASTM?

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

MR. BROWN: Okay.

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

MR. BROWN: Okay. We identified that.

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

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

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

MR. OTT: Oh, it is? Okay.

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

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

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

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

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

CHAIRMAN RYAN: Okay. Jim, any comments?

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

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

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

have someone audit that facility?

MR. OTT: Oh, of course.

MEMBER CLARKE: The outside lab as well?

MR. OTT: Yes.

MEMBER CLARKE: So those provisions are in here?

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

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

MEMBER CLARKE: Okay. Great.

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

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

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

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

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

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

MEMBER CLARKE: Thanks, Bobby. That

helps.

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

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

CHAIRMAN RYAN: Bobby?

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

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

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

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

CHAIRMAN RYAN: No, I understand.

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

MR. WIDMAYER: Mike?

CHAIRMAN RYAN: Yes.

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

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

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

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

MR. WIDMAYER: Okay. I just wondered if

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

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

MR. WIDMAYER: Thanks.

CHAIRMAN RYAN: Ruth?

MEMBER WEINER: Are you ISO compliant?

MR. OTT: Dave?

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

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

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

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

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

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

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

(Laughter.)

MEMBER WEINER: Okay.

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

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

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

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

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

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

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

been done.

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

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

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

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

MR. OTT: Just a second, Bobby.

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

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

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

of the guide.

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

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

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

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

have to be qualified also to audit a certain section.

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

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

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

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

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

Thank you very much.

MR. McCURDY: Yes, that's correct.

CHAIRMAN RYAN: Bill?

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

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

(Laughter.)

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

MR. OTT: It's a new document.

MEMBER HINZE: It's pretty new.

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

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

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

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

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

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

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

(Laughter.)

MR. McCURDY: Can I add a comment there?

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

But go ahead, Dave.

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. OTT: Into the preparation of this guide?

MEMBER HINZE: Of this guide, yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MEMBER HINZE: That's great.

MR. McCURDY: So we have that in there.

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

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

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

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

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

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

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

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

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

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

MEMBER HINZE: Thank you.

CHAIRMAN RYAN: Okay. Any other questions from staff?

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

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

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

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

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

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

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

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

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

CHAIRMAN RYAN: Thank you, Dave.

Jim Clarke had a question, and then Chris Brown.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN RYAN: Great. Thanks, Dave.

Chris, you had a question?

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

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

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

MR. OTT: So am I.

(Laughter.)

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

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

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

MR. McCURDY: Well, ISO is international.

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

MR. McCURDY: Yes.

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN RYAN: Any other questions or comments?

MR. McCURDY: A comment on that was that

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

CHAIRMAN RYAN: Yes.

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

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

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

CHAIRMAN RYAN: All right. Thanks.

Any other comments? Questions?

Bill, thank you very much for your time. It has been an excellent discussion, and you are well along the way. We'll look forward to see what kind of public comments you get.

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

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

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

Thank you very much.

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

CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission in the matter of:

Name of Proceeding: Advisory Committee on Nuclear Waste 174th Meeting

Docket Number: n/a

Location: Rockville, MD

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and, thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

Lindsey Barnes
Official Reporter
Neal R. Gross & Co., Inc.

Update and Status of RG 1.112, "Calculation of Release of Radioactive Materials in Gaseous and Liquid Effluents from Light-Water-Cooled Power Reactors"

Presented to:
The Advisory Committee on Nuclear Waste
November 16th ,2006

Presented by:
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Objective of Presentation

- Why update Regulatory Guide 1.112 now?
  - Recognize recent version of ANSI /ANS-18.1-1999, "Radioactive Source Term for National Operation of Light Water Reactors"
- Next steps
  - Update related NUREGs and GALE computer codes for further revisions of the Guide

PURPOSE OF REGULATORY GUIDE 1.112

- Comply with NRC regulations on calculations of effluent releases:
  - 10 CFR 20.1301,
    - "Dose Limits for Individual Members of the Public"
  - 10 CFR 20.1302,
    - "Compliance with Dose Limits for Individual Members of the Public"
  - 10 CFR 50.34a,
    - "Design Objectives for Equipment to Control Releases of Radioactive Material in Effluents-Nuclear Power Reactors"
  - 10 CFR 50.36a,
    - "Technical Specifications on Effluents from Nuclear Power Reactors"
  - Appendix I, to 10 CFR Part 50,

Supporting Material for RG

- **NUREG-0017,** "Calculation of Releases of Radioactive Materials in Gaseous and Liquid Effluents from Pressurized Water Reactor, **PWR**-Gale Code," Rev. 1, April 1985

- **NUREG-0016**, "Calculation of Releases of Radioactive Materials in Gaseous and Liquid Effluents from Boiling Water Reactor, **BWR**-Gale Code," Rev. 1, January 1979

- American National Standards Source Term Specification N 237, ANS 18.1 Working Group, "Radioactive Materials in Principal Fluid Streams of Light-Water Cooled Nuclear Power Plants," Draft, July 7, 1975

- ANSI/ANS-18.1-1999, "Radioactive Source Term for Normal Operation of Light Water Reactors"

Summary of Interim Changes

- Main focus is ANSI 18.1-1999, "Radioactive Source Term for Normal Operation of Light Water Reactors," because applicants will refer to this standard
- Update to current Part 20 applicable regulations, dual system of units, etc

Next Steps for RG 1.112

- April 2006
  - Plan was to update a series of Regulatory Guides
- Current Plan for RG 1.112
  - Administrative Changes (March 2007)
  - Update Gale Computer Code (Late 2007)
  - Update NUREG (2008)
  - Publish Revise Regulatory Guide (six months later)
  - …or Publish all-in-one

GALE Code – Key Features

- CALCULATION OF RELEASES OF RADIOACTIVE MATERIALS IN GASEOUS AND LIQUID EFFLUENT FROM BOILING/PRESSURIZED WATER REACTORS (GALE CODE)
  - **Calculates annual liquid/gaseous effluent source terms**
- **NUREG's**
  - **Provide technical bases for the defined parameters**
  - **Describes input format, sample problems, etc**
  - **Data needed for source term**

Revisions to GALE Computer Code and NUREG

- Review/update all parameters reflecting present fuel and reactor designs
  - Applies only to zircaloy cladding
- Make all parameters accessible to users
  - Numerous parameters built into code
- Does not provide capability to consider new process and effluent treatment technologies
- Does not recognize improvements in
  - Fuel cladding, burn up, pellet design and performance
  - Reduction in tramp uranium
  - Steam generator and condenser design
- Operates in FORTRAN with no windows interface

After High Priority Guides are Completed Whats the next step for RG 1.112

- Develop Multidisciplinary Working Group to:
  - Identify limitation and propose revisions in the GALE code for:
    - Fuel Cladding, burnup, etc
  - Analyze regulatory structure of RG
    - RG Standalone
    - RG incorporates NUREG
  - Identify pros and cons of using FORTRAN

THANK YOU

QUESTIONS??

RG-4.15 DG-4010
Quality Assurance for Radiological Monitoring Programs (Inception Through Normal Operations to License Termination)—Effluent Streams and The Environment

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174th Meeting of the
Advisory Committee on Nuclear Waste
Rockville, Maryland
November 16, 2006

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DG-4010 Supporting Authors/Members from

Multi-Agency Radiological Analytical Protocols Manual (MARLAP)

Carl Gogolak

Robert Litman

*David McCurdy

Robert Shannon

George Powers

*Teleconference

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DG-4010 Update Objectives

- Maintain similar structure for familiarity
- Review and update old references based upon availability and purpose–many no longer readily available
- Incorporate advances and updates of regulatory framework and QA/QC improvements into the Regulatory Guide
- Standardize nomenclature to be consistent with national and industry terminology
- Extended applicability: initial site characterization through decommissioning

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Move to Performance Based

- Performance based, NOT prescriptive
- Facilitates consistent environmental monitoring program development and updatable implementation over a broad spectrum of regulatory and licensee needs
- Shifts the effort from "for measurement sake" to "measurement with a purpose"

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Regulatory Position Topical Areas

- Organizational Structure and Responsibilities of Managerial Operational Personnel
- Specifications of Qualifications of Personnel
- Operating Procedures and Instructions
- Records
- Quality Control in Environmental Sampling
- Quality Control in the Radiological Laboratory
- Quality Control for Effluent Monitoring Systems
- Verification and Validation
- Assessments and Audits
- Preventive and Corrective Actions

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Organizational Structure and Responsibilities of Managerial Operational Personnel

- Define and document management structure including QA policy and function
- Authorities, duties and responsibilities within organization down to first-line supervision
- Responsibilities for review, approval of procedures, and evaluation of data and reports
- QA functions have sufficient authority to identify, initiate, recommend, provide solutions, verify implementation
- Reporting is at a management level independent of activity performance, costs, and schedules

ANSI/ASQC E4-1994 (Section 2.1.1)

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Specifications of Qualifications of Personnel

- Define and document qualifications of individuals responsible for performing quality-related activities
- Maintain proficiency by retraining, reexamination, recertifying, or performance reviews, as appropriate

ANSI/ASQC E4-1994 (Section 2.3.1)

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Operating Procedures and Instructions

- Written procedures for all activities that generate data
  - Dose calculations
  - Measurements
  - Sample collection
  - Sample management
  - Chain of custody
  - Sample preparation
  - Sample analysis
  - Data reduction and recording
  - Data assessment and reporting
  - Final sample disposal

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Operating Procedures and Instructions (Continued)

- Written procedures for:

Supporting functions	Ancillary functions
- Operation of process monitors	- Cleaning glassware
- Training	- Contamination control
- Preparation of QC SAMPLES	- Instrument CALIBRATION
- Collection of meteorological data	- PERFORMANCE TESTING
- Corrective actions	- Timetable for VERIFICATION AND VALIDATION of data
- AUDITS and records	

MARLAP Chapters 9, 11, 12, and 16 – technical laboratory procedures used
ISO/IEC 17025-2005 (Section 5.4) – content and quality of procedures
ANSI/ASQC E4-1994 (Section 2.5.2) – identifies procedures to be controlled

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Records

- Procedure revision, training, analytical results, audits, corrective actions, data reduction, analysis, verification, QC records for monitoring equipment, and others, as appropriate
- Easily retrievable and protected against damage or loss

ANSI/ASQC E4-1994 (Section 2.5) – types of documents
ASME NQA-1-1994 Basic Requirement 17 – administrative requirements
ISO/IEC 17025-2005 (Section 4.13) – control of records
MARLAP (Chapters 4 and 11) – documents to be retained

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Quality Control in Environmental Sampling

- Sampling solids, liquids, and gases involves masses, flow rates, or volumes
- ACCURACY, PRECISION, UNCERTANTIES and REPRODUCIBILITY
- MINIMUM DETECTABLE CONCENTRATION - individual samples
- MINIMUM QUANTIFIABLE CONCENTRATION - series of measurements

MARLAP (Chapter 10) – sampling issues affecting laboratory
MARLAP (Chapter 19) – measurement uncertainties
MARLAP (Chapter 20) – Measurement Quality Objectives (MQOs)

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Quality Control in the Radiological Laboratory

- Calibration and QC of Instruments, Measuring Devices, and Test Equipment
- Internal Quality Control Samples and Analysis
- Performance Evaluation Program (Interlaboratory Comparison)

MARLAP (Chapter 15) – geometry, source composition and distribution
MARLAP (Chapter 18) – continuing validity, background
ASTM D7282-2006 – instrumentation calibration parameters
MARLAP (Chapter 7 and 18) – acceptability of QC sample results

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Quality Control for Effluent Monitoring Systems

- Radioactive Effluent Process Monitors
- Flow Monitoring Instrumentation
- Grab Sampling of Effluent Process Streams
- General Quality Control Considerations

ANSI N42.18-2004 – radioactive source traceablity
HPS/ANSI N13.1-1999 – QC, maintenance and, calibration of airborne sampling instrumentation

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Verification and Validation

Demonstration that a method using performance-based method selection is capable to providing results that meet the MQOs or other requirements

MARLAP (Chapter 6) – detailed radioanalytical project method validation
MARLAP (Chapter 8) – tools for V & V, planning, acceptable criteria and tests
ANSI N42.23-2003 – limited guidance for radioanalytical validation
ISO/IEC 17025-2005 – limited guidance for method validation

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Assessments and Audits

- Assessments are independent of day-to-day operations
- Performed routinely, including management surveillance, peer, reviews, and READINESS REVIEWS
- Included in QA plan
- Performed by qualified QA staff

ASTME NQA-1-1994 (Section 18) – conducting an audit program and tracking
ISO/IEC 17025-2005 – establishing and conducting an audit program
MARLAP (Chapter 7) – statistical tests to determine laboratories MQOs validity

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Preventive and Corrective Actions

- Improve program and eliminate deficiencies
- Identify root causes of nonconformance
- For adverse conditions that are adverse to quality, includes the following basic elements:
  - Identification and documentation
  - Classification
  - Cause analysis
  - Corrections
  - Follow up

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Cited Regulations

- 10 CFR Part 20 *"Standards for Protection Against Radiation"*
- 10 CFR Part 30 *"Rules of General Applicability to Domestic Licensing of Byproduct Material"*
- 10 CFR Part 40 *"Domestic Licensing of Source Material"*
- 10 CFR Part 50 *"Domestic Licensing of Production and Utilization Facilities"*
- 10 CFR Part 52 *"Licenses, Certifications, and Approvals for Nuclear Power Plants"*
- 10 CFR Part 61 *"Licensing Requirements for Land Disposal of Radioactive Waste"*

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Cited Regulations
(Continued)

- 10 CFR Part 70 *"Domestic Licensing of Special Nuclear Material"*
- 10 CFR Part 72 *"Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste"*
- 10 CFR Part 76 *"Certification of Gaseous Diffusion Plants"*
- 40 CFR Part 190 *"Environmental Radiation Protection Standards for Nuclear Power Operations"*

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Summary and Projections

- Updated Regulatory Guide with latest references, standards, and regulations
- Update moves from *prescriptive* to *performance based* guidance
- Updated RG may stimulate additional RG documents, without additional modifications, including:

  Regulatory Guides 1.21, 4.1, 4.14, 4.16

MARLAP background follows

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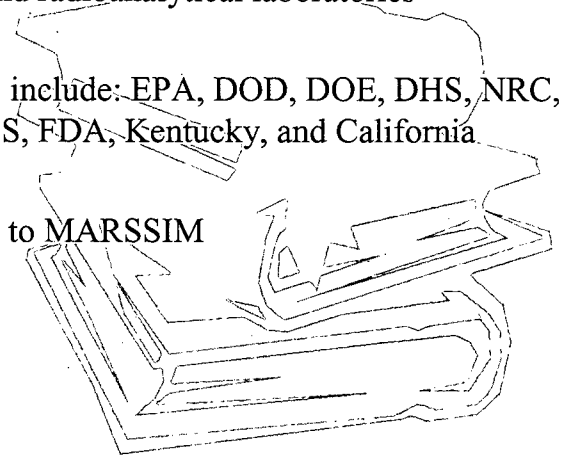
MARLAP has been referenced so: What is MARLAP?

- A multi-agency guidance manual for project planners and managers and radioanalytical laboratories
- Participants include: EPA, DOD, DOE, DHS, NRC, NIST, USGS, FDA, Kentucky, and California
- Companion to MARSSIM



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Planning Questions

- How much data do we need?
- How good does the data have to be?
- What will we measure?
- Where?
- How?

- *How will we know when to stop collecting data and make a decision?*
- *By using a graded approach – similar to MARSSIM*

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Data Collection Activities

Examples of MARLAP's applicability —

- **Site characterization**
- **Environmental monitoring**
- **Effluent monitoring of licensed facilities**
- **Decommissioning of nuclear facilities**
- **Waste management**
- Emergency response
- Background studies
- Cleanup of contaminated sites

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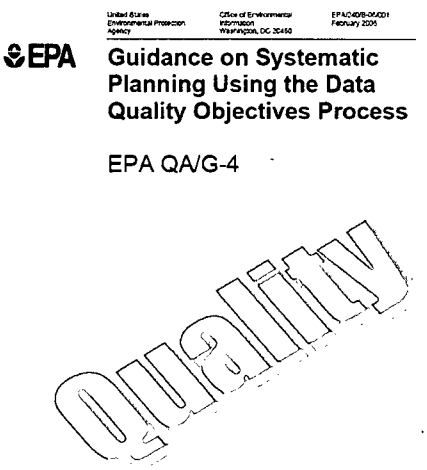
Data Quality Objectives

DQOs define the performance criteria that limit the probabilities of making decision errors by:

- Considering the purpose of collecting the data
- Defining the appropriate type of data needed
- Specifying tolerable probabilities of making decision errors



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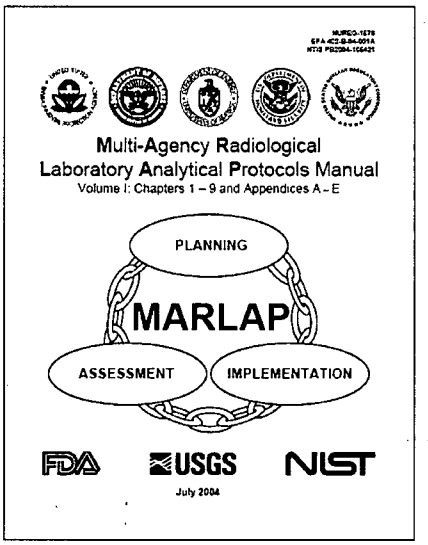
Measurement Quality Objectives

DQOs apply to both sampling and analysis activities

MQOs can be viewed as the analytical portion of the overall project DQOs

MQOs are the part of the project DQOs that apply to the measured activity concentration and its associated uncertainty



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Measurement Quality Objectives

MQOs are statements of performance objectives or requirements for a particular analytical method performance characteristic. For example:

- Method uncertainty
- Detection capability
- Ruggedness
- Specificity
- Range

In a performance-based approach:

- MQOs are used initially for the selection and evaluation of analytical protocols
- MQOs are subsequently used for the ongoing and final evaluation of the analytical data

The most important MQO is the analytical uncertainty at a specified concentration (the action level)

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Connecting the MQOs to the DQOs

- Decision errors are possible because there is uncertainty in the data
- One part of the uncertainty is analytical measurement uncertainty
- Variation among samples with space or time also adds uncertainty
- To limit decision errors, the analytical measurement uncertainty should be limited to a level appropriate to the DQOs

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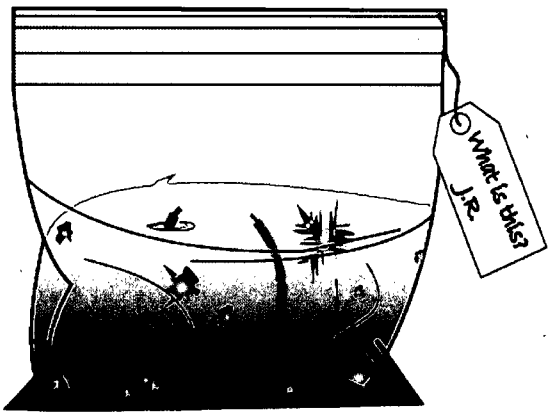

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MARLAP Recommends... (See handout for complete list)

- Using a **graded approach** to project plan writing because of the diversity of environmental data collection activities
  - *Small projects – use project narrative statement*
- Developing a **primary integrating project plan** that includes other documents by citation or as appendices
- Developing project plan documents that integrate all technical and quality aspects for the **life-cycle** of the project, including planning, implementation, and assessment
- Including a report on the **directed planning process** in the project plan documents (by citation or in an appendix)

Continued...

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MARLAP Recommends... (Continued)

- Including a **summary of the planning process** if the planning process was not documented in a report
  - Assumptions and decisions, action levels, DQO statement, and APSs (which include the established MQOs and any specific analytical process requirements)
- Using a **formal process to control and document changes** if updates of the original project plan document are needed

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Directed Planning Process

1. State the problem
2. Identify the decision
3. Specify the decision rule and the tolerable decision error rates
4. Optimize the strategy for obtaining data

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Decision Rules

Data are collected so that decisions can be made about ...

- ... individual samples...*as for bioassays*
- ... the mean of a sampled population ... *as for MARSSIM final status surveys*

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Sample Handling and Analysis
Analytical Items for Verification (8.5.1)

Direct evidence of the sampled material being properly analyzed is necessary:

1. Identification
2. Analysis and method
3. Complete reporting
4. Chain of custody
5. Sample size
6. Preservation
7. Validity of QC samples and results
8. Analysis requirements

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Elements of a QA Project Plan

Group A. Project Management Group	Group B. Data Generation and Acquisition	Group C. Assessment and Oversight
A1 Title and Approval Sheet	*B1 Sampling Process Design (Experimental Design)*	C1 Assessments and Response Actions
A2 Table of Contents	*B2 Sampling Methods*	C2 Reports to Management
A3 Distribution List	*B3 Sample Handling and Custody*	
A4 Project/Task Organization	*B4 Analytical Methods*	Group D. Data Validation and Usability
A5 Problem Definition and Background	*B5 Quality Control*	*D1 Data Review, Verification, and Validation*
A6 Project/Task Description	*B6 Instrument/Equipment Testing, Inspection, and Maintenance*	*D2 Verification and Validation Methods*
A7 Quality Objectives and Criteria	*B7 Instrument/Equipment Calibration and Frequency*	*D3 Reconciliation with User Requirements*
A8 Special Training/ Certifications	*B8 Inspection/Acceptance of Supplies and Consumables*	
A9 Documentation and Records	*B9 Non-direct Measurements*	
	B10 Data Management	

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