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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON NUCLEAR WASTE (ACNW)

160th MEETING

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THURSDAY,

JUNE 16, 2005

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The Advisory Committee Meeting met at 10:15 a.m. in Room T-2B3 of the Nuclear Regulatory Commission, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, Dr. 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:

NEIL M. COLEMAN

JOHN FLACK

LATIF HAMDAN

RICHARD K. MAJOR

SHARON A. STEELE

ASHOK THADANI

NRC STAFF PRESENT:

CYNTHIA BARR

CHRIS BROWN

LARRY CAMPBELL

JERRY CHUANG

DONALD A. COOL

ALLEN H. FETTER

E.V. HOLAHAN

ROBERT JASINSKI

PHIL REED

JAMES RUBENSTONE

ALAN RUBIN

BOB TRIPATHI

ALSO PRESENT:

MATTHEW BAUGHMAN, ISC

ANDREW BLANCO, OIG

JON DYKES, OIG

LYNNE FAIRABENT, AAPM

DAN FEHRINGER, NWTRB

BEN GROVE, Las Vegas Sun

NORMAN HENDERSON, BSC

ROBERT MACDOUGALL, BSC

DONNA SPANGLER, Exchange Monitor Pub

ENGLEBRECHT VON TIESENHAUSEN, Clark County, Nevada

I-N-D-E-X

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M-O-R-N-I-N-G S-E-S-S-I-O-N

10:20 a.m.

CHAIRMAN RYAN: Good morning. The meeting will come to order. This is the second day of the 160th meeting of the Advisory Committee on Nuclear Waste. My name is Michael Ryan, Chairman of the ACNW. The other members of the Committee present are Allen Croff, Vice Chair, and Ruth Weiner, James Clarke and William Hinze.

During today's meeting, the Committee will begin discussion of International Commission on Radiation Protection (ICRP) Foundation documents, will commence preparation of potential ACNW reports including comments on recommendations and standards regarding regulation for Yucca Mountain, ACNW recommendations on time of compliance, the April 1, 2005 Center for Nuclear Waste Regulatory Support Program review, DOE plans for transporting spent nuclear fuel and high-level waste to Yucca Mountain and a National Sealed Source Tracking System.

We'll be briefed by the staff from the Office of Nuclear Materials, Safety and Safeguards on risk-informing activities within that office. We'll discuss the outline of the proposed White Paper on High-Level Waste Transport issues and we'll comment on

the Committee's draft White Paper on Low-Level Radioactive Waste. Neil Coleman is the designated Federal official for today's initial session.

The meeting is being conducted in accordance with the provisions of the Federal Advisory Committee Act. We have received no written comments or requests for a time to make oral statements from members of the public regarding today's session. Should anyone wish to address the Committee, please make your wishes known to one of the Committee's staff.

It is requested that the speakers use one of the microphones, identify themselves and speak with sufficient clarity and volume so that they can be readily heard. It is also requested that if you have cell phones and pagers kindly turn them off or place them on mute. Thank you very much. And with that, we'll suspend for a minute and wait for our first speaker to arrive. Off the record.

(Whereupon, the foregoing matter went off the record at 10:22 a.m. and went back on the record at 10:28 a.m.)

CHAIRMAN RYAN: On the record. Let's get started again. Just for the record, can you introduce yourself?

DR. COOL: I'm Dr. Donald Cool. I'm the Senior Advisor for Radiation Safety and International Liaison in the Office of Nuclear Materials, Safety and Safeguards.

CHAIRMAN RYAN: Welcome, Don. Thanks for here with us.

DR. COOL: I apologize for being a bit late.

CHAIRMAN RYAN: That's all right. We had a draft agenda and a final agenda and there was a slight shift in time. So it's not harm for us.

DR. COOL: I must admit. I have never quite mastered physical schizophrenia and the EDO's office on the 17th floor and this meeting room here in Two White Flint.

CHAIRMAN RYAN: Got you. I'm with you. That's funny. What were here to discuss this morning, it's a dialogue with Don and folks in his office. I know Ann is here as well and other interested folks. We wrote a letter of November of 2004 on the then draft ICRP 2005 Consultation draft for that Principle Recommendations Update.

At that time, we discussed in our meeting and in our letter that there were foundation documents that were soon to be available. They had become

available and the Committee has generated a set of notes and thoughts on that. I thought before we turn that into a letter it would be useful to have a dialogue with those folks on the staff who are responsible to help the Commission formulate Commission comments back to ICRP.

So with that opening statement, I thought I would take them in no particular order, but just the order of which they became basically available and start with the draft consultation document entitled "Assessing Dose of the Representative Individual for the Purpose of Radiation Protection of the Public."

Don, let me offer a proposal to you and see if this is helpful for you. What I thought we would do is just verbally go through the Committee's comments, hear your reactions to our views and comments on the documents and then we can then incorporate the dialogue that we developed from that review into our letter that we might write relatively quickly.

DR. COOL: That's fine.

CHAIRMAN RYAN: Okay. Jumping right in, this Foundation document on the Representative Individual Office, some specific clarifications are useful but overall it offers a confounding set of

definitions of what they title "The Representative Individual." It's not consistent throughout the document. To be useful, the definitions, concepts and their applications need to be clarified. Specific and detailed examples would serve to better exemplify the intended meaning of the use of various dose assessment protocols and strategies discussed in the document. I think our overall conclusion as written the document is not helpful due to its lack of clarity. That's the starting point.

It's a very repetitive document. Basic ideas and approaches are repeated many times and unfortunately the definitions like "representative individual" are different in almost every instance. I'll give you some examples in just a second. For example, the Abstract Executive Summary and Introductions all cover the same thing but never the same way exactly and you could be left with uncertainty as to which definition is the one you really want me to think about or use.

There is some value in it. They do focus on things like nonstochastic or deterministic and stochastic assessments and what role each might play in a dose assessment. While that's useful, it's not terribly new and not terribly innovative.

But let me get to the key problems with the definitions. The representative individual is presented in the document, I'm on paragraph 23, states "Therefore, for the purpose of protection of the public, it's necessary to characterize an individual either hypothetical or specific who receives the highest dose which can be used for determining compliance with the dose constraint. This is defined as the representative individual." How can the representative individual be the one that gets the highest dose? Representative of what? The maximum, I guess. So it's a confusing use of the terminology.

In paragraph S-9 which I guess is the summary paragraph, a slightest different definition is found. The representative individual is the hypothetical individual receiving a dose that is representative of the most highly exposed individuals in the population. So it's not the highest dose now but it's probably something akin to a member of the critical group, but not exactly the average member of the critical group. I guess representative could be average or mean or mode or something. I don't know. So again, it's confusing.

Paragraph 60 and 70 offer details regarding the representative individual but many of

these concepts are hard to reconcile with the definitions they already cited. For example, in paragraph 66, it says, "In selecting characteristics of the representative individual, reasonableness, sustainability and homogeneity must be considered."

Let me just tell you their definitions of those terms. "Reasonableness implies that characteristics realistically apply to an individual and are not outside the range of what an individual encountered in day-to-day life." That seems to me to be more of average kind of view of things rather than the maximum or a member of the maximally-exposed group. "Reasonableness of characteristics must be considered whether probabilistic or deterministic methods are employed." If you do a deterministic approach, how do you know it's reasonable because it's an opinion? It's a selection of a value without any justification. So I challenge that thinking a bit.

"Sustainability and homogeneity are aspects of reasonableness. In the deterministic approach, the question of reasonableness in selection of characteristics is related to that of homogeneity because the dose constraint is intended to apply to doses derived from the mean characteristic in a reasonably homogeneous group." Anybody help me figure

that out.

"Homogeneity addresses the degree to which extremes in particular characteristics are or are not included in the assessment." It's vaguely like a distribution with some kind of a statistic that describes the distribution or two like a mean and a standard deviation. It's very odd with what I do with this definition what it means and again, I'm struggling with how I reconcile it against representative individual and the way they defined it across up above.

So at the end of the day, I'm stuck with the fact that they tried to construct a representative individual as being a useful calculation or framework but the definition are so conflicted in the document, I don't know where to go with it. So my view of it is rewrite it or figure it out or do something but with conflicts within the report, further work needs to be done to make it useful. I think that's the consensus of the Committee. That's No. 1. What do you think?

DR. COOL: A couple of observations. As the staff has gone through this and first let me put a general caveat in. We're assembling the staff comments but we haven't gone through a management incurrence or anything. So what you're going to hear

today are personal views in some cases, some idea of where the staff thinks they may be coming down but with considerable caveat. So I'll try to tell you where each of the statements are in relationship to that set of guidelines.

A number of us in the staff have identified the same sort of issue of confusion stated in different ways in different places. So we would very much agree with that observation.

Having said that and now I'm going to put on my staff hat of the old days which was back when I did rule-makings many years ago and say, "It's very nice to say that it's confusing. Is it possible to say which of the interpretations you've seen is the one you think we ought to tell them because we can tell them to rewrite it and probably lots of people will, but if we have a preference, say for example the one where representative is something which is more akin to the average member of the critical group and set that middle set of things and getting away from some of the extreme language you were quoting?" If we actually expressed a preference, we might actually be able to influence them a little bit more.

I know a little bit about how this draft was developed. The way it looks now is not

surprising. That's a personal observation. So the one thing I might suggest that the Committee think about here is of those variations, does the Committee have a view to what would be the correct one to standardize on if ICRP were going to do so?

CHAIRMAN RYAN: Let's take that in two parts, Don. I think that's a good challenge and one that the Committee can think about. But what I struggle with is if the ICRP is the international recommending body for countries across the world that have a radiation protection program and we could certainly say something about a representative individual to us is, if you just limit me to the choices of what's in the document, we could rewrite parts of it for them and say this appears to us to be a better definition.

But by the same token, we have pretty well established concepts in our own system now of average member of the critical group or REMI, R-E-M-I, or things that are in play and in use. I wonder what offering a different definition here would mean from a U.S. perspective of how that would improve radiation detection practice here. If we -- Let me tell you why I'm struggling.

DR. COOL: Okay. Let me hold a mirror

with a little bit of a colored film on it then which is what I think I hear you saying which I think could be useful is you have a number of different variations of the definition. Here we have tried to be consistent in using an approach which is an average member of a critical group, a reasonable maximum, and avoids the extremes and the very high percentile definitions.

So in moving, in reexamining this document, this Committee's view would be that the statement such as the maximum exposure doesn't represent what we would prefer the concept to be or some language like that. And I'm, in fact, not suggesting particularly in a letter that you might send to the Commission that you actually attempt to rewrite the paragraphs unless you really want to send a very long letter.

CHAIRMAN RYAN: No. I think on this document the Committee's view is that the representative individuals doesn't advance the ball in any productive way and that the average member of the critical group whether REMI concepts which we use as the average member or a representative of the higher exposed group with some detail on how to get to that is working just fine. Drop it is I think where I

personally am. I don't see it adding any value. And just from a perspective of everybody's adopted previous concepts that's put forth by the ICRP. So now start over and do it again. For what added value?

DR. COOL: Yes. Reading between the lines in the ICRP document, I suspect that the rationale for trying to introduce term because ICRP likes to create a term to represent a particular idea was the attempt to get away from a critical group and an average number of people because those terms just don't fit in when you start to use actual distributions and probabilistic approaches.

CHAIRMAN RYAN: They sure didn't get to a probabilistic set-up in this document. There's nothing in this document that let's me then get to a probabilistic risk assessment approach with three different definitions of a representative individual. So they failed to go on that one.

DR. COOL: There you have a statement then.

CHAIRMAN RYAN: Okay. Any other comments? Ruth.

MEMBER WEINER: I had the same problem that Mike had which is that representative seems to mean different things in different parts of that

paragraph, whereas average member of the critical group is well-defined. REMI is well-defined, but representative is not and I think the term, introducing another term, just be dropped.

But perhaps you can explain something to me. Why are sustainability and homogeneity part of reasonableness? I didn't understand that statement.

CHAIRMAN RYAN: You're not alone there.

MEMBER WEINER: Sustainability of what and homogeneity of what and why are they at all connected to reasonable?

DR. COOL: I will give you personal views on the subject because certainly there's not a staff view on that particular but personal views on the subject. There is at least I think some reasonable connection, pardon me for using the word reasonable, but there's a connection if you start to look at the selection of various parameters that you'd use to specify an individual. One of the questions that was raised as I recall was if I'm going to pick an individual, I'm going to define their characteristics, I want to make sure that the characteristics you picked actually constitute a viable human being.

For example, if you suggest food intake of 25 liters of water per day, that is neither reasonable

nor sustainable over any period of time. If you suggest that the hunter/gatherer for your scenario is able to shoot himself two deer per day to provide for his entire family, he probably could pull that off for a relatively short period of time but unless he's very highly mobile and a very, very good shot he couldn't sustain that for a number of years.

So the sustainability question as I have understood it is to question whether or not the kinds of characteristics you would select and the parameters you'd use for those could in fact be sustained by someone over a significant period of time such that it would actually be an individual who would be present.

MEMBER WEINER: Let me stop you right there and just say that's what it should say. I'm not arguing that it says the wrong thing. I'm arguing that it's confusing and if the statement had said exactly what you just said, it would be very clear and I agree with you.

DR. COOL: We are grateful that our transcriptionist is going to be able to capture all of this for us.

CHAIRMAN RYAN: Just let me add, Ruth, I think there's one aspect left out and you touched on it in your example of time. There's no temporal view

to how these definitions work. I mean they're kind of point definitions in time. So it's not a very sophisticated view of what a representative individual is either in terms of habits, practice, spatial distribution of issues or temporal distribution. It's just not a construct that could be analytically very easily without an awful lot of interpretation by the user.

MEMBER WEINER: Can I follow up? Does homogeneity then mean that the two liters per day or one and a half liters per day or whatever is done by the entire -- Is homogenous over the entire critical group? In other words, if you ascribe some parameter, that that parameter is a parameter for most of the individuals in the group rather than just being an outlier. Is that what homogeneity means?

DR. COOL: Again, as a personal belief, that is my understanding that homogeneity was a description around critical group which has been used before. A critical group has to be small enough that the kinds of characteristics and the variations are not going to be very large. So you have people who have similar dietary intakes, similar water intakes, similar various and sundry things.

And having said that, I know I have heard

folks in various international meetings, Jacques LeChard from France for example, making observations of those calculations that he's been part of around Chernobyl and noting that even in those little towns where when you look at the individuals and you try to stock of the parameters and eating habits and you think they would be a very homogenous population, yet they observed vast differences in the actual doses they were calculating for different individuals within this very small town. So there are lots of things that go into it.

CHAIRMAN RYAN: That's an interesting example because I would say that when you have an actual exposure that you're tracking you'd probably ought to do a better job of trying to figure out doses assigned to individuals and the idea of a REMI or a member of the critical group may not really be useful.

DR. COOL: Yes. My reading of this document in fact sort of says that. It may not say that very clearly but this construct was for looking forward where you didn't have individuals and you should be using all of the detailed information available in doing current where you have data or retrospective where you can grab some data.

CHAIRMAN RYAN: Right. Jim, any

questions? Allen, no. Bill, no. I think we have an idea that we're on the -- We understand what are your comments and they seem to comport with our own that there are some definitions and this needs some work to be turned into something that could be at least understood better or what the intent was or how it relates to REMI.

DR. COOL: As I said, the staff in pulling it together has observed the differences.

CHAIRMAN RYAN: Okay.

DR. COOL: The staff has also observed that some of the things that they've said about the number of different dose coefficients going into the future is reasonably consistent with some of the things that we've done in long-range projections and again using all of the details if you're looking backwards because there's a couple of other pieces that we didn't really talk about here. But I don't think we've identified things which were inconsistent with current Commission policy in those areas.

CHAIRMAN RYAN: Okay. Let's see. Moving on to the document entitled "Biological and Epidemiological Information on Health Risks Attributable to Ionizing Radiation: A Summary of Judgments for the Purpose of Radiological Protection

of Humans Committee on Task Group Report C1 Foundation Document ICRP." I guess overall this document suggests some incremental changes to risk factors of cancer as the endpoint and there's no real dramatic news in this document.

I point very quickly that BR7 as I understand it is eminent within weeks to come out and that will certainly guide us in the United States as a committee, the National Academy of Science report. Let me just quote their finding that I thought was helpful. The Foundation document suggests small adjustments to "detriment adjust nominal probability coefficients for cancer" and then "for cancer and heredity disease at low doses dose rates and dose rates the use of a simple proportionate relationship between increments of dose and increments of risk is a scientifically-plausible assumption." So they're confirming in essence the LNT approach for radiation protection of humans.

I think it's important at least from my own personal perspective to point out that that kind of a policy framework of radiation protection of humans is certainly guided by radiation biology but maybe not necessarily tied to fundamental questions of radiation biology in which there's ongoing research of

mechanisms of injury and cellular levels and protein levels and all those kinds of things. So that's not inconsistent with current practice and current regulation, I guess, in the United States.

Another thing the Foundation document states in that regard is knowledge of the roles induced of genomic instability, bystander cell signaling and adaptive response in the genesis of radiation-induced health effects. It's insufficiently well developed for radiological protection purposes. In many circumstances, these cellular processes will be incorporated in epidemiologic measures of risk. So I think they recognize some of these new issues of genomic instability, bystander effects and adaptive response kinds of effects but it's not a mature subject at this time.

The one I think more practical question that was raised here is the proposed changes in weighting factors for protons and neutrons were noted. These judgments are fully developed in the ICRP Committee to Foundation document for the basic dosimetric quantities used in radiological protection. This additional report provides the substantive detail from the earlier recommendations and the document indicates "new radiation detriment values and tissue

weighting factors have been proposed. The most significant change from ICRP 60 is related to the weighting factor for breast, gonads and the treatment of remainder tissues."

One thing I just did for the fun of it was to take and just to note they've recommended a pretty significant change to the proton weighting factor and that it be lower from five, the value recommended in ICRP 60, to two. Current CFR 20 regulations have a quality factor of 10 listed for high energy protons.

I guess my own view is that that's a relatively small radiation protection question probably related more to certain medical applications in high energy accelerators and things of that sort than it is to a broad spectrum of licensees across the NRC or agreement states. But I just note that it's a fairly substantial change from what we have in our current regulations to what they're currently recommending, a factor of five.

I also took the equations they're now recommending for a quality factor of neutrons and calculated using their current models what the quality factors would be and then compare that to what's in the current 10 CFR 20.1104 and created the ratios. The differences range from a low value of 1.21 to a

high value of 2.2 and that high value is that neutron energies in excess of 2.5 MEV, the highest category listed in the table. So I think in the bigger picture of neutron dosimetry those factors that are around 1.25 or 25 percent are often well along the lines of what errors in an estimate of dose might be.

It might be helpful to consider how to change and incorporate those quality factor changes for radiation weighting factors and the tissue weighting factors. I think our previous recommendation said there's no urgency to do that immediately but it could be captured in an update to either regulations or guidances as effective and appropriate for the staff and the Commission to do so. That's the point we don't really see that we have any different view based on a detailed review of the document.

DR. COOL: Right. I don't think we disagree with you. Your discussion just now, in fact, wandered a little bit between the two documents.

CHAIRMAN RYAN: I'm sorry. I'm jumped ahead.

DR. COOL: And the second and the third document do, in fact, have a lot of cross connections.

CHAIRMAN RYAN: Right.

DR. COOL: As the one related to biology and the one related to dosimetry using the short-handed terminology for it.

CHAIRMAN RYAN: Yeah, I jumped right ahead to the third document without reading the title.

DR. COOL: An observation. We commented and I think your letter may have also commented as I recall that when we commented on RP 05 last year that we really thought they ought to wait for BR-7 and do an analysis. We still think that's the case.

CHAIRMAN RYAN: And we do too.

DR. COOL: And if, in fact, it does come out shortly as we've been led to believe then it ought to be available for them to look at. Although that examination may not be consistent with the schedule that they laid out in a different document within ICRP's website. But that would be one of the observations we'd make.

Another observation at least a couple folks have made and this is more of a question than anything else, it was interesting. You have ICRP 60, you had RPO 5 and you have the Foundation documents. The numbers moved each time. And when you start to look at why they moved, you discovered that it was just a couple of little things that were changed

updated and it resulted in the entire system reracking.

While from one perspective that's not surprising, in the other perspective it does perhaps lead one to wonder about the relative robustness and stability and whether or not we have confidence in what's been laid out here if between RPO 5 and this Foundation document they changed a few calculations and we get yet another set of numbers. I think that's something that the staff is likely to make as an observation more as a question because I don't know that we have a recommendation for them to do this, that or something else. But it did tweak some curiosities.

CHAIRMAN RYAN: We didn't do any of the detailed calculation and verification. We didn't have access to that.

DR. COOL: This was laying the older recommendations from last year side by side with the Foundation documents. They're different. What moved?

CHAIRMAN RYAN: And why? So it's always a question. It's interesting. I think we're certainly agreeing the position of the staff of where they're heading to wait for BR 7 and see what that's says. And I did jump over the third document title as

I jumped right to Radiation Weighting Factors. Thanks for catching it up. I'll read the title just for the record, "The Draft of the Discussion in a National Commission on Radiological Protection Committee to Basis for Dosimetric Quantities Used in Radiological Protection" and that's really the quality factor issue.

And again just to summarize our view is that with the exception of the larger numerical value for protons but recognizing it's a relatively small and pretty small kind of radiation protection issue across the broad spectrum of issues that 10 CFR 20 addresses and the relatively small changes in the neutron quality factors that this is something that probably should be considered to be picked but there's again no urgency to do so. It can be done in the normal course of an update for it and the many other reasons perhaps, it's not something that needs critical or immediate attention.

DR. COOL: Yeah. Staff is in a similar position. Certainly, once the scientific information has settled down and been finalized, then it does need to be looked at in terms of trying to consider the updates for the system.

CHAIRMAN RYAN: Okay.

DR. COOL: I would note one thing which isn't in the Foundation document. Again and for the record, on ICRP's website, there was a brief summary of the results of the ICRP Commission Meeting in March 2005 and I think in there was an observation that some of the other detailed information like the ALIs and DACs, the things which would come out of these, are not yet available and won't be available for another several years beyond when these come out.

And of course, if we wanted to start translating some of this into the regulatory structure, that would not only translate into things within the definitions of the weighting factors, little table in Part 20 but also would logically need to translate into all those numbers in Appendix B. There is not such a small task and so this would contain all the information necessary to go do that kind of work yet.

CHAIRMAN RYAN: Yes. We did actually take a look at that report from the main Commission meeting and in fact I was going to add the point that I know the advice that licensees get is if they want to use a newer model for whatever reason whether it's an internal dose model or something else, they certainly can approach the Commission and ask to do that in the

particular dose evaluation. There is a mechanism to use more recent models if licensees want to or need to for a particular evaluation. It's not something that just sits idle.

DR. COOL: That's correct. We have on several occasions and with the Commission's approval to do this accepted application requests to move to ICRP 60 methodology and coefficients as a block to follow the models for preapproval for use in the programs.

CHAIRMAN RYAN: Right.

DR. COOL: And we've done that for several licensees over the last years. That would continue to be in play as we continue to move forward. I would hope that we wouldn't end up with a situation where we would have two or three different systems running simultaneously but that's radiation protection.

CHAIRMAN RYAN: Okay. We'll certainly take that comment forward that the ALIs and DACs are not untouched by these changes in weighting factors in this document. Any other comments or questions? Ruth.

MEMBER WEINER: This is just a question because I also read the draft report on Health Effects of Low Levels of Ionizing Radiation and that's not

what it's called but it was yet another discussion of the linear non-threshold theory. What has occurred to me is what the Health Physics Society did actually was at very low doses, very small doses, to separate the fact that the linear non-threshold theory is in fact a very good regulatory tool and is the only one we have and we have not identified a threshold to separate that from the simple use of a conversion factor that you multiple dose by conversion factor X and it gives you cancers.

That is the problem that I think creates a communication's problem and it creates a problem that I don't think you mean to create. In my mind, and this is just a personal view, the two are separate. I fully accept the fact that we have never identified a threshold and therefore we use the linear non-threshold theory as a regulatory tool.

CHAIRMAN RYAN: Careful, Ruth. There are examples where there are thresholds.

MEMBER WEINER: Oh, yeah, there are, but we have not for very low doses. The document says this and other documents say it too. But still we continue to use you go down to 10^{-5} rem, you multiply it by something and then you say in this population of one million people there are going to be X cancers.

Is there any way to clarify that? The simple use of a conversion factor I believe creates a communication's problem.

CHAIRMAN RYAN: I was standing and sympathize. When you see that done, then it's wrong. But it's a misuse of a statistic.

MEMBER WEINER: Yeah.

CHAIRMAN RYAN: Epidemiologically, if you have a large enough population, theoretically you can determine any increment if the population is large enough for an effect. But often people will take a risk estimator like 10^{-4} cancers per rem or some other number and say that applies to me. Well, that's just stupid mathematics and statistics. It doesn't make any sense. It's wrong, flat-out wrong. It's the wrong way to do it.

So how do you clarify that with folks? You just simply tell them it's not appropriate to apply a population statistic to an individual. It's a population statistic. It's not an individual statistic. So it's bad science to try and do that and I guess other than pointing out it's bad science, I don't know how you fix it because you can't fix it.

Then the other concept that it's embedded in your thought is how do you deal with very small

doses at some very small fraction of background and try and discuss what they mean. The answer is again if you look at the power of statistical evaluation necessary to resolve anything about increments of background you can very quickly get to population sizes that are more than the number of people on the earth.

So it's an intractable problem from that standpoint and one that I know is in the popular literature a lot, but one from a science point of view, there's a very clear answer to it. It's just wrong to do it.

MEMBER WEINER: Yeah.

DR. COOL: I'll make one observation and this is not disagreeing or otherwise for the statements that you made but noting that if you look at the entire set of ICRP documents that are out as Foundation documents, you have these documents here which we're talking about the details of the science and talking about what they have or don't have in their models. Then you can go over to the document that we're going to talk about in just a moment on optimization where in fact they specifically recommend that you no longer do the collective calculation which is I think exactly one of the points that you were

making.

CHAIRMAN RYAN: Yes.

DR. COOL: So in that sense, I guess you could argue that ICRPs or at least part of ICRPs heard that discussion because in fact in the optimization document, one of the things it suggests is moving away from the single collective calculation to a, what's the word they use, disaggregated approach.

CHAIRMAN RYAN: With that introduction, now the "Optimization of Radiological Protection, Broadening the Process," a report by the ICRP Committee Task Force on Optimization and Protection. I think in our letter we talked about the fact that optimization is a concept that at least in terminology is different from the way we think about it and we often think about ALARA as our view of optimization.

We had help from Dr. (DANA) Powers at ACRS and his insight into how mature ALARA programs at nuclear power plants would be confounded by the language and tenor of this Foundation document and again my own view is that it doesn't really change anything. It just offers a different set of terminology on which to offer the same concept.

I do think it is useful that they pointed out that collective dose is not a helpful concept

having that background and at these very low levels. In earlier times, collective dose was used as a metric to compare one, for example, accident calculation around facilities. You could say it's Facility 1 versus Facility 2 and a relative comparison was helpful but not all that useful but in an absolute way, it was misused often as being a meaningful quantity. My version of it is that it just doesn't really offer you much insight.

Let me just take a look at our notes here. Let me just read what we said in the letter, the current ICRP recommendations regarding optimization. The Committee questions whether the draft ICRP recommendations are really improvements. "ALARA as practiced in the U.S. provide a framework for accomplishing much of what the ICRP says about optimization. ALARA is well understood and ALARA programs identify both dose reduction opportunities and other safety issues. The draft ICRP recommendations would unnecessarily complicate existing ALARA principles and application with new terminology of dimensions."

So I think we're sticking with that. We didn't really see anything new in the Foundation document that would change our view on that.

DR. COOL: I think we would agree with you. I think it's interesting to observe or let me make this observation. If you look at what is said by ICRP, this is the first time where they have said in one of their documents they move away from a simple collective calculation to use some of the other dose attributes to explicitly bring in other safety issues, prevention of accidents, minimization of waste, etc. and to involve stakeholders in the process.

So if I look at it from ICRP's perspective, this certainly is a broadening and expansion of what they have said before. Having said that, that's exactly what we do and have done on a routine basis and it's not inconsistent with the things that we've done and the things that we've expected of our licensees and applicants and our own behavior in terms of trying to involve stakeholders in the decision process.

This, I think, doesn't contribute substantially to our being able to move the ball forward, but it could be. This is a gentle praise I suppose. It's nice that ICRP has not written something that's actually a little bit closer to the way we have been intending to do things. They've used slightly different words and I don't know whether

that's the difference between us colonists' perversions of English versus the European's version or otherwise. But there is some movement towards a commonality which is in fact that which the Commission already does.

CHAIRMAN RYAN: I agree, Don. I think it's important that we capture our comment on collective dose in a little bit more detail. The other thing I did, you mentioned the stakeholder comments that they offered how to do a little bit of that.

So I actually did a little bit of background work and it's noted in the Foundation document. I'm going to read here some notes that provide ICRP's views on the role of the stakeholder. I think the Committee believes that the Commission has developed significant initiatives to involve stakeholders in the regulatory process.

Just as some examples, these initiatives are documented in SECY-90-8019, Public Communication Initiative, DSI 14 April 24, 1998 and more recently, the Commission's Performance and Accountability Report for Fiscal Year 2004 which is NUREG-1542, Vol. 10. And even more recent examples, the Committees attended a two-day decommissioning workshop where there were a

lot of detailed stakeholder participation and communication and members of the public and so forth. I think just as three small examples there are certainly programmatic and real live examples where what the ICRP talks about are in play.

DR. COOL: And so I think I would just reaffirm. I believe that what they have said is not at all inconsistent with what we do.

CHAIRMAN RYAN: Right.

DR. COOL: Certainly, we have much more developed programs and a lot more details and anyone who is going to do a new program would need much more than what was contained in this document to be successful at conducting that type of activity. I also note that there is a growing continued database of how people do stakeholder interactions, both that we have here and the Nuclear Energy Agency. Radioactive Waste Management Committee has a whole on--going forum related to stakeholder involvements interactions which has been a relatively deliberate attempt to try and continue to learn about stakeholder interactions not just in the United States, but a variety of other places. So there's a large amount of data that's available of which this pretty much only qualifies as waving a little flag that says "This is

now an important issue. Please see a lot more details to do it right" or something like that.

CHAIRMAN RYAN: Okay. Any other questions on this document?

MR. HAMDAN: I have a question, Mike.

CHAIRMAN RYAN: Please, Latif.

MR. HAMDAN: When they write a comment like this, ICRP, and I assume they have people who speak English and others have other languages as their native languages. How do they do it? Do they write in English the first time or they write it in different languages and translate it or how does that go because the confusion of the comments as we read them, Mike alluded to that, even the feeling that maybe this is coming from more than one source and more than one language. Thanks.

DR. COOL: What I can guarantee you is that it was written by more than one person and for many of those folks, English is not their primary native language. In the groups that I have participated in over the years, most of the drafting has in fact been done by English. There are a number of folks in various countries, in Germany, France and on and on, who are quite facile in English and you can have tremendous conversations.

The little differences start to show up when you actually try to write a text which then needs to get rather precise. So all the little nuances of how someone who nominally thinks and talks in French, for example, and then writes their idea down in English, they wouldn't write it the same way that we as someone here in the U.S. would write it. Of course, I make the same observation about my friends in the U.K.

MEMBER WEINER: The problem is the idiom. I've done a lot of translation and the problem is that you need to find the right idiomatic expression for the idiomatic expression that is in the native language.

MEMBER HINZE: Don, is there an avoidance of any national standard or any national view so that there is a real international view? In other words, let me try that again, that there's an effort to not select the specific wording of any national standards and regulations but to make certain that they differ from those so that they are truly international.

DR. COOL: I don't think the answer is either yes or no. These are international committees. There are people on any one of these task groups from a wide variety of sources and while members of the

committee are there as technical experts and not as representatives of their particular organizations, a few of us on occasion being governmental, many of them being research laboratory and other sorts of things, we all still obviously would come to the table with a background on what we have and we all bring examples.

And as in writing any document, there is the occasional desire of someone who has already written down some nice words and everyone can happen to agree with them to use them. So it does get used on occasion. On the other hand, there are enough differences around that a particular phrase from somebody's writing will have somebody who wants to tweak it somewhere.

MEMBER HINZE: I've served on enough international committees.

DR. COOL: It goes around and goes around.

MEMBER HINZE: Yeah.

CHAIRMAN RYAN: Just to add, Bill, I think there's a dimension too that sometimes we lose track of in the U.S. about ICRP. They're making recommendations for programs as big as the one in the U.S. and France and U.K. but they're also making recommendations for smaller more emerging programs that may have medical uses and not much else or non-

nuclear power programs and things of that sort.

MEMBER HINZE: Sure.

CHAIRMAN RYAN: There's a broad spectrum in the audience to which the ICRP is writing. So I think part of this issue of language and detail and so forth might be in that area as well.

DR. COOL: There's some of that and you see that and more as you look at, for example, IAEA's attempt to try translating it into their basic safety standards and guides.

CHAIRMAN RYAN: Right. So just consider the wider body. I think that's part of it.

MEMBER HINZE: Right.

CHAIRMAN RYAN: The last document is titled "The Concept and Use of Reference Animals and Plants for the Purpose of Environmental Protection." We did not address this in our initial letter. I did respond to Commissioner McGaffigan's question at the October ACNW briefing and we did review this document in detail and find that what we said in that Commission briefing was still substantiated. They really had not, by their own admission, have created this logical construct and there doesn't really seem to be any detailed scientific data that says that changes what we believe and I'm going to quote from

the 1991 ICRP Report. "The Commission believes that the standards of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk. Occasionally, individual members of non-human species might be harmed but not to the extent of endangering whole species or creating imbalance between species. At the present time, the Commission concerns itself with mankind's environment only with regard to the transfer of radionuclides through the environment since this directly affects the radiological protection of man."

Later in this new Foundation document, they say, "The Commission still believes that this judgment," that is what I just read, "is likely to be correct in general terms because the steps taken to protect the public by reference to dose limits for them have resulted in strict controls and limitations on the quantities of radionuclides deliberately introduced into the environment."

Nonetheless, there's a whole structure of a logical construct, I think, is the phrase that I heard Larzer Holm (PH) talk about in his presentation to this committee without any real, to use a vernacular, technical meat on the bones of this

logical construct. So I think our view is that we would recommend the Commission not take any action at all in this area until this is developed further or until evidence to the contrary that contradicts the two statements I read becomes vetted and available through the scientific process.

DR. COOL: At this point, staff is planning to reaffirm comments we made before. The Commission is very clearly on record about having some grave misgivings about moving to standards like this. In the process of looking at it, we've identified lots of things that we tweak curiosity or tweak credibility depending on how you look at it.

CHAIRMAN RYAN: Don, I would ask. Are you having any trouble with this buzzing? Okay. I just want to make sure our record is not interrupted by the jackhammer. Thank you.

DR. COOL: So we would be making a fair number of more detailed observations playing out discontinuities and consistencies. As you have noted, they make a lot of statements. There doesn't appear to be the basis for the need.

Around here, sometimes we refer to what's the burning platform. What's our reason for deciding we have to jump and that's not entirely clear what

that burning platform is. Or maybe it's unstated underneath. There are other pressures that someone is putting on them for other reasons that make them believe that they need to do something more. In fact, I think the text makes some references to that.

In the end, I'm not convinced individually that this puts much more meat on the bones. Again, if I were to put a very old hat on from the days now many years ago when I was in the Office of Research and make the personal observation that this would make a wonderful research plan, but it's not a policy doc.

CHAIRMAN RYAN: I think we're in the same place. I point out that from our own previous transcript at our working group meeting that we had on the draft document itself back some months ago that one of our representatives from the EPA said that basically human risk assessment drives clean-up decisions from the EPA's perspective and that ecological risk really wasn't a huge factor, but sometimes the ecological assessments really recognize that clean-up improved the environment, that kind of thing. So there was no apparent driver for this to be used from that perspective either and those comments we had earlier on.

DR. COOL: Right. I think it's also maybe

important for a complete record to note that because of NEPA and because of endangered species acts and other things, the Agency and the staff did do environmental assessments, environmental impact statements, and do look at specific types of flora and fauna on occasion because of requirements and have been able to do that and have been able to make judgments about those. So it's not a matter that there is no mechanism available for examining things that legally we are bound to in certain cases and have done so.

CHAIRMAN RYAN: And again I think we can conclude on this whole document in question if the Committee continues to hold the view that, expressed in its briefing in the Commission, there is no evidence to contraindicate the principle that by protecting man the environment is protected and the Foundation document fails to make the case that separate recommendations are needed. Questions? Comments?

VICE CHAIRMAN CROFF: I have a question here.

CHAIRMAN RYAN: Yes.

VICE CHAIRMAN CROFF: In reading this, there seems to be something of a little bit slippery

that's happened between what the ICRP said, was it in `91 that original quote?

CHAIRMAN RYAN: Yeah.

VICE CHAIRMAN CROFF: And what they've just done. In the `91 quote with regard to nonhuman species, they very carefully differentiated between putting the species at risk and potential harm to individual members of a species which I infer that you don't want a risk that will wipe out all of the oysters or the whole species. But in the more recent document, it lumps together protection of humans and protection of other species but humans are protected as individuals.

We're not really concerned about the existence of the human species in radiation protection at all. Is the intent now that they're trying to segue from protecting a nonhuman species to protect individual members of nonhuman species?

DR. COOL: That's a very good question for which I'm not sure there is a crisp answer. My reading of their document is in fact that they don't quite now what they want to do. So in fact, they've decided that the logic construct of having a nice parallel system to allow them to do detailed analysis and do dose calculations would be at an individual

level because that's how you would do a dose calculation.

What I don't know and which I don't think this says unless I missed it someplace is whether in the end that would lead you to individualized protection or not. That clearly is a major policy issue and I'm not sure there's any basis to decide whether or not there is a direction that ICRP even thinks it wants to go right now.

I would note that ICRP has said that and they are creating a new committee, Committee 5, starting with the term that begins in just a few weeks to further examine this. It's not at all clear to me exactly where they're going to go individually.

VICE CHAIRMAN CROFF: I understand the uncertainty there that potential change in ICRP policy maybe deserves a little bit of a highlight at some point. We don't know whether it's real but at least to get people to think about whether it exists or whether it should exist.

CHAIRMAN RYAN: You're right, Allen. I think the view that we have at this point, Don, is they have not provided any evidence, any evidence, to contraindicate this long-standing principle that if you protect man, you protect the environment. We

could go through lots of current radiation biology and current study on species. I can think of 100 different insect species that will be here long after any radiation exposure that would take the humans out of the picture.

And I'm not trying to be flip about it. There really is a very large body of evidence from fundamental genetic cellular studies right on up to species studies that say that if you protect man you protect the environment. It wasn't something that was arrived at trivially in the United States or in other countries that adhere to that principle on designing their radiation protection strategies.

But I'm struggling with not so much the policy side of this document, but the fact that there really is no cited evidence to say this needs to be done. The fundamental question is why did you do this. It's a logical construct. Well, you know that's great but what does that mean? It doesn't really advance the ball of radiation protection in a way that's transparent to me.

DR. COOL: And I would simply note what I think you've already quote that even in this document they affirm that there's nothing to indicate that this is necessarily incorrect, but blah, blah, blah. So

that inherent disconnect is present even within their document and unresolved.

VICE CHAIRMAN CROFF: I think my point here is everything that just went back and forth between the two of you is correct as long as the issue is protection of nonhuman species. If they translate or shift the issue to protection of individual nonhuman species or individual members of nonhuman species, then potentially there's some statistical probability that radiation would kill one of a million oysters or whatever and then there is at least an impact, whereas the species wouldn't be threatened. That's why the shift is important.

CHAIRMAN RYAN: Again I understand the construct you've created but there's absolutely no -- I mean the level of detail and the data you would have to have to substantiate that statement is hundreds of years away. It just doesn't exist.

VICE CHAIRMAN CROFF: All I'm cautioning against is a sort of very subtle shift in policy and then the ah-ha which changed the problem to over here and they may well be some evidence, I mean, some statistical probability at some level that radiation could hurt a nonhuman species.

CHAIRMAN RYAN: Frankly, I doubt it but I

understand the logic of what you said. But from a standpoint of demonstrating it with scientific certainty, I just don't see how you can get there.

VICE CHAIRMAN CROFF: I guess I'm just coming at it from the viewpoint that there's something to be watched there by the ICRP.

CHAIRMAN RYAN: Clearly, what the ICRP does with this is an important issue to take up, but I just see it as a flawed approach at this point. I mean there's no evidence to the contrary and they affirm their previous position in this document.

VICE CHAIRMAN CROFF: I agree.

CHAIRMAN RYAN: Yet, on we go.

DR. COOL: Dr. Croff, if I could summarize that in my words. Not only have they not made the case, but they have no idea at what level or why they want to protect it yet or who, what, where or when.

CHAIRMAN RYAN: Or what measure?

DR. COOL: Or what measure?

CHAIRMAN RYAN: I can understand RAD in any material because RAD applies as energy deposit per unit mass. What does REM mean?

DR. COOL: And that's one of the questions that they identify.

VICE CHAIRMAN CROFF: I'm suggesting more

that they may be trying to redefine the problem or the issue very subtly.

CHAIRMAN RYAN: We got it. I understand what you're saying.

VICE CHAIRMAN CROFF: That's all I'm saying.

CHAIRMAN RYAN: But I don't think we'll be able to substantiate that any better than what they have here so far. All said. Ruth.

MEMBER WEINER: There's a substantial body of data that basically supports the current position that if you protect humans, you are protecting the rights of the environment and that's data that you can get from any one of these very large sites like Hanford, Savannah River, large industrial sites where there are large areas that are protected from human intrusion.

People can't go there and yet you find animal species that ingest fairly sizable amounts of radioactive materials, enough to leave radioactive spore and there's no impact on either species or the individual animals. At Hanford, they track mule deer, and things like that. There's no evidence that the radiation hurts them. In fact, there's no evidence at all and yet they are quite significantly exposed and

I'm sure there are similar areas all over the world.

DR. COOL: I would leave you with the observation that someone shared with me one time that the biggest single impact is whether or not the humans are present.

MEMBER WEINER: Exactly. That observation has been made in the arid lands ecology study along the Columbia River that the impact, most detrimental impact on ecosystems is human activity.

CHAIRMAN RYAN: Thank you. Jim.

MEMBER CLARKE: If I could follow up on what Ruth said. I think that was the point that the representative from the EPA was making that if ecological risk was used at all in a cleanup decision it was used to argue against cleanup because cleaning up to human health protection standards for a particular area would destroy the habitat for a sensitive species. That's been the outcome pretty much based on my experience anyway and apparently it's this one.

DR. COOL: And it's interesting to note that in my recollection of things that have been looked at with endangered species and otherwise it wasn't the radiation dose of the endangered species. It was the impact of the construction or other issues

on the particular species in the area.

CHAIRMAN RYAN: We've circled back to the fact that we agree with the original statements and see nothing to controvert those statements. Don, thanks for your insights and sharing your views of our comments. I think our next step is to take these comments and turn them into a relatively short letter which I hope we can accomplish this afternoon and this evening and we'll have it on our letter writing session tomorrow morning. So we'd welcome you back to go through the more traditional letter writing session now that we've discussed these issues in the open forum.

DR. COOL: We'd be pleased to do that. We'll see if we can synchronize the schedules a little bit better.

CHAIRMAN RYAN: Yes, indeed. In fact, I was just going to suggest we'll pick a key theme. We're going to start the letter writing, I think, promptly at 10:00 a.m. So we have one short discussion on the letter that Bill Hinze will be taking up. So a few minutes after 10:00 a.m. will work just fine and again, no problem. We were happy to wait for the discussion. We're a little ahead of schedule now anyway. So that's fine. Thanks again

for your insights.

DR. COOL: Very good.

CHAIRMAN RYAN: Okay. Thank you. With that being said, we're on schedule for a presentation after lunch and I think we can break here until 1:30 p.m. when we'll discuss letter writing. Is that correct? For that session, we will need to be or not need to be on the record.

MEMBER WEINER: Not.

CHAIRMAN RYAN: Not. So we're not on the record from 1:30 p.m. to 3:30 p.m. but we are back on the record at 3:45 p.m. All right. Okay. Thank you. We'll adjourn for lunch. Back at 1:30 p.m. Off the record.

(Whereupon, at 11:34 a.m., the above-entitled matter recessed to reconvene at 1:30 p.m. the same day.)

(The session from 1:30 p.m. to 3:30 p.m. was not recorded.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

3:34 p.m.

CHAIRMAN RYAN: Let's go back on the record. Dennis, welcome and we appreciate you updating us on Risk Informed Regulations for NMSS. Thanks for being with us.

MR. DAMON: Thank you. I guess I should introduce myself. My name is Dennis Damon. I work for Wayne Hodges who's the Deputy Technical Review Director to the Spent Fuel Project Office in NMSS and my job position is Senior Level Advisor for Risk Assessment for NMSS.

The purpose of the briefing is to describe, as the slide says, status and nature of NMSS's approach to risk-informing activities across all of the divisions in the office and it's more specifically to describe the structured process that's been developed for risk informed decision making. But before I get into these topics, I ought to give a status on really what the program status is itself because up until this fiscal year, this program was being carried out by a risk task group. It was originally in the Division of Industrial and Medical Nuclear Safety and then later was attached directly to the NMSS front office. That risk task group no longer

exists. So there is no budgeted resources for this type of generic guidance that's coming from the office level. Rather all the activities that are being done that are risk informed are in the divisions themselves and being run with budgeted money from the divisions.

So the methods and information that were generated by that risk task group have really transitioned to a implementation phase by the divisions. But to provide some degree of coordination and oversight, Wayne Hodges has been appointed the SES champion for this generic activity and then there's myself who is the advisor for risk assessment. I'm available to provide help.

But for the specific activities if you would like a briefing on those, they're really done by the divisions. You've actually received a briefing on some of them as part of this meeting from the Division of Waste Management and Environmental Protection that they have their own risk informing program as does High Level Waste which I'm sure you're more familiar with both of those than I am.

Then there's the other divisions which also have activities. There are about a total of 12 of these specifically identified and managed risk informing activities in the divisions and those

activities are described in this document that's at the last bullet of this slide, "Risk Informed Regulation Implementation Plan" that's published and updated every six months, the latest version of which you can find on the website for looking for SECY-05-0068 and Attachment 2 to that SECY paper is this plan with description of the activities and milestones in it. So that's the big change that's happened here in this program. It's transitioned from about a six FT task group to me and Wayne on our spare time.

The NMSS approach to risk informed regulation, you've seen this before. I'm just reminding you that the approach is different from NRR where basically they have one type of licensees. We have all kinds of licensees and activities. So the actual types of public health impacts vary in their qualitative nature and quantitative nature between these different activities and the availability of actual quantitative risk information varies between the different divisions. Therefore, how you can use that information, the risk informed things, is varied. The approach that's been developed is to recognize the variability and deal with it.

CHAIRMAN RYAN: Could we stop there a second because that's something I think we had

discussed in a letter earlier on is the use of non dose-based metrics.

MR. DAMON: Right. That's it. When we did it for NMSS, we had to realize that there are -- You had to look at all the different kinds of impact, worker risks, general public, routine exposures and accident risk and deterministic effects because you get everything in NMSS.

CHAIRMAN RYAN: You do in reactors too.

MR. DAMON: Yeah.

CHAIRMAN RYAN: You can think of those same things. So I find the fact that they are all the same and NMSS is all different to be a little empty as a reason to do it. And I find it challenging to think about how you take a short term impact, pick anything you want, and compare that on an apples-to-apples basis with a long term stochastic risk of some endpoint like cancer. So I remain skeptical that that's a useful set of metrics when you consider that they're really apples, oranges, grapes and bananas. Help me understand that. I just asked that question earlier. So many you can give me some insight there.

MR. DAMON: In the work we've done, we've recognized that there are these different apples and grapes and things and we tried to keep the things

separately identified so that people would recognize that. That's one reason that those risk guideline things, there were six of them, we wanted to make people realize there are different kinds of things here and maybe they're not all going to be treated exactly the same.

You could try to do that. You could try to treat everything the same but you're submerging this information which seems like the direction of guidance where people are going is to disaggregate things and make sure everybody's aware of where all the pieces are. So that's the way we have been going for a long time.

CHAIRMAN RYAN: And again I think the Committee in its previous observations was disheartened by the disbanding of the task work because it seemed you were gaining momentum and after working well, became productive.

MR. DAMON: There are still people assigned to be the points of contact on this generic work that's being done. So it's not being abandoned exactly. Like I say, it's in implementation phase. We have to get the people in the divisions to understand and adopt and learn and practice this. If it's always just the risk task group, it's not going

anywhere. That's what I mean by implementation. It's just other people have to do it.

But to help the process, this thing that the risk task group, really it was only one of the things the risk task group worked on. They worked on a number of different things but this one thing was a common framework that started before I was involved. It started back in the beginning of the idea of risk informing the non-reactor area.

So they developed a framework to describe the fact that in NMSS, you have to deal with different things and so there were two kinds of guidance that were developed. One was a screening guidance on deciding when to use quantitative risk assessment and that's a little bit too black and white of a statement.

The way I really think of this is it's guidance on how to determine how to risk inform something and what scope you can do it at. Then the other kind of guidance is it was a general risk-informed decision making guidance. So it more reflects some guidance that I believe came from either the ACRS or ACNW that the agency ought to do more of this. That is structured decision making.

So that's what this is. It's a structured

decision making method on how to think about risk together with other factors to inform things. But it was primarily focused on changes to regulatory and it did not address how to risk inform license review and inspections.

Like I said, the divisions have about 12 of these specific risk-informing tasks that you can monitor through reading the Risk-Informed Regulation Implementation Plan. Like I said, the way I think of them they fall into three areas. They fall into changes in requirements, license review and inspection because those are the three major ways of categorizing the activities that the staff does and the guidance that was developed so far primarily focused on number one and the other two remain to be done.

Now some divisions are specifically doing these things. They are risk informing license reviews and inspections. Some of their programs, in fact, are these things. But there's no generic across-the-office kind of guidance to help them do that. Each one of them is doing their own thing basically.

CHAIRMAN RYAN: Don't you have some general documentation on implementation?

MR. DAMON: There's no general generic NMSS guidance on how to risk inform a license review

for example, what's the process, what are you trying to accomplish or anything. So each division that's taken that on is doing their own thing there. I mean the concept is understood but you know better than I do what they're doing in high-level waste with the risk insights baseline study and sensitivities on actual bottomline risk metrics. But when you go into a place like fuel cycle, they don't have a comprehensive single bottomline risk metric.

CHAIRMAN RYAN: Where are they getting their guidance to develop it?

MR. DAMON: Their licensees do a thing called integrated safety analysis in which they identify all the accidents and things that can happen and what the outcome will be and they make a gesture on what the likelihood is but it's not really quantitative. So they have that information.

CHAIRMAN RYAN: That wasn't my question. That's what the licensees are doing. How does the staff, is there any guidance they use to develop their program for risk informing their activities?

MR. DAMON: Like I say, what I'm trying to point out is there is this generic guidance that I was going to describe in the rest of the presentation.

CHAIRMAN RYAN: Okay.

MR. DAMON: But what I'm trying to say is it doesn't specifically tell you how to risk inform a license review.

CHAIRMAN RYAN: I'm with you.

MR. DAMON: Okay.

CHAIRMAN RYAN: Thank you.

MR. DAMON: This is a synopsis of what you probably know is that the availability of risk information is different in the different areas of NMSS and the high-level waste as I say at least in the post closure phase, you have a total system performance analysis capability to actually quantify the risk and you can do sensitivity of various technical issues too. So you can get the sensitivity of the bottomline risk to these various factors that go into the assessment. It helps you focus your review on things that might actually make a difference.

The Division of Waste Management and Environmental Protection (DWMEP) has a similar situation except different in that it's multiple things that they have. As opposed to having one facility, they have all these different ones. IMNS (Industrial and Medical Safety), they have done the Byproduct Risk Studies which covers all 40 systems.

It covers all these myriad of things that they regulate. It assesses routine and accident risk and it does individual risk and industry collective risk. They have a resource there and they are risk informing. They have done what they call the multi-phase review of their program and they are risk informing. They've risk informed, restructured some of the inspection programs and they are working on two, I believe, of their standard review plans and trying to risk inform them based on this quantitative information in this study.

I'm currently trying to help them risk inform a relaxation of regulatory requirements in the Part 30 area and the interesting thing that I'm finding is that that Byproduct Risk Study doesn't necessarily help you because what happened was when you relax the particular requirement, you get a new set of accidents that can happen that weren't in the original study. So you have to generate the information de novo when you do that.

I realize the same thing happened to me when I started trying to reason about a thing in the Spent Fuel Project Office. They had a risk study and proposed to relax something and it turns out when you relax that requirement, you're going to get a

different kind of accident you never had before. It was criticality risk and so it's interesting how this works. You may do a comprehensive risk study but in the end, you might not actually use it when you go to actually risk inform something.

CHAIRMAN RYAN: I think you hit the nail on the head as the value of a risk assessment. It's a system. It's a zero sum game. If you change the rules, you might change the risk. If you change the risks, you might change the profile of things that can go wrong or go right.

MR. DAMON: Yeah, that's something I think the staff has to realize is that you do a risk assessment and it says risk is low in some area. That doesn't mean you can do anything you want over there in that area. If you change something, the risk might not be low anymore. Then like I said, fuel cycle facilities, they have these comprehensive accident risk information things called ISAs that covers every process in every facility that they regulate that could have a serious accident. But it's not really fully quantitative.

Then in Spent Fuel, there have been several risk studies and there's an awareness of what routine doses are and accident risk for these specific

studies. But what we have in SFPO is a multiplicity of designs and a multiplicity of sites. It's really a hard nut to try to do a comprehensive risk assessment of that much stuff and in the end, it might not be what you needed for a specific study. So the way to deal with these kind of situations in my view is to wait until you have a question to answer and then do the study.

CHAIRMAN RYAN: If you're lucky.

MR. DAMON: So this is an example of the variability that I put in here. It's risk informing license reviews and I've actually already said this stuff that the three divisions I have on the top are doing it and they're able to make use of comprehensive quantitative risk information. FCSS has guidance on how to risk inform their reviews in the Standard Review Plan (SRP) but it's pretty top level guidance.

Then there's all this qualitative risk information from the ISAs and FCSS does have a project to develop guidance on how to help staff focus on how to risk inform their actual reviews. So it's a supplement to the guidance that's already there. Then SFPO has standard review plans and interim staff guidance, a lot of which helps the staff focus on

what's important and they have a number of risk studies that also would help the staff identify what has higher risk than something else. But there's no comprehensive -- There hasn't been a dedicated specific effort to make everything risk informed. There was a proposal to do so but the resources just weren't there to start it this fiscal year. That's what I mean by things vary across.

This is the process you've seen before. When I said there's a structured process, this is the screening process, the overall process, of deciding whether you're going to do a quantitative risk informing effort in some way. This screening was really put in place in my view to prevent something that often happens which is people go do a risk assessment before they identify what question they're trying to answer.

What I often see happen is they calculate the wrong stuff and you can't use it to answer the question you have when you get to the end. This is just to force people to think up front about what they're trying to do and then whether it's worth doing given the cost of what it will cost you.

That's what this screening process here is in the diamond up there in the middle of deciding

whether to risk inform involves those questions like that. What is the question you're trying to answer? And secondly, what's it going to cost you to do it this way and is that really worth it?

If it is, you proceed on. You do the risk evaluation to generate the information that you need and then in step four there, you apply a structured decision making method that uses that information and other information, not just risk information. That's the key thing here is that risk informing has a little risk in it but when you read the definition that the Commission wrote of it, it's risk in other information and that's really the essence of the thing. It's a comprehensive thing so that's typically how poor decisions are made. You don't think of all of the impacts of what the different alternatives to your decision might be.

This is the overall process. Another way of saying this is this is a screening. This is a method for deciding whether you're going to do quantitative risk assessment in a particular area. But to me, the real value of it is to focus people on generating the information that you'll actually need in the end if you're going to risk inform something. So this is the screening step I was talking about.

Step 2, what is the benefit or usefulness of generating risk information. Do you have a safety question? In the case of the Part 30 rulemaking, for example, the objective here is to gain efficiency and effectiveness by not having requirements in their regulations that really aren't providing any real substantial risk reduction benefits. So they're trying to relax certain specific requirements and not have their staffs waste their time reviewing all this stuff in a license submittal.

CHAIRMAN RYAN: What would be an example of that?

MR. DAMON: One of the specific ones is they require certain -- Manufacturers of certain devices like wrist watches with --

CHAIRMAN RYAN: Promethium or tritium.

MR. DAMON: Promethium or tritium paint on the dials, to do a prototype testing and quality control testing and the requirements and the regulations are very specific and very -- There are very specific, prescriptive requirements on what they're supposed to do. So they have to set up a program that does that, send it in. It has to be reviewed by the staff and the staff feels like this may not be worth, at least the quality control

requirements, may not be worth it because the devices that are in the list of things that --

They're talking about timepieces, ionizing radiation instruments, smoke detectors and, what's the other one, electron tube indicator light things. Most of those things, they have to make the attachment and containment effective or the device won't work properly.

So the belief is that even if you relax the actual requirement, the manufacturers are going to still do it and also there are industry standards on how the things are supposed to be made. The NRC is just adding another layer of regulation to something that probably doesn't need it. The other thing is the source strengths of these things are very small or microcurie amounts of stuff. That's the reasoning there. They think maybe they can relax that prescriptive quality control testing requirement and not really lose any safety.

CHAIRMAN RYAN: So just to take the example a step further. I'm just guessing at the moment. They're looking at something like at least a potential for a failure rate that's higher without a control than with a control and maybe they look at dose consequence or some kind of assessment of is

there an increment of dose at all or is a little tiny bit or whatever it might. That's the kind of thought process you're outlining.

MR. DAMON: Yeah. They've done -- The risk from these devices was assessed in a very top level way in this Byproduct Risk Study, but there was a more detailed study done, NUREG-1717, in which the doses that you might get from things were looked at and because the sources are small, the doses are very small. So even if anything happens, it's really a very small dose. So that's the reasoning that's going on there. They haven't done the rulemaking. It's in process.

The idea here is to ask that question up front. If you want to do a risk assessment and illuminate this issue, what are you proposing to do? In this case, you're proposing to relax a testing requirement. As I mentioned earlier, what I found was when you looked at the Byproduct Risk Study and also NUREG-1717, there was no accident in there that was --

The kind of things that would happen if you relax a testing requirement is sort of as you indicated. You might get a higher defect rate, paint comes off of the thing or sources aren't attached properly or something like that or they might put more

source in the device than they're supposed to, something like that. Those kind of malfunctions or defects or accidents or whatever you want to call them, they weren't part of the risk studies that were done because they didn't anticipate those as being significant things because they had the quality control and prototype testing.

That's why I say when you know the question up front, then you're more likely to do the risk assessment to generate the answer to the question. That's the first question you ask in the screening thing.

Feasibility is the next question. Technical feasibility. Can you do a risk assessment of this, whatever it is you're dealing with or is it really beyond the state of the art? Then another feasibility question really is is what you're proposing to do worth the money you spend on it. You don't want to spend more money doing the study than you're going to gain from whatever it is you're going to use it for. There could be other considerations that might lead you not to risk inform something that basically the decision has already been made as to how something's going to be done.

So the result of applying the screening

process to different things is that not all things would be risk informed. You wouldn't necessarily do a risk study for every dance or every single question that ever came up. You'd only do it when it was worth doing.

Step 4 is the other thing I was going to run over because it's where work was put into this and that is structured decision making methods. This is not really something new around here. There's a type of analysis called a regulatory analysis that's basically required to be done when one does rulemaking.

But it's also -- If you read the guidance documents on it, NUREG-BR-0058 and -0184, it indicates in those documents that really regulatory analysis is the tool that can be used to guide the staff's decision making on regulatory decisions, not just rulemaking but things like relaxing license requirements and various other decisions that relate to safety requirements. So it really has good guidance on what are all the factors you need to look at in making a decision about regulatory requirements.

The way I think of it is there are two different types of decision criteria in these documents. One of them is specific individual

considerations and the other one is a single comprehensive value impact analysis or what most people call cost benefit analysis that you typically try to do quantitatively or mostly quantitatively. That's where you're trading off.

Value impact analysis is an optimization process as is one of the ICRP principles, optimization, ALARA. It's the same kind of thing. It's an optimization of the situation. In that tradeoff, the risk impacts is one impact and cost is another category of impacts and the regulatory decision you're making may be imposing a new requirement or relaxing on. So the impact on risk could be to cause risk to go down or up and then you're trading that off against cost impacts.

The other interesting thing that happens in this process and happens more in NMSS than it would in reactors and that is as we mentioned at the beginning of this is there are multiple kinds of risk. You have the workers. You have the public. You have routine doses and accident and you may be --

CHAIRMAN RYAN: How is that different? Help me out there. I don't get that. You're stuck with why NMSS is different than we are.

MR. DAMON: It's not different in the

sense that NRR doesn't have these things but it's different in the sense of the primary source of risk in a reactor is the core and what's in there getting out. In NMSS, these things could be decoupled. So you don't have one source of risk. You have different things going on. So you can take --

CHAIRMAN RYAN: Could you give me a concrete example that's different?

MR. DAMON: Yeah.

CHAIRMAN RYAN: The reason I'm struggling is if you look at a reactor, it's not that simple. You have an aux building. You have a waste handling building. You have trucks rolling in and out with stuff on them, low-level waste, fuel coming in. It's just as complicated in terms of activities, actions and levels of risk and level of material and motion. You get refueling outages. You get people mopping floors. There are all sorts of ranges of activities in a reactor. It's not a cartoon with a box in the middle. I just don't see them as being dramatically different and I'm not criticizing you. I'm just trying to have you help me understand.

MR. DAMON: No, I think you're right that I've exaggerated the difference. But you would find greater variability in the profile. If you look at

the different components of the different kinds of risk as you moved among different things in NMSS, the magnitudes of these things go all over the place.

CHAIRMAN RYAN: They do in a reactor. If I'm taking a box of low-level wasted and putting it on a flat bed truck and taking it out, it reads .01 MR per hour. The risk there is it falls and hits on the head. The radiological risk in that element is kind of small. So I challenge you to convince me that there is a different range of relative risk in a reactor versus an NMSS application.

Now the range of licensees I grant you is very different. If somebody is licensed to have 100 curies of something or other versus a power reactor, in the aggregate, has a different aggregate view of risk. But in terms of the range of risk, the range of accidents and things like that, I still think that it's an oversimplification to just say that NMSS has a bigger range. I challenge that.

MS. STEELE: May I just offer one example? I'm thinking in NMSS you have the glove boxes, those kinds of manual operations like that and you're in close proximity to it.

CHAIRMAN RYAN: People have stuff in glove boxes in reactor buildings.

MR. FLACK: If I could jump in for a second.

CHAIRMAN RYAN: Please.

MR. FLACK: I'm also going to be talking about this next month, comparing reactors to non-reactor activities.

CHAIRMAN RYAN: Sure.

MR. FLACK: I think with the reactor, the big difference between the reactor and non-reactor world is, I guess there is a couple of things, but I think the main thing is in the reactor world the risk is driven by severe accidents. These are large events that affect many population out there. That's really what's driving the risk. That's what PRAs look at, basically the consequences of a large release or damage event.

Now in the non-reactor world, you have a bunch of smaller population, a very small population. In some cases, it might only be one person and there's a lot of diversity in the way the source is effecting that population. That doesn't mean that you can't use the same logic. I think you can all roll it up to something very simple and that is the source material moving in an uncontrolled way out of where it's supposed to be, how are you going to mitigate that,

what barriers you're going to have and what is the dose.

When you get to that level, it applies, that thinking applies across the board. You can apply that to every type of activity. But as you do that, then it depend more on what the activity is and where the risk is coming from and so on and then you branch out. You apply it as you need to for each of those activities. But you're right. At some level, you roll it all up. It becomes the same problem.

CHAIRMAN RYAN: And again, from a conceptual standpoint, an NMSS licensee has the biggest accident it can evaluate, the co-breach or whatever it might be in the reactor but some version of that for a NMSS licensee.

To come back from the other angle, if you look at the Impro measurables, what are they all about? They are about routine operational improvements, incremental improvements. Keep the water clean in the reactor. You get less corrosion. You get less headaches. Reduce your radiation control areas. You have less dose during maintenance activities. There is a lot of very practical on-the-ground work that's exactly the same as for an NMSS licensee versus a reactor.

MS. STEELE: The culture.

CHAIRMAN RYAN: So they are very different facilities with very different total number of curies in many cases. But I challenge us to think about and I know we're going to learn more about it from some of the experts but I just see a difference here.

I mean I see the difference as being somewhat arbitrary and not really substantiate when you're really cut it down to the principles and practices or fundamentals of risk assessment. I'm just thinking out loud. Again, I'm not criticizing Dennis at all for his thoughts and views here. He has good insights from what's happened, but it's a thought I challenge.

MR. DAMON: What I'm really trying to get at here is that there is diversity. The principles of what you're doing are the same. In fact, this stuff here, this Reg Analysis structure to framework in fact applies to both. It's for reactors and for non-reactors and for anything. In fact, it's Office of Management and Budget John Graham's office up there. They do it for every regulation in the government. So it's very generic in that sense, the principles.

But what I'm saying is that if you do a risk assessment of a reactor like John Flack said,

you're usually focusing on the core metal accident and that's it. When you go over to something in NMSS in high-level waste, you're focusing on chronic releases and vulcanism, a totally different physical phenomena than they had in the reactor site.

CHAIRMAN RYAN: But again the structure of the analysis is the same.

MR. DAMON: Yes. The thought process should be. That's what we were advocating is that we're trying to promote the idea that the staff should think about things in a structured way that's really the same for everything you do. It's just that when you come to a specific situation, some of the risks are trivially ignored and you get a different profile of what really drives the decision depending on where you apply it.

But the virtue of the structure approaches as you have a checklist which is actually in these documents and you make sure you've thought of everything and haven't missed something. The one that they told me about was -- What was that? It was a case where somebody was getting concerned about the fact that the inhalation doses to some workers was rather high. So they made them suit up or put in a requirement to have them wear the breathing apparatus

and everything and then it took them twice as long to do the work and they got more of an external dose.

CHAIRMAN RYAN: And that dose went up. That's the PMI case.

MR. DAMON: Yeah, so you have to have a checklist and say, "Okay, I'm going to take this action. How is it going to affect this component of risk and this one and this one and the cost and everything else?" So that's the virtue to me of these methods is it's comprehensive and forces you to think things, run down a list and make sure you're not doing something that will have unintended consequences and not really be the preferred choice.

So it's kind of an emphasis I'm putting in here on the fact that it's as in the definition of risk informing. It's risk and these other things and this is a list of some of the things. It's not the whole list. It's just to give an example that there are different things. The first one is limits on doses or risks. That's individual risk usually that we're talking about there. Some of it's in the regulations.

Another consideration is compliance. If you have some decision that you're considering making, you still have to comply with all of the other

regulations that you're not proposing to change. And the third is defense in depth which you may propose a change and have an effect on that. Maybe removing a layer of defense in depth, it may look like a good decision from a risk perspective because the risk is still low. But if you've reduced yourself to the point where you're relying on one barrier is between you and something serious, you may not want to do that. So that's defense in depth.

Safety margins is a similar thing. It has to do with dealing with uncertainties and then there's common defense and security. Their security requirements may affect your decision on something where you're thinking about safety and then you have to think about security too. Then this last one is the one that the risk task group worked on which is screening based on risk guidelines of negligible risk. They used to be called safety goals because they're similar in magnitude to the reactor safety goals.

CHAIRMAN RYAN: How is all of that going to be documented and brought forward? I mean how is that going to be immortalized?

MR. DAMON: We're going to produce a document soon.

CHAIRMAN RYAN: When can we have a view of

that?

MR. DAMON: Soon.

CHAIRMAN RYAN: We would like to probably review that and comment on that as early as possible.

MEMBER HINZE: Are you going to have considerations criteria for these various considerations for making an evaluation of these?

MR. DAMON: Yes. Right. Most of this stuff -- Well, some of it they will and some of it they won't. What I say by number 6 screen based on negligible risk guidelines, they are very explicit criteria for that and it's an analog to what's already in NUREG-BR-0058 and that is when you do back-fit for reactors, they have a screening step that you do up front that's based on a criteria related to the reactor safety goals, the subsidiary guidelines of LRF and CDF. They do a screening process up front.

So if you're proposing a new regulatory requirement and you're going to -- Yes, if you're proposing to do a new regulatory requirement, they first look at the impact on CDF and LRF and they run through the screening. If the impact is just too small, then the regulatory, you trip out and say this is not worth doing. It's not worth imposing a new requirement that really doesn't have any significant

benefit.

So we've created an analogous thing for NMSS based on these negligible risk guidelines. It's a way of screening, tripping, yourself out of a process before you waste your time going too much further and doing because the comprehensive value impact analysis which is the next step of backfit is more costly usually to do that than it is to just do the LRF/CDF stuff or the analogous thing for NMSS.

CHAIRMAN RYAN: Do you cover human reliability?

MR. DAMON: It doesn't specifically -- The work we've been doing in this area of systematic decision making doesn't talk about human reliability as a separate subject. It's a part of this whole thing. But in the other work, the risk task group was doing there were several things that were done. There was a training class on human reliability and human performance methods that was developed and make available for the staff. NMSS staff were sent and are taking those back classes.

The other thing was the Office of Research started a program to -- By the way, the Office of Research has -- This development of this structured method that's done here has been jointed effort by the

Office of Research, the risk task group people and the contractors at Brookhaven. And not only that, but separate groups of the staff were set up, the NMSS staff outside risk task group from each of the divisions and so there were many different groups organized to do this as a joint project.

But in the human reliability area, the Office of Research started a specific program to look at human performance technology needs in NMSS. So they have done a survey and they've published. In Phases 1 and 2, they did a survey of what are the human performance resource, or what do they call them, resources what's the state of the art of human performance assessment and use of technology in the different divisions of NMSS. They published a report on it

And then they did one on what are the needs. What are the missing pieces in the divisions in those areas? And now this year, they're based on the assessment of needs. They went to the divisions and they're doing two specific human performance tool development projects, one on spent fuel handling which will support both Yucca Mountain and ISFSI type spent fuel handling. Then the other one is on medical, some new problems with medical devices. They're looking at

the human performance issues with certain medical devices.

That's what's being done in the human reliability area and human performance area. That was initiated as part of this overall comprehensive thing. There was a need to look at human performance issues across NMSS. But like I say, in this thing, human reliability analysis might be a part of what you did in the risk assessment.

CHAIRMAN RYAN: But at this point, that's kind of something that a specific group or division would decide they need to address based on how they view that particular license activity versus a generic guidance to be considered.

MR. DAMON: Yeah. That again the nature of how the human performance comes into the risk in a given area, it varies. In the spent fuel handling area, there are different areas of human performance. One way of looking at this, this has all been my ways, is there are only three kinds of risk, the risk you overlook, the risk you identified and accepted. All the risk of it is human error. Somebody made a mistake whether it was in manufacturing, design, operations, maintenance. Somewhere along the line, somebody made a mistake.

So I look at most of risk assessment as either external events or it's human error. But the specifically human performance aspect of that like in fuel handling, there's drop, events where you can drop the fuel or drop the cask or have a vehicle, a transporter vehicle, do something wrong there. There's a lot of that in the risk and you do a risk assessment on the spent fuel operation. There's a lot of that stuff in it. It's all human performance.

So that's basically all I had to say. I think from what you said you understand what this structured approach is and now the next phase is to try and get more and more of the staff to understand it and use it when it's appropriate. But there's always this problem of limited resources to do these things. The staff of the different divisions has set up certain projects that they feel they've been able to support but there's still other areas where we just don't have the resources to pursue risk informing certain things.

CHAIRMAN RYAN: Interesting.

VICE CHAIRMAN CROFF: I've read a number of the documents that have been supplied, the background and some of those that you've mentioned and it seems to me there's an aspect of that that's maybe

almost counterproductive. It starts out using the word "risk" in a phrase, risk informed. Almost immediately that is translated to PRA and thereafter, PRAs are discussed with -- I'll say the impression it leaves is that PRAs are large complicated things to be undertaken in large projects, I guess, that can afford them if you will.

I think it's counterproductive in the sense that that isn't or shouldn't be true. It goes back to your process diagram where the first decision is do I risk inform or not. I don't think there's a decision there. The answer is yes. The issue is how quantitative should the risk assessment be, how detailed should they be and those should be appropriate to the circumstance and what's involved.

But I don't see where there's an option there and somehow the system is leaving the impression that risk informing is a very onerous kind of a thing and that there's a decision to be made and it's optional. I don't think it should be made optional. It's the management decision that should be how intensive it should be and maybe it would be much better received to articulate it in that way and set it forth in that way.

MR. DAMON: I'm glad you said that because

that's actually my view as well is that it's not black and white. It's not do you risk inform or don't. It's how do you do it. Given the limitations you may have in a given circumstance, how do you risk inform.

CHAIRMAN RYAN: Maybe that's the cut I've been reaching for too, Allen. If you talk about Yucca Mountain and reactors, they both have kind of the more full bore PRA sorts of approaches where NMSS licensees may not. I'm circling back to live conundrum here and saying Allen's put a good point on them that you shouldn't be in the mode of saying are we going to do a risk assessment or not or risk-informed evaluation or not. It may be a simple one or it may be a complicated one but you ought to do it anyway.

VICE CHAIRMAN CROFF: And a lot of what you said is much more reasonable but the documents don't come across that way for sure.

MR. FLACK: If I could just add to that and we talked about this because I mentioned this to Dennis. The whole initiative goes back to what's known as the PRA policy statement and they do use PRA up front. It says to increase the use of PRA across all regulatory activities. I mean that was the policy of the Commission that came down which is consistent with your comment because I think that had they used

this to say is this consistent with the PRA policy statement and the fact that we need to increase the use of PRA as a decision but not to decide whether we need to, that decision had already been made in the PRA policy statement.

Now the question is why don't you. What is the big deal of not being able to do this? Is it that expensive? Is it going to cost that much to build an infrastructure to do this? Okay, how much and why isn't it worth it? So the burden is on not using it at that time, not to decide whether to use it or not. I think that's right in line.

CHAIRMAN RYAN: That's a piece of it.

VICE CHAIRMAN CROFF: It may not be not using it. A PRA doesn't have to be a hugely complicated thing.

CHAIRMAN RYAN: That's right.

VICE CHAIRMAN CROFF: And there's this mind set that it is because the examples we see that are labeled that way are these like Mike mentioned, reactors and these other things where we put millions and millions into it. But it's that misconception maybe that's part of the root of it.

MR. DAMON: One aspect of that that I've learned in trying to apply risk-informed reasoning to

some of the decision situations that we've encountered in NMSS is often you don't have to do a comprehensive risk assessment of every single risk associated with a facility to answer the question you're answering. If you have a specific question, you may only have to assess one aspect of the risk to see what the effect is and it can be quite simple.

In many, many cases, it is the systems in the NMSS that they're relying on for safety are simple things. Often it is a human being that's being relied on which I don't know if you call it simple or not but surely --

MR. FLACK: But the issues doesn't only apply to non-reactors. There's a cultural issue here and even though PRA is complicated and so on for reactors, it's still difficult to get people to think about it and continuously having to go back and have people that have thought about things in a deterministic way for many years to revisit that thinking. That's where I think the crux of the issue is. I think it's a cultural thing and it needs to change and it's slowly changing. But there's more resistance I think using PRA because they've been going down a certain road for so long.

CHAIRMAN RYAN: A good example from my

standpoint and my own experience is the bounding analysis for low-level waste operation. Everybody immediately says, "Class C hardware is the bounding case because it's the highest activity." When you look at radiation exposure as an example, it's not the Class C hardware because there's a limited number of shipments per year and it turns out scattered radiation dose for Class A is more important.

Then you take it out of the radiological zone. All of a sudden it's heavy lifting because you're lifting anywhere from seven to 20,000 to 40,000 pounds on a sling and crane. So there's a whole new set of occupational safety questions there and material handling, the typical hand and foot injuries from material handling or back injuries.

I guess what I'm trying to get at is that there is a tool to systematically go through those things and I'm not saying that the NRC regulates occupational or safety or others. But somebody has a human reliability failure that could result in exposure or an accident or something of that sort. So they're not unrelated. Ruth, you have a comment.

MEMBER WEINER: I have a couple of comments. This is a different slant. Since the normal operation of anything is the most likely

operation for any facility, you get the impression that a risk analysis focuses on off-normal operations and does it because the probability of off-normal operations is usually so much less than normal operations does it communicate too small?

Risks look very small because you're looking at off-normal operations. You're looking at something where the probability is very small. In spite of the risk triplet what we really do in practice is multiply probability and consequence. That's the way you do it. Do you see any kind of communication difficulty there in communicating risks just generally to the public to anyone because when you look at off-normal operations your risks are usually very small?

MR. DAMON: I'm not sure what you're asking. We certainly have had the experience and the people associated with this effort in NMSS that as you move between different parts of NMSS where it may be in different areas they're concerned about different sources of hazard that the people have a different perspective on things. If you're talking about accident risk to somebody in an area where accident risk is trivial, they're not interested in your story.

MEMBER WEINER: Yes.

MR. DAMON: We have that kind of problem. But there are other people around who have a broader perspective. Maybe they've worked in more than one area or they've been associated with one of these comprehensive risk studies like the Byproduct Risk Study. They looked at routine and accident and they drew the conclusion which you just annunciated which is that the routine risk is much higher. The normal exposures are where all the risk is in those applications.

In fuel cycle where I worked for a number of years, it's the other way around. Most of the facilities work with uranium, low-enriched uranium, and the routine doses are pretty small. But they work with some pretty dangerous chemicals and then there's the risk of criticality. So at least that's the area where you probably have to do more work to make sure you don't get a problem than working on the routine side.

CHAIRMAN RYAN: Dennis, just another quick question. From the licensee's perspective all across NMSS, how is this being received? If I'm a licensee, where do I go to find out what I'm expected to do in this risk-informing area?

MR. DAMON: First off, unlike what NRR has

done, I don't think -- How do I put this? There's the Division of Waste Management and High-Level Waste in which risk evaluation of chronic exposure and off-normal situations are quantitatively assessed and used right from the regulation itself. It's a regulatory requirement.

In those areas, that's sort of an area where you have a framework established to use risk-based reasoning and risk-informed reasoning and it doesn't run into a conceptual roadblock with the staff. But if you move over to one of the areas where assessment of risk is not part of the regulatory structure, you run into the fact that first off people aren't very familiar with the concepts you're talking about and then there is resistance of other kinds part of which is just practical difficulties of doing some of these things. So there are more problems there.

I'll give you an example here. In other words what I'm trying to say is that on the NRR side it took them a long time to go from a point where they were doing a risk assessment, a wash, I can't remember the wash, a wash 1400. There was one before that and then wash 1400.

PARTICIPANT: 740.

MR. DAMON: And then individual plant

evaluations and you march down this path and over a period of years, you use this stuff to look at decisions and finally they reach a point where they start to trust things.

CHAIRMAN RYAN: Yes, it's a 25 year learning curve and significant resources being devoted to it. I appreciate that. The reason I ask the question is that with each division doing its own thing and just because different people are doing it in different settings, it will likely evolve in different ways. I'm not saying that's necessarily good or bad. It would seem that the expectation is there'll be a variety of implementation successes or failures. I just wonder what should we think about that. Should we comment on it? How do we move forward here?

MR. DAMON: I think there can be more. It is a long term process. I think there's a process of the staff becoming more familiar with these technologies, these risk technologies and using them in the areas where they're helpful. There are training classes set up for that.

But I think there are successes going on all across NMSS. They're moving in positive directions in a lot of different things. Even the

area I was in which was fuel cycle when they started the Part 70 rule-making which has a risk, it's a risk structure to it, it's identify what can go wrong, identify the consequences and do something about the likelihood.

So it's a risk conceptual structure right in the regulation and the interesting thing was is the industry resisted the concept of this partly because it sounded like we wanted them to do quantitative PRA across all of their facilities and again they thought this will cost millions of dollars and what's the benefit. They resisted that. But what I've observed has happen now they're years later. They've all done ISAs and they're talking to the staff about reviewing them and stuff.

What I find is I go to a workshop where they're talking about this stuff and now they're all talking risk terminology. They've learned the conceptual structure. So there's been a transformation there that has happened in the last eight or ten years. That's the kind of thing, one thing, that's beneficial because I think for accident risk what I found is that trying to quantify something clarifies your thinking. Try to identify specifically and write down what is the access sequence and what

makes it likely or unlikely and it clarifies your thinking about things. In fact, I remember Norm Raspus (PH) in saying he felt being able to put an event tree up on the board and say, "This is the accident sequence I'm talking about here" was the biggest benefit of doing wash 1400 because you clarify what you're talking about. Those kind of things are going on.

But what I see as the next phase of this stuff and it is happening is risk informing on license review guidance documents and risk-informing guidance for doing inspections, not to say that the existing guidance doesn't have stuff in it about how to do a risk-informed review, but I see a potential there for improving things.

CHAIRMAN RYAN: Inspection time is a precious commodity. There's no sense not to focus on the risk-significant issues.

MR. DAMON: Yeah. The inspectors do that and there is training and guidance to help them do that. It's just that in certain areas the absence of a fully quantitative risk information has inhibited that a little bit. There are areas where it can be improved and some of the divisions are taking that on if they have it budgeted down there to try to do

something about it.

It's just like it was mentioned before. Just because you can't afford and don't have full quantitative risk information doesn't mean you don't risk inform. It just means you have to learn how to live with that limitation.

CHAIRMAN RYAN: We have the advantage of having John Flack and Ashok Thadani going to help us next month with some information from the reactor side so we learn a little bit more about it from that perspective. I'd ask you. What would you recommend we think or do about continuing to risk inform at NMSS or advise the Commission or ask for resources or put the team back together or whatever it might be? I'm not trying to put you on the spot but if you had anything you wanted to suggest that we could look at productively or evaluate productively and help continue the risk-informing process and not lose the momentum that your team developed, we'd be happy to hear that.

MR. DAMON: I think some of the thoughts that you've expressed here today are the helpful kind of thing, the idea that it isn't really a question of whether you risk inform. It's how you do it because risk informing to me is just as it says and the

Commission defined. It's using risk and other information to improve your decision making and that's why in this presentation here, I really didn't talk a lot about -- I didn't just talk about the risk. There were these other things.

CHAIRMAN RYAN: I understand.

MR. DAMON: And so encouraging the value of the bodies like the ACNW is to encourage the Commission and the staff to continue to try to learn and benefit from these technologies for making decisions and assessing risk and including normal exposures all in one thing and using that to improve your regulatory process. I think one of the dangers is that some people when you say risk informing, they're thinking of using PRA in some area and it's not just using PRA. It's doing this stuff that's in this presentation here.

CHAIRMAN RYAN: Sure.

MR. DAMON: So if they think it's PRA and they're thinking about the area they work in and they say, "PRA doesn't make sense" or "It's not important in my area" then the idea is "Hey, we don't need this risk-informing stuff." But when you understand risk informing is really an effort to focus the staffs. It's the outcome. It's an outcome. You risk inform

when you're focusing on what's important to our safety mission.

CHAIRMAN RYAN: I think John hit on a point too that I think you agreed with that all our view of bounding assessment is an older culture that probably needs to change and a lot of people in NMSS activities I'm sure today still say, "I have a bounding assessment. I'm okay. I understand the risk." Well, nothing could be further from the truth. You understand that bounding case but you have no idea what the real risk is and something unrecognized in that bounding case could invalidate your bounding analysis. There are lots of examples of that.

VICE CHAIRMAN CROFF: Can I ask a question? You mentioned a forthcoming guidance document at some point. About when do you expect that to become available and will it become available as a draft or in final?

MR. DAMON: It's going to be available in a form that will be characterized as available to the staff for trial use. That's the phrase that's used. So it's not like this is official guidance that's been endorsed by the Commission. Follow these rules. It's here it is. Try this out and see how it works and give feedback back to me and Wayne Hodges about how

well it's working and change it if it isn't working in some area or needs to be adjusted or supplemented. That's what we're looking at, generating something and then make it available for trial applications.

The difficulty -- And I expect it to be available soon. There are certain -- It had to go through some screening and stuff because there's a number of things that have come up since the thing was generated, sensitive information, screening project and some other considerations. So it should be available soon, but like I say, for trial use and it doesn't cover everything. But it does give the generic framework.

VICE CHAIRMAN CROFF: But at that point, it would be available for open discussion in a meeting such as this.

MR. DAMON: Right.

VICE CHAIRMAN CROFF: Okay.

MEMBER HINZE: let me ask you another question. How do you validate your procedures that you present in your regulations? As I listen to you, Dennis, one of the things that comes to mind in the preparation of these regulations, it seems to me that that probably is a segmented preparation. How do you make certain you've covered all the bases and you

haven't had any holes in the process or overlaps?

MR. DAMON: Are you talking about developing a regulation?

MEMBER HINZE: A regulation. Right.

MR. DAMON: A regulation?

MEMBER HINZE: Right.

MR. DAMON: The regulatory analysis that's in here, that has to be done if you are in fact doing a rulemaking. You're required to do this regulatory analysis which as I say essentially has a checklist of all things.

MEMBER HINZE: So there's a template that there is.

MR. DAMON: Yeah, there is those two guidance documents that I mentioned earlier in the thing, NUREG-BR-0058 and -0184.

MEMBER HINZE: Okay.

MR. DAMON: And that marches an analyst through a bunch of things that they have to analyze. The thing however -- What we were trying to encourage here is that that structured approach can be used not just for rulemaking but also elsewhere and also that it should be used up front to determine what the rules -

MEMBER HINZE: Rules should be.

MR. DAMON: What the rules should be as opposed to "Okay. After we figure out what we want, then we slap this justification on the end here." The value of that stuff is using it up front even if you can't quantify everything exactly. It's a process to make the decision correct in the first place is the way I look at it.

CHAIRMAN RYAN: We didn't touch on it but I think it's implicit in the things you've been saying that and your last point kind of hit on it that if you don't know everything exactly, that's precisely why you do it so that you can get some feel for what you're certain or uncertain about and by how much so that you can maybe either enforce your level of confidence as being appropriate or learn you really don't know what you're talking about which could be an endpoint for risk analysis. So there's an uncertainty analysis value to it as well.

MR. DAMON: Yeah. There's a -- I don't know if I can mention this. There are other efforts going on in here at NRR to use essentially the same thing, structure, reasoning, lay out the analysis, address the uncertainty, explain to the decision maker "this is how the pieces all fit together" but recognize that this piece here is relying on this

analysis here which has a certain range of uncertainty to it. I did some of this stuff very early in my career and there are different ways of presenting that uncertainty information in way you can explain to a decision maker whether you can rely on it or not.

MR. FLACK: Yeah. If I could just follow up on that too. I know, Dennis, you mentioned before that it's best to come with a question that you're trying to answer and use the risk assessment to do that. But the risk assessments that are being done in NRR and other regulatory processes are being used to ask the right question. So you see it all laid before you and maybe you haven't been asking the right questions. So in that context, I think that's what you were mentioning, Mike, there's a benefit for just putting in an infrastructure that allows you to do that and if you don't have the infrastructure, you're just picking in my estimate let me see if this is the right question and you go which I just find inconsistent in the way we've been doing business in the reactors.

CHAIRMAN RYAN: Right, and to be fair, I think that the reactor side having 25 years of experience, they're getting smarter and asking better questions up front. But I would venture a guess that

in 1981 or 1980 after wash 1400 came out, they might not have been hitting the fast balls as well as they are now.

MR. FLACK: That's true. In fact, today we live with design-basis events and accidents that we deal with in the regulatory process.

CHAIRMAN RYAN: Right.

MR. FLACK: For those that are not generated by risk assessments. Those were chosen sometimes in bounding ways and now we're revisiting those because we missed the accidents that were driving the risk and then we put in accidents that are so unlikely that they need to be revisited because we're allocating resources in the wrong direction. I think you also have that on the non-reactor side when you talk about these scenarios like the Intruder for example.

CHAIRMAN RYAN: So on the NMSS side, maybe that's a lesson learned to say maybe we ought to recognize that updating and flexibility and changing them and letting them evolve is all part of the process too.

MR. DAMON: There was a lot of discussion during the development of this diagram and I've been through this, let's see, there's this diagram.

There's a more complicated version of this with arrows and boxes going all over that this process isn't a one-pass thing like this. It's almost sometimes you do the whole thing simultaneously and then you iterate and the reasoning process is much more complicated because when you get to this step the way I say John is saying it --

MEMBER WEINER: We can't see what step.

MR. DAMON: When you do this step and you get the risk information certainly you learn all kinds of stuff and then you start asking new questions and you go back to step 1 and redefine all kinds of things. You may learn new issues and the issue you started off addressing you go off and do something different or you have identified a more clever way of solving the problem that you originally identified by when you get to step 3 there. So it's an iterative process.

I've been participating with some people from NRR Research in a similar effort dealing with a diagram that's almost identical to this and they had the same problem. When you put the diagram down, you can put the feedback loops in there. But there's feedback loops from every box going to every other box and it just --

CHAIRMAN RYAN: They're all circles.

MR. DAMON: It becomes a big complex thing. So one way of dealing with it is just say this is it but it has feedbacks from every part of the thing. As you learn more, you go back and revisit the stuff that you did before and you're constantly iterating.

MR. FLACK: Provided you don't screen it up first. Right?

MR. DAMON: Yeah. You could make a mistake. It could be a mistake. You could screen out something which you probably should have done. Another thing that I want to mention about this is the methods that we've been working on are oriented all around quantitative information from a quantitative risk assessment and one area we did not address which we realized in retrospect is there's a tremendous amount of quality of information you get out of risk assessment and that there really needs to be guidance for the staff on how to do that.

If you are a person who has professionally worked in risk assessment for a long period of time, they learn how to do this thing, how to take a risk assessment apart and learn things from it. But the staff, I think there's a benefit to explaining that

process to the staff so that they realize that that's really -- Probably the bigger benefit of doing an assessment like this is the things you learn from looking at the insides and the guts of the things, not the bottomline number.

CHAIRMAN RYAN: Any other questions or comments? Latif.

MR. HAMDAN: Yes. Dennis, thank you very much for a very good presentation. Now you would issue the guidance soon. What's your thinking of what's actually going to happen? What I mean by that is how do you see different divisions in NMSS doing what you think they'll be doing.

MR. DAMON: I would say that the Part 30 rulemaking is a thing that fits exactly the guidance that we issued. So you can follow it. There's an area where you just follow the guidance that was written there. As I mentioned in going over this stuff, there's no generic guidance on how to risk inform license review or inspections. Those are probably areas.

This is what Wayne Hodges said. He said, "Hey, this is where the staff spends most of their time is doing these two functions. If you're going to gain efficiencies and effectiveness in the staff, we

need to figure out how to do this part in a risk-informed way." Well, this stuff here stocked short of that, it has the architecture of the different factors that will go into that process. But when you get an inspection and license review, there's a whole other aspect to this thing that needs to be added on to that. That's where I think the real future benefit and work ought to go.

It's like the Yucca Mountain risk-informed review. There's all those technical areas in Yucca Mountain and it doesn't make sense to do equal effort in every area. You have to focus on what --

MR. HAMDAN: But doing the reading on, any reading at all now, they're going to receive this.

MR. DAMON: On how the staff will --

MR. HAMDAN: Yeah.

MR. DAMON: The staff, I think, in most cases the way these things like inspection and license review parts are handled, they work with regulations, regulatory requirements and standard review plans. So the risk-informing process can be done in the process of revising those documents in a way that makes the staff, it gives them guidance so that they automatically learn. I mean the staff knows, many of the staff know, that they want to focus on what's

important obviously and just saying that refining the guidance might help them to be sure that they in fact do that.

CHAIRMAN RYAN: Dennis, as we think about how to move forward on this question of risk informing NRC activities, I'll just put in the broadest possible term, we're reaching for what should be our focus and you can say lots of nice things that might not be effective or might not be received or be useful or be out of order or be not right, we're really looking to John and Ashok to help us understand more of what's been done so we can better think about what ought to be done next and what ought to be done in other areas.

So we're reaching out to you, I think, to help us see some of your vision on where the real opportunities are. If we did these five things, we'd be a lot further down the road and help us. You've given us some good insights today on the processes you've use. I think the documents that will be forthcoming will help further educate us on what the staff is being given as trial guidance. So maybe we can help comment on that and think about specific examples perhaps or other things. Anything you can do to help us there would be great.

MR. DAMON: Like I say, this stuff is

mostly talking about task work. It was focused on risk-informing changes to regulatory requirements.

CHAIRMAN RYAN: Right.

MR. DAMON: I think in the future that's something that should be done and they should do it as part of a regulatory analysis type process. But I think the real future of risk informing in NMSS is in risk informing license reviews and inspections. That's where you'll get the benefit.

CHAIRMAN RYAN: Sure.

MR. FLACK: I should follow up on that. I should point out that Research has recently been sent an SRM by the Commission to risk inform Part 50 and that's a huge task. In light of that, you may start to think of what's next, how to risk inform which parts of the regulation if you were to chose which one you would want to do. What would be the best one?

CHAIRMAN RYAN: I would suggest Part 61.

MR. FLACK: That goes without saying. Right?

CHAIRMAN RYAN: Dennis, thanks very much. This was very informative. I guess I think we're at the point where we would be thrilled to write a letter to support your activities in risk informing NRC

processes but I'm not sure exactly what the content would be at this point that would be focused and helpful and on point. So maybe we'll defer that discussion until next month when we hear from Ashok and John and hopefully you can participate or at least be with us when we hear that information. Maybe we can talk about it again or at least give you the benefit of our discussion there and see where we're going.

MR. DAMON: Okay. I'll be here.

CHAIRMAN RYAN: Okay. Thanks very much. We appreciate your time. We have two final things on the agenda for today. One is a draft White Paper on high-level waste transportation issues. Ruth, you were the lead for that.

MEMBER WEINER: That's not there yet.

CHAIRMAN RYAN: So that's a pass.

MEMBER WEINER: That's a pass.

CHAIRMAN RYAN: And then draft ACNW White Paper on low-level waste.

MR. FLACK: Do you want to keep the record on?

CHAIRMAN RYAN: I don't know that we need it at this point. Do we? Okay. We'll conclude the record at this point. Thank you very much. Off the

record.

(Whereupon, at 4:58 p.m., the above-entitled matter concluded.)