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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON NUCLEAR WASTE

(ACNW)

154TH MEETING

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TUESDAY,

OCTOBER 19, 2004

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ROCKVILLE, MARYLAND

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The Advisory Committee met at 8:30 a.m. in the Auditorium of the Nuclear Regulatory Commission, Two White Flint North, 11545 Rockville Pike, Dr. Michael T. Ryan, Chairman, presiding.

COMMITTEE MEMBERS PRESENT:

MICHAEL T. RYAN, Chairman

JAMES CLARKE, Consultant

ALLEN G. CROFF, Member

DANA POWERS, ACRS Member

RUTH F. WEINER, Member

ACNW STAFF PRESENT:

JOHN T. LARKINS, Executive Director

ACNW STAFF PRESENT (Continued):

NEIL M. COLEMAN

JOHN FLACK

LATIF HAMDAN

RICHARD K. MAJOR

ALSO PRESENT:

EDGAR D. BAILEY CRCPD

MICHAEL A. BOYD EPA

DON COOL NRC

KEITH ECKERMAN ORNL

E. VINCENT HOLAHAN, Ph.D.
NRC

RICHARD J. VETTER, Ph.D., CHP
Mayo Clinic

C O N T E N T S

P R O C E E D I N G S

(8:36 a.m.)

CHAIRMAN RYAN: It's five minutes past our starting time, and unfortunately two of our panel members must be en route, Mike Boyd from the EPA and Ed Bailey from the Conference of Radiation Control Program Directors. I think we're trying to hunt them down now. So without further ado, I'll go ahead and get started and read our opening statement.

The meeting will come to order. This is the first day of the 154th 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 Ruth Weiner and Allen Croff.

Today the committee will conduct a working group meeting focused on the June 2004 recommendations of the International Council on Radiation Protection. 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 requests for 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 staff.

It is requested that speakers use one of the microphones, identify themselves and speak with sufficient clarity and volume so that they can be readily heard.

Before starting the first session, I would like to cover some brief items of current interest. Dr. Richard Denning, Battelle-Columbus, has been appointed the newest member of the Advisory Committee Reactor Safeguards. Dr. Denning is an internationally recognized expert in the field of risk analysis and severe accident behavior of nuclear reactors. He has been associated with advisory committees on reactor and nonreactor nuclear facility safety, including the Department of Energy's Advisory Committee on Nuclear Facility Safety.

A 100 page report on the status of NRC's decommissioning program is available on the Agency's electronic document system, ADAMS. The access number is ML0422500080. We'll make that number available to anybody that needs it. I'll read it again now: ML0422500080.

Geophysical Research Letters has accepted

for publication a paper authored by Mr. Neil Coleman and Drs. Bill Hinze and Bruce Marsh, who are all affiliated with the ACMW. The title of the paper is "Testing Claims About Volcanic Disruption at Potential Geologic Repository at Yucca Mountain."

MR. COLEMAN: Excuse me. That's Bruce Marsh and Lee Abramson.

CHAIRMAN RYAN: Lee Abramson. I guess I read that wrong or it was typed in there. I'm sorry. Lee Abramson. Thank you.

The lead author, Neil Coleman. I appreciate the correction.

Our opening day today is to again hear commentary and thoughts on the Council on Radiation Protection and Measurement, ICRP, June 2004 recommendations. A few weeks ago, back in September both Roger Clark, the current Chairman of ICRP, and Lars-Eric Holm, the Vice Chair and, I guess, Chair-designate or soon to be chair at Roger's retirement, came and gave detailed briefings to staff in a morning session and was open to members of the public session in the afternoon presenting the exact same material.

So the ACMW is going to take up that material and hear from the expert panel that is seated across from us, including Don Cool from the NRC staff,

Ed Bailey hopefully soon to arrive from the Conference of Radiation Control Program Directors, Michael Boyd from the Environmental Protection Agency, Keith Eckerman from the Oak Ridge National Laboratory fresh off the plane from China and soon to be heading on a plane to Russia so that he'll circle the globe here within a couple of weeks, Rich Vetter from the Mayo Clinic and also a member of the ACMUI Advisory Panel, Vice Holahan from the NRC staff.

Welcome, gentlemen, and we appreciate your participation this morning.

The purpose of the working group meetings are to develop information necessary to provide a letter to the Commission and, two, to understand the technical bases for the draft June 2004 ICRP recommendation; three, to review these recommendations against current NRC regulations and practice; and four, to identify aspects of the ICRP recommendations that may warrant further study.

I might also add as an introduction that Dana Powers from the Advisory Committee on Reactor Safeguards has joined us. Dana is the member of the ACRS who follows the radiation protection and, particularly, the ALARA issues for the ACRS.

Dana, welcome, and thank you for your

participation today as well.

Without further ado, I'd like to turn the meeting over to Don Cool, who is going to provide us with an overview of the June 2004 ICRP recommendations.

Dr. Cool, welcome. Good morning.

DR. COOL: Good morning. Thank you.

I feel a little bit like the old, lonely end here. Hello, fellow panel members way down there. Hopefully this will fill in as the morning progresses.

It might actually be appropriate to consider time distance shielding, in this case distance being the appropriate variable given the cold that I caught in Beijing as well. So you will pardon my voice if it gives out during the course of this time. We'll try to repair this.

What I will attempt to do over the next few minutes is to give you a brief overview of the draft ICR recommendations that were posted on the Website a few months ago.

Let's go ahead and go to the next slide.

ICRP, the International Commission on Radiological Protection, has been an organization which for more than 50 years has been providing advice and guidance in radiation protection. Their last set

of recommendations were published in 1990. So it has been approximately 15 years, and they have been going through a much more open public consultation process in the development of this set of draft recommendations.

The draft was published on their Web. It's www.icrp.org. If you want to go and get it, it's a PDF file. You can download it.

They will be accepting comments to their Website through the end of this year, that is, December 31st, 2004.

In addition to this, those of you who have read it probably know that there are a number of places in that draft where there are references to documents not yet available at the time it was published. Those have been nicknamed in ICRP some of the foundation documents.

In their meeting in Beijing last week, the ICRP was considering those foundation documents, and I believe that at least four of them have been agreed for publications as drafts on the Web for comment in the coming weeks. I am expecting that it will probably be two, three, or so weeks before they actually get up on the Website. They will be available, I understand for 90 days.

So there will be some measure of overlap in the comment periods when some of those foundation documents are available and when the recommendations are still available. Although I didn't put them on a slide, I wasn't exactly sure what they were at the time of developing these. The foundation documents that I believe have been agreed to be tentatively put on the Web include from Committee 1 a document on low dose extrapolation, also from Committee 1 which is the biological committee a rather compendium document on effective dose epidemiology by standard effects, and a variety of other things that underlie the biological and radiological considerations of the document.

A report from Committee 2 related to the dosimetric quantities and weighting factors. Committee 2 is the committee that looks at modeling. Details on that, he's a member of that committee, and a report from Committee 4, the practical applications committee on some of the definitions of the individual.

A fifth foundation document related to optimization also from Committee 4 I understand will be getting a bit more drafting and will not be available as soon as the others.

We can go ahead to the next slide.

The contents of the draft 2005 report, a variety of things. I will touch briefly on each of these as I go through the next few slides to give you a quick overview. If you compare this list to the agenda you'll see a high degree of similarity across a number of these topics as we look at some of the quantities, biological aspects, the general system of protection, the quantitative recommendations -- everyone likes to get into the numbers -- optimization, some statements they've made with regard from exclusion, which I think we're going to want to look at, medical exposure, potential exposure and protection of the environment.

Go ahead to the next slide.

My purpose in walking through these is not to give you a lot of detail because we will be doing that as we proceed, and if you were here a couple of weeks ago and hear Roger Clark's presentation, you'll know that he also provided quite a bit more detail on a number of these topics.

But the draft recommendations do contain proposals for new values for the weighting factor, both radiation weighting factors and the tissue weighting factors. The radiation weighting factors, those factors that are applied to the different types

of radiation, alpha, beta, gamma, protons, and neutrons, to try and allow for the varying effects that those radiations have in tissue, the biological weighting factors which we'll be talking about considerably more, the relationship of the various potentials for induction of specific cancer in a particular tissue to the overall rate of induction in the body.

Of particular note, there are a couple of things in the tissue weighting factors that have raised some interest in that the weighting factor has increased for breast, female breast, and it has been decreased for the gonads, which has resulted also in some reduction, actually a fairly considerable reduction in the estimated contribution of hereditary effects to the overall risk of radiation.

If we move on to the biological aspects, the report covers a number of topics. The first thing you may notice is that what you used to hear of as deterministic effects are no longer called that. They're now being referred to as tissue reactions.

I will tell you a number of little stories as we proceed of things that were discussed at least in the side bars during Beijing. There were a number of us who asked them, well, isn't a tissue reaction

most any reaction of a tissue, including perhaps even cancer induction and otherwise.

But that is a term which they have chose to represent the acute effects. These are the things like the burns and the various radiation syndromes that are more specifically related to large doses of radiation.

There's also quite a bit of discussion in the report on cancer mechanisms, the epidemiology nd updates that support that, genetic susceptibility, the hereditary effects, as I said, some new information on which seems to indicate a decrease in the contribution of heritable effects over the first two generations and some discussions of various non-cancer diseases, bystander effects, and otherwise.

I'm in hopes that when the foundation document from Committee 1 is published that a lot of the gaps which are not filled in at the level of detail in the recommendations have already been published will be available and hopefully will stimulate further comment.

As everyone is already interested in the numbers, some of the media questions come up. Well, did anything change in terms of the actual nominal risk coefficient for cancer induction, and the answer

is a little bit.

The 1990 column is what was published in ICRP's Publication 60 and 90. The numbers of here in 2005 are from the draft. This year you can see a slight reduction in the fatal cancer probability coefficient, and similarly a slight reduction in the detriment numbers.

Having said that, ICRP doesn't see that that is a huge difference and that these numbers continue to support the quantitative recommendations and the fact that they have not changed in numerical values for dose limits or the maximum constraints that we'll talk about.

Moving on, the general system of protection. This is the three principles as they are now articulated today. You're probably used to hearing about justification, optimization, and limitation. You might immediately notice that these are in slightly different order. Justification, they're quantitative recommendations. You can read limits there, but you also need the word "constraints," and we'll talk about that in a moment.

And then optimization. That is a deliberate move on the part of the ICRP to emphasize to a much greater extent than they have previously,

first, the protection of the individual's doses from any particular source, and the establishment of those quantitative recommendations as the boundary for the optimization process rather than sort of the vice versa.

Previously a lot of people said first you optimize protection and then you look to make sure that no individual was exceeding the limits. We structured that the way, in fact, most people do it. You make sure that you've complied with the limitation criteria, and then within that you try to achieve the best available protection.

If we can move on, topic of justification. Not changed dramatically. That benefit needs to be looked at in the introduction of any particular source or activity. What is new now in these draft recommendations is actually stepping back and recognizing that most decisions to decide to introduce a particular source or do a particular activity and environment are made not only on radiation protection criteria or the doses that might be available, but on lots of other issues which go into deciding whether or not you're going to do something.

So the radiological considerations are really only one part of that. ICRP continues to

clearly suggest that things should be introduced only when they are justifiable, but they have acknowledged that this does not have the same sort of ultimate role or sort of make the presumption that a competent authority, a nuclear regulatory commission or similar sorts of agencies to ours actually have in their power in many cases the ultimate decision to decide to do or not do some particular activity.

There may be national security interests and otherwise that result in deciding to do particular things with radiation or radioactive material, and the doses that may be achieved are only part of that.

The note on the bottom, ICRP also looks at medical Committee 3 of ICRP that has been devoted specifically to medical, and medical is treated a little bit differently. We'll talk about that. Obviously when you're deciding whether or not to expose the patient there are a whole other set of decisions and criteria going into setting what you're going to do and how much of it you're going to do.

If we can move on, over the years ICRP has had five or six or more, depending on how you wish to categorize them, different bases for selecting numerical criteria for their various recommendations. The recommendations in 2005 have attempted to try and

unify that not by changing the underlying bases. This is one of the things I would suggest to you is not very clear in the drafting of the recommendations, but rather as a way of being able to benchmark the various bases and uses for the constraints according to a level of concern which is based roughly on the kinds of considerations around what naturally occurs in the environment.

The actual background, about one millisievert per year, 100 millirem per year. I will attempt to be bilingual for you. In that process I may mistranslate, and please forgive me if I do so.

That's the natural background, nominal average without including radon. So this is the cosmic radiation in normal terrestrial radiation of K-40 in your body and such things.

Quantities of radiation are doses smaller than that, generally do not receive as much worry. Doses above that number you generally want to do more until it comes to a point where everyone will always do something, and there's a point on the bottom. You'll notice that there isn't actually a point on that. It just sort of stops, where people rare, if ever, do anything to try and modify the actual doses that would be received.

So those levels of concern roughly then translate into a scale which you can also use to look at the quantitative recommendations that the Commission had laid out.

The Commission lays out both dose constraints, which is a topic that has been considerably strengthened and elaborated on, I believe, within this draft, and limits.

Now, I think first and fore most it's important to understand what ICRP thinks they mean when they talk about each of those terms. They use the word "limit" in the context of the quantity which would be applied to the protection of a particular individual, say, me from all of the possible sources to which I might be exposed.

So if I was in a working situation and there were a variety of places that I was working or sources that I was receiving, the limit should apply to the sum of all of those different source contributions.

A constraint is a criterion that is applied in the relationship of a particular source to my exposure. So if this is my source, the constraint is the boundary of what that particular source should contribute to me.

They make that distinction, in part, recognizing that it is very difficult in most circumstances, certainly in most all circumstances for members of the public to actually exercise any feasible regulatory control over all of the possible sources and know that you've always captured the sum and provided protection.

But it's relatively straightforward to know what the relationship is of any particular source.

Mr. Ryan?

CHAIRMAN RYAN: Just a quick question, Don, and medical is apart from that? That's treated separately?

DR. COOL: Medical is treated separately from that. That is correct. They will use the word "constraints," and they will use a variety of other terms, but they do have a different meaning in the medical context.

CHAIRMAN RYAN: Okay. I think that's an important point, that you know, we're talking about, I guess, from our perspective regulated sources that are regulated by either the NRC or agreement states, not medical exposure and not radon.

DR. COOL: Correct.

CHAIRMAN RYAN: Okay. Having said that, of course, recognize that the ICRP recommendations do talk about radon, and Mike Boyd, who I see has snuck into the back here --

(Laughter.)

CHAIRMAN RYAN: Got you, Mike.

-- can talk a little bit more about how that does or doesn't match up.

I perhaps should have noted that ICRP has three general categories of exposure which would be occupational exposure, public exposure, and medical exposure, and they treat medical as a very different box.

DR. COOL: Okay. No, I just want to make that clear that that, in fact, is a different box. When you use the dose limit, you say protecting the individual from all sources to which the individuals is exposed. That's not exactly correct. It's all sources except radon in medical.

CHAIRMAN RYAN: Yes.

DR. COOL: Okay.

CHAIRMAN RYAN: Being careful because there is a box in which radon in the work place might also be included if it was above certain action levels and had to be incorporated or if you were working with

materials that were naturally outgassing radon and some of our source material folks might do.

DR. COOL: Sure. We're recognizing that the radon exposure in that circumstance is a trivial fraction of total radon exposure.

CHAIRMAN RYAN: True. If we can move on, the recommendations for constraints. They have grouped them into four categories in an attempt to simplify the scheme of radiation protection. This is another item that the committee may wish to think about a little bit.

There are more than 30 different constraint numbers in the various documents of ICRP that have been published since Publication 60 in 1990. One of the things that ICRP was attempting to do was to see if there could be something more simple than all of these individual different constraints.

Their methodology for attempting to do that was to look at categories of situation and to suggest a maximum or typical maximum constraint that would apply to that category. One hundred millisievert for emergency situations for workers other than direct life saving or other particular activities, things where public evacuation relocation, some of the very high levels of existing exposures all

would fit into that category; these are situations where there really aren't any either individual or societal net benefits from the individual doses at that level.

The second category, 20 millisieverts, two rem. These are, by the way, per year in all cases. The number typically seen for occupational exposure. Keep in mind that with Publication 60, ICRP moved to looking at the 20 millisievert per year as the basic occupational number.

Their limits have a bit of flexibility, that is, ten millisieverts over five years, a maximum of five in a year, average of two in a year. They've set the constraint level at two in a year, two rem per year.

The one millisievert, 100 millirem public exposure level, and they've suggested that as organizations, operators, or others who may then set more specific constraints within these maximums, that there is no reason to ever set a constraint below .01 millisieverts, hence the term that they've used, "minimum constraint."

That is one of the things which poses just a little bit of a logical conundrum. How can there be a minimum in a table of maximum values, but the logic

behind this is that there would be no reason to ever set a constraint number, assuming that always optimize below a constraint, below the .01 millisievert.

By the way, that does number happens to be the same number that they suggest for exclusion. It poses another bit of interesting conundrum, whether you would be optimizing in an area which when you get a few pages over is the basis for them setting exclusion and exemption levels.

Let's move on to optimization, and we're going to be talking this about a little bit later. Optimization is the third principle providing complementary protection beyond the constraints in order to improve protections for the individuals. ICRP in this document has, as they have put it, broadened the application a bit.

The picture is not entirely clear what all "broadening" means. They have drawn some connection to the safety culture organization as being indicative of the similar sort of continually questioning and improving environment that constitutes the qualitative approaches to optimization.

They have recognized and, in fact, encouraged the involvement of stakeholders in the decision making process in terms of what the optimum

solution would be.

And there is a bit of discussion around the use of collective dose versus what they have referred to as a dose matrix or the various attributes of the does that are important to the decision. We'll be talking a bit more about that this afternoon and going into some of those details.

Go ahead to the next slide.

Exclusion from the recommendation. Previous ICRP recommendations have had some discussion around exclusion, particularly for radon and some of the other natural materials. The ICRP in this draft is suggesting that this can be expanded and have suggested that the system of protection not be applied to activity contractions below and they have two sets of numbers: for artificial radionuclides, alphas and beta gammas, and natural radionuclides in the uranium/thorium series and a separate number for Potassium 40.

If you're trying to figure out where those numbers came from, I believe you will find they match that which was developed in the rather laborious and difficult process within the Atomic Energy Agency, the AIEA, through their development of a document on exemption exclusion and clearance.

During the development process that was referred to by its number DS161. IAEA published it just a couple of months ago as GSR 1.2. It's a safety series guide of the International Atomic Energy Agency, publicly available on their Website for exemption and exclusion in clearance levels.

These numbers match those numbers as values which could be exempted or excluded. They were developed in the context of moderately large quantities of material for clearance or international transport.

There is also an alignment now with decisions that have recently been made within the food and agriculture organization and the world health organization or drinking water and for food in the Codex Alimentarius.

We can go ahead to the next slide.

Speaking of medical just briefly, there are several different types of justification that they would suggest apply, both a generic justification, as is this particular procedure a reasonable procedure to do. General terms, more specifically, is the procedure right for this particular patient? That's what doctors are always supposed to be doing.

Optimization, which in this case is very

much different. It doesn't mean trying to just minimize the dose, but trying to make sure that you get the right dose to do the job, whatever that may be, taking the picture or destroying the particular tissue.

Constraints in this case not really applying to the patients themselves, other than various benchmarks of good practice for various kinds of activities, but constraints for comforters and caregivers, this is one of the things that is a little bit interesting.

If my daughter, for example, were in the hospital and I wanted to be there and attend and help to provide with her care and comfort, as many family members often like to do, patients often like to do that, it's good their well-being. ICRP would suggest that that actually constitutes something that they would consider as medical exposure, and they would apply a constraint which would be roughly equivalent to occupational exposure, not the one millisievert member of the public.

Moving on to potential exposure, not a new topic for ICRP. There are several documents that have been published where if they are suggesting that a risk constraint can be used analogous to the dose

constraints, the probability of incurring the dose and the lifetime condition or probability of death from the dose giving you risk numbers in a variety of settings. This gives you a mathematical number not unlike what you get in PRAs and various things.

And of course, going along with that, all of the dangers associated with very small probabilities and very larger consequences and various and sundry other things which they acknowledge.

This has been expanded just a bit with the suggestion in these draft recommendations that this methodology may also be an appropriate way to try and look at some unique circumstances, such as particles, such as trying to deal with surveys of contaminated land, where you may have particular hot spots, and trying to go through some sort of mathematical I'll say "algorithm" rather than "rigmarole" to determine what the chances of an individual in the amount of time an individual might be on that spot versus other areas, to give some measure of quantification around dealing with some of those highly nonuniform exposures.

Go ahead to the last slide.

Protection of the environment is a new area into which ICRP has been pushing rather

aggressively over the last few years. There was a report published jut about a year ago this time which laid out some of the initial recommendations the Commission made to itself to move forward.

Their aim is to try and develop a policy and framework on environmental radiological protection that would provide a common approach to dealing with doses to humans and doses within the environment.

There is currently a task group of the main Commission that is actually trying to develop some reference forma and flora. Yes, that means a reference tree and a reference bunny and a reference frog and a reference few other sorts of critters, as one way of going about and looking and being able to benchmark and quantify the kinds of effects that might or might not be seen within the environment.

ICRP has been clear that they do not see that this is actually a problem which requires there to be significant changes to effluents or protection that's currently being afforded for most circumstances, but heretofore there has been no systematic way to try and actually assess and compare the various impacts or to provide a demonstration that more and more often, particularly in the European Union, the OSPAR Convention, otherwise which requires

a demonstration with regards to what the effects, and so this is to try and move towards a process that would allow there to be some demonstrations of information and some consistency.

In the new term of ICRP, the next four years starting in the summer of 2005, there will be a fifth committee on environmental protection. Jan, again, Pentreath from the U.K. will be the chair of that committee and will be pursuing this particular work.

Dr. Ryan, with that, that concludes my quick, galloping synopsis through the recommendations, and hopefully sets the stage for our discussions today.

CHAIRMAN RYAN: Well done. Thank you, Don.

A quick question. You mentioned in passing collective dose. Are we going to get into that a little later on or should I ask that question now?

DR. COOL: Well, I've got it as a couple of slides when I talk about optimization this afternoon.

CHAIRMAN RYAN: We'll wait until then. Okay. that will be great.

Any other opening questions for Dr. Cool?

DR. POWERS: Yeah, I have a couple of questions. You brought up the issue of safety. Safety codes to enforce is a popular concept now. There's a lot of discussion. I guess what I struggle with, it seems like the document has kind of an offhand [inaudible due to NRC audio system failure] on safety culture. It sounded like a good idea. Here; go read this reference, and I have not read that reference.

What I want to know is if they have in mind some way to measure safety culture. They see it as something a regulatory authority would address or is it just good advice for an operator. And is there a view that the plain text of their words on safety culture in any sort of an alignment with the concept of safety culture [inaudible due to NRC audio system failure].

DR. COOL: Okay. Let me see if I can take those in order. Anything related to measurement? Not that I have seen.

Related to the overall development and safety conscious work environment? Yes, I think that they're sort of seeing it in that context. There are not a lot of words to this. This is an area where --

and you made an observation a minute ago -- they have picked it up. They have not said very much about it. It is not entirely clear exactly how they see all of the relationships.

The foundation document related to optimization is the one foundation document which I understand the main Commission did not approve for publication on the Web in the next few weeks because it was not yet ready because of some of these issues and needing a bit of further development.

Their suggestion, having seen some of the drafts is that this is something which regulators would probably want to be looking at as making requirements. Don't ask me exactly what they would necessarily mean by that, and for the operators to pick up and use.

I think at this moment they have taken it just sort in the generalized view that optimization, thought of in its broadest terms, is always looking to see if you can improve protection, which is the exact same mindset as a safety conscious work environment and always questioning and trying to improve your particular situation and involving the individuals.

Beyond that, I don't know that there is a great deal of rigor at this point.

DR. POWERS: Safety culture, of course, is a big problem, and it has been my personal observation that we presume everyone has a good safety culture, and then we promptly send in lots of investigators who find out [inaudible due to NRC audio system failure], and so the safety culture gets defined by events.

The other concept that emerges in connection with safety culture [inaudible due to NRC audio system failure], and probably as the day goes on I'll have a lot to say about that, but that puts it in another real problem.

CHAIRMAN RYAN: Ruth?

DR. WEINER: Don, just tell me if my question can be answered later on and I won't dwell on it now, but as you can imagine, I have a great many questions about your last slide. The whole notion of potential environmental damage to species other than people, is there any evidence -- I know that some of the sites like Hanford that I'm very familiar with have been wildlife preserves for quite a long time, and of course, there has been considerable exposure from the French drain system, and so on.

Is there any evidence for chronic damage, radiation damage, to non-human species?

DR. COOL: Not that I am aware of, and I

think that ICRP in acknowledging that there is not a driving need is looking to try and take some of that information and, through their references and benchmarks, be able to indicate the kinds of doses and situations which, in fact, do not appear to have led to that, but there's no systematic way of doing that at the moment.

That is what I think they would tell you, putting words in Lars-Eric Holm and Jan Pentreath's mouths.

DR. WEINER: So they're trying to define -- let me see if I have this right -- they're trying to define a reference system to show that, in fact, the doses that might produce something are so large that doses that we have in the environment, nothing happens. Is that where they're going?

I don't understand the impetus for this whole move.

DR. COOL: Yeah. Well, it actually is a little bit easier perhaps to answer the second question. Internationally, in particular, there are a variety of treaties, particularly in the European Union, OSPAR and others, which have required increasing degrees of rigor of quantifying environmental effects, drives to reduce all effluents

to zero, period, end of discussion.

This is an effort not necessarily to say that X amount of dose has no effect, but to be able to have a system whereby you can show what your effluents might be, what the doses might be, and then be able to compare them to what is known or not known about effects, to be able to say, "See, I am in a range where there are not effects to provide a demonstration."

DR. WEINER: Thanks. That's a very good answer.

My other question is completely separate, and it deals with the potential exposure method for hot particles. How would that notion apply to something like the Iowa radon study where you're basically estimating how long people spent in certain environments that might or might not expose them?

We have a lot of studies that are similar, but that one comes to mind as being one that the EPA, I know, depends on.

How does this notion of potential exposure apply to that study?

DR. COOL: That's a very good question, and it is not elaborated on in the recommendations report, nor any of the other draft documents that I

have seen. So I could speculate, but I don't think that would be appropriate.

CHAIRMAN RYAN: Jim Clarke.

DR. CLARKE: Just to follow up on what Ruth was asking, is it accurate to say then that under protection of the environment the aim is really to develop an initial framework for evaluating potential radiation effects to non-human species?

DR. COOL: Yes.

CHAIRMAN RYAN: Thanks. I guess we'll press on and I'm sure we'll be back to Don with other questions as we go along.

You'll notice on the agenda that we have a section for biological aspects of radiation protection. Unfortunately, with all of the experts being first in China and then in Europe over the course of these two weeks, we were just unable to match our schedule here with travel schedules of the folks we had hoped to invite to participate.

I think Dr. Cool has certainly covered the overarching questions, those being that the major issues are that the weighting factor, the tissue weighting factor for breast has changed and that the overall risk factors per sievert, per rem or per millirem of exposure have been modified slightly, but

not to the extent where the ICRP needed to change any fundamental recommendation.

So leaving those conclusion points on the table, as Dr. Cool so aptly pointed out, I think we'll try and capture what other biological comments we might as the talks progress. We certainly have Dr. Eckerman here, who is well known to us all and to the greater audience, and internal dose calculations, he can speak to some of these issues in more detail than I can.

So with that said, I'd like to just go ahead and move to our next presentation, which is updated of the ICRP recommendations regarding quantities used in radiation protection.

Dr. Eckerman. Welcome and thanks for fitting this into your world travels.

[inaudible due to NRC audio system failure.]

CHAIRMAN RYAN: Why don't we just take a five-minute, very quick break, and we'll work out the technology question and we'll come back in five minutes.

Thank you.

(Whereupon, the foregoing matter went off the record at 9:22 a.m. and went back on

the record at 9:29 a.m.)

CHAIRMAN RYAN: All right. Thank you very much. Thank you, Theron, for getting us back on track.

Dr. Eckerman.

DR. ECKERMAN: Thank you.

I guess another reason to update the operating systems from Microsoft, but anyway, we are on line.

So following Don's excellent presentation, I'm going to say a few words about dosimetric quantities, and the earlier presentation certainly made my job a lot easier here.

This slide shows you the two foundation documents that are to go up on the Web that are really important with respect to the quantity you're dealing with. I've got a little different title, I think, than what Don was referring to, but the one that biological and epidemiological information on health risk attributable to ionizing radiation, that's of course the one that we all really get into maybe one's consideration of what the nominal risks are they're carrying forward in their recommendations and define their definition of detriment, and then, of course, end up with respect to the tissue weighting factors,

and you'll see where all of this fits together in later and later slides here.

And then, of course, the Committee 2 foundation document is the basis for the dosimetric quantity in radiological protection. So those are the two principal foundation documents that are important in this presentation.

And as Don mentioned, they will be up on the Website, and actually the Committee 2 did more with that one than the Committee 1 document, but the draft is in pretty good shape, Committee 2's draft. We've got a little editing to do, and it ought to be up in a couple of weeks, if we get past the security clearance area.

Next slide., please.

CHAIRMAN RYAN: Just a quick question, Keith or Don, because both of you are involved. I'm becoming more and more nervous that the time that folks will have to comment on these foundation documents is a narrow overlap with the comment period for the main recommendations.

Has there been any thought or discussion of extending the comment period for the principal recommendations based on the -- I think Professor Clark indicated that they would go up in October, and

now it sounds like November for part of them and later for others.

Any feedback on that point?

DR. COOL: There was no discussion during the meeting last week in Beijing. However, there may have been some discussion amongst the main Commission. Keith and I as members of the committee were finished Thursday evening. The main Commission continued through the weekend.

I have not heard anything that says that they're going to extend the comment period. They may not have been asked that question or pushed in the comment very much. That may be another one of the things that the committee, I think the staff may also be looking at that, and others asking for some additional time due to the foundational nature -- pardon the pun -- of a number of these.

You're right. There is a very minimal overlap as we're turning out on these.

CHAIRMAN RYAN: Well, I think as Dana Powers has pointed out, as he's developed a number of questions on ALARA and, you know, optimization and those kinds of concepts and without those foundation documents, we're kind of aligned in terms of really understanding what is in the foundation documents.

So I guess at this point that's something that I want to say the committee and Commission, and try and get the right ones, the ACNW ought to think carefully about discussing in its letter, but the timing just seems to be under tremendous pressure for getting these things through a process without really, you know, giving people the benefit of the foundational documents.

DR. COOL: Yes, that's true. Just one observation. Where we have identified a number of concerns, such as the ones that Dr. Powers has laid out, and given what I believe to be the status of some of the considerations in that area, getting those comments to them at this point, recognizing we don't have the foundation document, may actually have an opportunity to influence the foundation document in this particular case.

CHAIRMAN RYAN: Right, and that's the one, if I recall, you said is kind of last in line in terms of being finished.

DR. COOL: My understanding is that that was last in line because it was not as well developed and ready to go at the meeting in Beijing. So that's my reason for suggesting that, in fact, if we develop a specific set of things with specific suggestions of

things that need to be included or places where there is a clear confusion or difference from what we can see, laying that out for them may provide them an opportunity to help hone their skills as well.

CHAIRMAN RYAN: Okay. Thank you.

And, Keith, sorry for the interruption, but I thought that was a good point to raise that question.

DR. ECKERMAN: Okay. This slide I just put in to remind you that principally ICRP's system is intended for developing of prospective guidance, that is, defining what is good practice that serves as the basis for a regulatory system and focuses principally on the stochastic effects.

And as Don mentioned, in the bottom of the slide there are deterministic effects, which we used to call non-stochastic effects, and then we decided to call it deterministic effects, and now there is a new name for that: tissue reaction.

So I just threw this slide in.

And the next one, the next slide, please.

Going back now to the dosimetric quantities, of course, there are the ICRU operational quantities, which are principally used with respect to external radiation fields. They're defined as

measurable quantities that represent or that adequately characterize the ICRP's protection quantities.

So things like personnel dose equivalent Hp(10) and the ambient dose equivalent, so there are those operational quantities to deal with, and then the protection quantities themselves, and of course the effective dose that is the principal irradiation protection quantity of ICRP and equivalent dose, of course, in specific tissues.

The next slide will go deeper into this. I think between the ICRP 26 system, of course, as Don already mentioned, dealt with these three principles for radiation protection and a set of limits particularly on stochastic effects on the effective dose.

Next slide.

Those were changed a bit in ICRP 60, the 1990. However, the principles still remain the same, those three tenets of radiation protection.

Next slide.

So getting back now, I mean, what can I say new about the dosimetric quantities? Well, absorbed dose, of course, is the basic quantity, and ICRU would define that as a point, and it is just the

physical quantity that represents the imported energy per unit mass, and a Gray, of course, is one joule per kilogram.

The next.

Equivalent dose was the terminology adopted in 1990 instead of dose equivalent. They put the adjective out front, and that's the protection quantity, the product of the absorbed dose due to the radiation R in a particular tissue times the radiation rating factor. So this is, of course, the working equation with respect to an equivalent dose.

And the next slide says the ICRP has decided to rename that quantity. Instead of equivalent dose, they now refer to that as the radiation weighted dose. This is largely due to ICRU having dose equivalent and equivalent dose and then there's a bit of confusion as to which one you're talking about.

And so the ICRP had decided to give up its use of equivalent dose and term it radiation weighted dose, and needless to say, there was discussion about changing the name of a quantity when it it's still the same thing as it was before. Whether this is any degree of simplification or evolution in the protection system, but anyway that's the current

decision to rename that as the radiation weighted dose.

Next slide.

Then the prime protection quantity is the effective dose, and this allows one -- of course it was introduced without a name in ICRP 26 to provide a means of adding, if you will, external and internal doses, the external radiation field and the doses, the tissues resulting from the intakes of radionuclides, and it's just the sum over specified tissues of the product of the equivalent dose, and a radiation weighting factor for that tissue.

And so that's the working equation, and it represents the same health detriment as if that does was given uniformly to the body. So this is a way of taking care of the heterogeneous nature of the doses associated with the intakes of radionuclide.

So this is the prime protection quantity in the ICRP system, and of course, this relates back to the stochastic effects.

The next slide.

Well, this just mentions the idea of the committed dose, which is largely a bookkeeping quantity and simply assigns the dose that's expected from the intake of a radionuclide over the time period

that it may reside in the body, and the commitment period for the worker is taken to be 50 years, and when you're dealing with members of the public, the committee in an age dependent sense is taken to page 70 for children.

Many of these intergals (phonetic) emerge before that time period. So there isn't as big a conservatism in here as you might think when you first think about accumulating the doses over those protective time periods.

The next slide.

So we're going to get now and look at what's kind of starting to look at the changes that are coming along, and this is the current values for the radiation weighting factors that we've been using, and for protons this value has been five, and there was a functional step function representation of the W sub R for neutrons that was applied.

Next slide indicates that what's been changed is the protons are going down, too, and of course, neutrons will have to show a corresponding change since protons contribute substantially to the dose.

There was a continuous curve that was published in ICRP 92, a recent publication. However,

there's still some ongoing look at W sub R for neutrons. So it's still a topic under review, and of course, it will be addressed in the Committee 2 foundation document.

So there's a group within Committee 1 and Committee 2 still looking at the neutron issue, particularly what's going on at very high energies.

Next slide.

Now going back and looking at the tissue weighting factor, this was the situation we had in ICRP 26 with the gonads representing, of course, hereditary cancer because at their largest weight, breast, lung and bone marrow and in the thyroid surfaces not showing a high degree of sensitivity, and at that time there was 30 percent of the weight left to unspecified tissues that collectively are referred to as the remainder.

And at the treatment of the remainder in Publication in 26 and Publication 30 was to apply that remainder to the dose to the five highest irradiated tissues that weren't specified.

The gonad weight, is it corrected on this?

If my memory is correct, they hereditary effects at equilibrium over all future generations, if you will, and of course, the breast area is, of

course, the sensitivity of the female breast.

Next slide goes in 60, published in 1990, the gonads had a -- well, there were additional tissues added to the consideration, and of course, when you specify additional tissues, these have to add up to one. So the difficulty of talking about tissue weighting factors is, of course, the value for any particular tissue, represents the values for all of the other tissues sine they have to add the one.

But there were a number of new organs explicitly brought into the colon and stomach cancers; urinary/bladder, liver, esophagus were added. Bone surface and skin was explicitly included at this time, and then the remainder got down to .05 at this set.

Now, the gonad weight again here now was back to looking at the hereditary effects in the next two generations. So one was looking at the grandchildren, if you will, of that set.

There was a complicated -- at this time the ICRP decided to not have an explicit consideration of the or limit, if you will, on the equivalent dose in a tissue and used the effective dose to control everything, and so there were still some tissues in the remainder that were not being addressed that control even at 20 millisieverts on the worker might

result in some highly irradiated tissues, for example, like the spleen or the airways, extra thoracic airways. The doses could be rather high.

So the remainder had a complicated procedure to try to take care of that in which the weights would be split and applied in a different manner to those highly irradiated tissues, and there was also in the effective dose of ICRP 60 and that weighting system, there was concern about the additivity of the effective dose quantity. So a scheme was introduced to treat the remainder to get away from that selecting of the five highest and to try to make the quantity more additive.

That resulted in actually a very complicated procedure for the remainder, and you only had five percent of the weight on the remainder anyway. So within the radiation protection system, the additivity really wasn't a significant issue.

The next slide shows where at least where things are proposed right now.. There are some new tissues entering into this that are shown here in italics. The gonads now have dropped all the way down to five percent. As Don has mentioned, there are substantial changes in the considerations in the hereditary effects.

There is a component of ovarian cancer, of course, in such as the ovaries that's imbedded in there, if you will, as well, and so the system is collapsing down to .12, .05, and .01 as it's the numerical values that are applied to a number of these tissues.

The remainder now has jumped back up now to ten percent of the weight, and there will be an explicit listing of tissues to be addressed under the remainder.

The additional organs that have been added really don't fully grasp with or, say, resolve the issue with respect to some isolated tissues, but the kidney, of course, is going to be important here for a number of radionuclides since that's the route of elimination, urinary excretion of any systemic activity [inaudible due to NRC audio system failure].

The information with regard to the gonads and the ready area affects, of course, are largely covered under the UNSCEAR document, which has been published, and we'll get into the basis, I think, for some of these I think in a little later slide. So next slide. Maybe right now.

So I've got a few slides that touch on the biological data. So the sources of this information.

The main change here is that the starting point is the incident data rather than mortality data that was used earlier. So the nominal cancer risks are based on incident data. The bulk of the considerations that come from the A bomb survivors in the life span study, that's the major input.

However, there are -- for example, the bone surface considerations are still based on the Thoratrast experience on bone cancer, and of course, the thyroid studies. The coefficients are based on studies specifically looking at thyroid cancer in other populations.

So the three factors or sets or kinds of data that go into computing these nominal risk estimates are the baseline cancer incidence data that exists in the population. Then there are site specific incident risk estimates from various studies that fall into or that are available to consider, and then the five and 20-year cancer survival studies, statistics from those studies come into play here in determining the detriment consideration.

Next slide.

The Committee 1 foundation document looked at the issue of the linear no threshold consideration, and commented on that the DNA damage information

mechanisms are a bit supportive of linearity down to about tens of milligray. Of course, none of the EPI studies on human populations have sufficient power to so of demonstrate that.

As Don mentioned, the bystander effects and the genomic instability considerations, Committee 1 looked at those and at this time indicated that they really weren't going to be able to address those with respect to the risk considerations.

The dose and dose rate reduction, the effectiveness factor that's used to go from the high exposure cases down to the low, the value of two is still being used.

The detriment now, the health detriment is being tasked to consider, of course, the incidence of the cancer, the lethality and some reflection on the quality of life associated with those that do survive the cancer.

And the data are really being averaged over an Asian and Euro-American population. so this is the kind of information that's being transported, for example, from the Avon survivors to these populations and the detriment examined within those population groups.

The next slide.

And Don has already shown you these. For the whole population, the health detriment is 6.5 percent for sievert. I hope my numbers are going to agree here with what Don had showed you earlier. A danger of 7.3 percent was a value that we had in in ICPR 60. If you go to the adult worker, it's four and a half percent for sievert and 5.6 percent for the ICRP 60. These are the detriment numbers.

And as Don pointed out are the numerical changes and some shifts you see in the data, but they're not terribly significant in the overall course of setting radiation protection guidance.

Next slide.

So where do the shifts come from? Well, as already mentioned there are hereditary risk that's been revised substantially. We're now talking about something like 20 cases for your 10,000 per sievert rather than the 100 cases that were considered in ICRP 60. So there is a real reduction in the hereditary risk.

In addition, there's a recognition that not all of those hereditary effects are really legal, so there's the validity fraction of .8 being thrown into the data.

The breast cancer risks are higher by

about a factor of three, and the reason for that is largely those Avon survivors that were exposed as juveniles are now entering into that period and contributing the breast cancer to the data.

And there are other studies that would comparably indicate a corresponding risk of breast cancer.

Thyroid, their age now is recognized as a stronger factor than what it was earlier, and there are some gender issues that are folded into the consideration of the thyroid risk. So the numbers may not change that much, but they're distributed. Things are distributed a little differently.

And so those are the major changes in the fundamental data that's influencing the W sub Ts.

The next slide. I guess I'll have to do a bit of Committee 2 advertising to let you know what we're up to, and there are some ramifications. So this is why I'm doing this.

We're switching over to a Voxel-based anatomical model. So there will be an adult male and adult female model that's going to replace the old ORNL hermaphrodite model that has been used for years.

So if you go gender specific, that's the message there, that we'll be having to deal with

tissue doses in males and females, and of course, the work is first being addressed with respect to the worker.

There is also an effort, of course, to replace the nuclear decay data information that was in ICRP Publication 38, and this is a joint ORNL-JAERI effort and actually under the auspices of EPA, and we've processed 1,035 radionuclides.

This is going to give about 200 more nuclides with half-lives greater than ten minutes than what we addressed in Publication 30, which is the significance here.

And of course, there's an ongoing effort to update the biokinetic and dosimetric models. This, of course, was largely started in those series of publications that began after the Chernobyl accident and has continued with respect to it, the first being driven by age considerations, but it is continuing on, of course, with update nuclides and elements, the models that we hadn't addressed earlier.

The next slide.

Well, the Voxel phantom, of course, comes with medical images, and of course, it does have an improved anatomical realism in picking the body. From a dosimetric standpoint, if there are external

considerations, the organ doses, you don't expect a major change in the transport percent.

Internal, at very low photon energy you can see maybe an order of magnitude difference in the photon component of the dose between two organ, which is largely a function of what the separation may really be in those.

There's an effort, of course, when you go to the medical images, you're picking a particular individual data, and there was a tremendous amount of work that has been put into this effort to have these phantoms or the computational phantom represent the reference value. There has been a lot of work to accommodate the kinds of data that were in Publication 89 with regard to organ sizes and so forth.

The next slide.

Well, this shows you the kind of cross-section if you haven't looked at such a thing.

The next slide, male, and of course, you can identify all of the tissue in that slide.

Next slide.

Just a little update to tell you where we are with respect to the nuclear decay data. Actually here we've got to process 1,034 radionuclides. There are about 200 additional ones beyond. Ten minutes

ICRP had used as the criteria on half-life for which it would compute a dose coefficient per intakes of the radionuclides.

And so there's about 200 more than what we had addressed in Publication 38 that was done in this update.

The next slide.

I'll close here by speaking a little bit more about the gender averaging issue which has come up. I think both Committee 1 and Committee 2 are wrestling a bit with this.

The tissue weighting factors are gender averaged, and when we have these CT based phantoms, of course, we're going to come out with gender specific organ doses, and so it's a question now of how do you really put the effective dose together because you've got a quantity that's gender specific and then you've got weighting factors that are already averaged. So how best to really compute this effective dose; does it really make a difference in what the detriment considerations are? And of course, this is the topic for ongoing discussion.

So the next slide shows actually some very recent -- these are calculations actually I did in Beijing -- where the consideration here is that if you

constrain the intake of these radionuclides to 20 millisieverts in the average worker; so somehow you'd get a positive of male and female, and then the question is what's the detriment distributed between these two people?

And so you go down the list here, and ruthenium is kind of interesting because it's a nuclide in which the detriment is -- this in ingestion. So the detriment largely there is reflecting colon risk, and so there's a slight difference in the colon detriment contribution that males and females get.

But the significant one out of here is the Iodine 131. So in this case the females' detriment is about a factor of three higher than what the male value would be.

So there is some questions about how we're going to handle that particular issue.

CHAIRMAN RYAN: Could you tell us why?

DR. ECKERMAN: Well, it's because of all of the differences in the tissue weighting factors, and so much of the -- and there is a -- this is averaged over the population. so there is a higher thyroid risk coefficient in the female for thyroid cancer, particularly, and of course at younger ages.

So these a reflective of all of those considerations

CHAIRMAN RYAN: I guess I'm probing because I don't understand. Is it based on the epidemiology of the cancer risk or is it based on the dosimetry?

DR. ECKERMAN: No, it's the cancer risk data.

CHAIRMAN RYAN: Okay.

DR. ECKERMAN: So there is a difference in the detriment for males and females, and that reflects through here with regard to the thyroid and iodine.

Next slide.

I think that's it. Thank you very much.

CHAIRMAN RYAN: Thanks, Dr. Eckerman.

Questions? Down on the end, Dana?

DR. WEINER: How do we know that dose delivered over time, that the effect is cumulative?

DR. ECKERMAN: Well, there have been some studies that have been done to look at whether the dose is cumulative.

You know, that there are repair processes going on and so forth, but those repair processes, of course, are completed with regard to the latent health effects, I should say. And so this is a n assumption

that's in the system, as has been tested in various other animal species and so forth, but there isn't, of course, a means of really having the statistical power to do this in an epi study on humans.

DR. WEINER: The next question is just probably my own ignorance. How do five and 20-year survival rates feed into the effective rate?

DR. ECKERMAN: Those enter into the determination of what the detriment is, and so they then enter in both with regard to speaking to the lethality fraction, as well as the consideration of quality of life that's applied to folks who are actually survivals.

So there's a subjective consideration that goes into defining the detriment.

DR. WEINER: But it's actually you translate this quantitatively?

DR. ECKERMAN: Yes.

DR. WEINER: The final question is how long do you think it's going to take for this to penetrate to the various places, the environmental impact statements and so on, health considerations, where these numbers are used because we have a number of models that we put in these factors, and it's difficult to update them, and people are always back

20 years. I mean, there are still some cases here where you're not even up to IPRC 60.

So do you have any estimate of how long this is going to take?

DR. ECKERMAN: Based on past experiences?

(Laughter.)

DR. ECKERMAN: We still have things that are still driven by publication, too. So that's been, '59 to.

A lot of the dosimetric data that, of course, was available post ICRP 60 is being used, the dose coefficients are being used in a lot of applications now. So that has been sort of accomplished at least with respect to equivalent dose without a real -- well, both NRC and DOE and DPE, of course, have been using the later dosimetric data.

But it's a long process to get all of these things imbedded in the regulatory process. It's way too long a process.

CHAIRMAN RYAN: Keith, I'm reminded of what you have commented on previously to the ACNW regarding FRG 13, and I think it's true. Correct me if I'm wrong, Don or Vince, but licensees are the ones that want to use the more updated dosimetry in particular analysis or are authorized specifically to

do that.

I think that's true in agreement states, Ed, as well.

So the information is there, and it's accessible to licensees to use. Did I get that right?

DR. COOL: Essentially, yeah.

CHAIRMAN RYAN: Okay. A licensee who wants to make it a standing part of their protection program needs to apply to be able to use it because, of course it is different from what's in publication, 10 CFR Part 20.

We have been granting those. We look a bit skeptical when a licensee following an event or something then tries to backfit their data if they weren't already approved to have their program run it. That we don't look very kindly on.

CHAIRMAN RYAN: right. I understand that. Thanks for clarifying that.

Ed, do you have any comment from the agreement states with respect to that point?

MR. BOYD: I think we might be a little more lenient in using it to evaluate an event that has occurred as opposed to looking at it prospectively.

CHAIRMAN RYAN: Right. Okay. Thanks.

Allen.

MR. CROFF: Yeah. You mentioned a couple of changes in the radiation weighting factor. What underlies the change in photons? There's some general uncertainty, I'd say, in the neutrons. Sort of what's going on there?

DR. ECKERMAN: Well, the change in the protons largely comes out of joint working group with ICRU and ICRP, and it goes back to initially the relationship between the operational quantities, those calculated in the -- the dose equivalent with he sphere, that really relied on the QLET relationship, where ICRP in setting up the protection quantities backed off to looking at the weighting factor as a function of the incident energy.

And so there was a calibration scheme that carried on there, and that's largely where a factor of two comes into consideration, and said that the setting the W sub R at five for protons was actually an over estimate.

So this is just sort of a redo of the physics and dealing with the QLET relationship in the sphere. And this is discussed in ICRP Publication 92.

The neutron, of course, is -- you have to have a correspondence between the quality factor for

neutrons or their weighting factor for neutrons and that for protons because recall the proton being a major part of defining the energy deposition for neutron interactions. So there should be an agreement there.

Part of the considerations at the high energy end come into play with regard to space radiation and, of course, there's interest in the air crew problem of dosimetry, and at the high end at least, once you get a very high neutron energies, the neutron weighting factor ought to collapse back again to what the proton data would tell you.

That's at least where the physics takes you. You're outside of, of course, again, the realm of really having a lot of experimental data to add onto the weighting factor, but the physics data would suggest that at the very high energy the two ought to correspond to one another.

And again, that's issue that's part alluded to in ICRP 92.

CHAIRMAN RYAN: Keith, you touched a couple of times on uncertainty type questions with regard to the ratios for a female to male detriment, and I've heard you talk previously about the overall uncertainty and internal dose calculations and models

and kind of the history of how those uncertainties have evolved over time.

Could you give us your insights there, please? I wanted to pick your brain for the benefit of the committee and the audience on, you know, how you think that's going and what in these new recommendations, you know, are really the critical things for us to focus on on internal dose estimation or external dose estimation, for that matter, but really the internal side of things.

What's the good news and how are uncertainties progressing?

DR. ECKERMAN: Well, the uncertainty question is, of course, difficult to deal with, but in the context of a radiation protection system. However, despite that, when one tries to at least acknowledge what the uncertainties are in the data and where they come from.

Actually Committee 1 has at least the draft that I saw of their foundation document, does also have a section where they talk about some of the uncertainties and the risk coefficients and the weighting factors not in a real quantitative sense, but at least defining where the sources of the information are.

With respect to the internal emitters, the biokinetic information is really the dominant source of the uncertainty. There is, of course, within the lung model, for example -- many of the models that have been now developed, and there will be a new model for the elementary track that will be available in the next go-round for the dosimetry; many of these models that are being developed and in trying to appeal to the physiological basis for the processes and so forth, I wouldn't say that they were all mechanistic, but they're trying to deal with the physiology as well as the element of specific information.

But the behavior of aerosols within the lung and the ability to address the different compounds and their solubilities, define what the absorption is to the systemic uptake of blood, if you will, is, of course, very important.

And then the processes by which we have between model, the fate of that material as it is distributed amongst the organs and eliminated from the body, that tends to be, I think, the dominant source of the uncertainty.

And a lot of this you can characterize by at least looking at the quality of the information that you have to develop those models, and of course,

it varies considerably across the spectrum of radionuclides I'd be happy to deal with.

But one would hope that these dose coefficients would be within a -- you'd like it if we were within about a factor of three, I think would be very good.

CHAIRMAN RYAN: But a factor of ten may be reality?

DR. ECKERMAN: And a factor of ten or higher may be reality on some radionuclide.

CHAIRMAN RYAN: The reason I asked the question is, you know, we do have regulations that allow, for example, in the case of an intake for a specific case by case evaluation and their are protocols and details for how to do that. I can envision in my own mind that tritium is probably a whole lot easier to deal with as a vapor than, say, plutonium or some other inert or insoluble actinide or oxide.

So I appreciate and recognize this is a great range in the certainty values, and we also probably think more these days about air samples rather than bioessay samples and characterizing the work place rather than characterizing the worker after the fact, although both are good ways to think about

doing internal dosimetry for those few cases where it's important or where exposures have occurred.

I guess the $64,000 question to me is: what do these new ICRP recommendations provide us as moving the ball forward, given that reality that we've just described.

DR. ECKERMAN: Well, I think this is a part of a continuing evolution or I hate to use that word right now, but progress in the modeling effort. I think the kinds of dosimetric modeling that was done, say, with respect to the ICRP 30, there's been a substantial improvement and change in philosophy, say, post Chernobyl where ICRP and many others had to become more realistic in the way things are being modeled and so forth.

So in some of the earlier work there was a tendency to be conservative in the selection of parameters, and of course, the degree of conservatism would increase rather substantially as you went down each of the models between the lung model, the systemic model and so forth.

The newer efforts clearly recognize that these models are going to be used in different manners, and so there really is an effort to become realistic in the dose estimates, and I think with

respect to the dosimetry, my own little area, that's one of the virtues where data and newer work-up is. It's the realistic treatment of exposures as best we can.

CHAIRMAN RYAN: The other thing I heard you talk about which I'd ask you to talk a bit about again is the modeling for an adult, an adolescent, and an infant or a child. I think that's an interesting area where there probably has been some improvement in the representativeness, I guess is the best word, of models for a particular exposed group or individual.

DR. ECKERMAN: Well, that development of the age specific dosimetry, of course, provided a lot of new directions in the whole modeling process because prior to that the models were largely really constructed just as curve-fits to observations on workers.

And the details with regard, say, to how the material is moving within the body and the length between the excretion routes that are important with respect to bioassay and internal dose was largely -- was very tenuous at best.

And so as the issue changed to dealing with age, it was necessary, of course, to apply to a larger body of information than what we had with

respect to just looking at workers, and that brought in the physiological information.

And I think that's been imbedding, trying to imbed that work-up. It has been very important with respect to treating long-lived radionuclides like your actinides, which intake is as a child, but it would be with the individual through the course of his life, and how that radionuclide moves within the skeletal system and is eliminated from the body, it's very important to accommodate that in the evaluation doses.

So the age consideration provided a considerable stimulus for improving this whole approach to modeling, and with respect to the benefit to the worker population is, of course, that there now is an explicit interaction between routes of excretion and the material within the body that's defining the doses to the various tissues of the body.

So that has provided, I think, a considerable benefit to both the occupational consideration as well as --

CHAIRMAN RYAN: So we're really talking about both anatomical and physiologic reality in the modeling.

DR. ECKERMAN: Yes, yes.

CHAIRMAN RYAN: Okay. Thanks.

Jim, do you have any questions? Any other questions from ACRS members?

I guess at this point what I'd suggest is that we're probably at a point where we could take our scheduled break, which we sort of passed through having missed a speaker. Why don't we return here at 11 o'clock rather than 11:15, and we'll have time on the agenda for public comments prior to our lunch break.

If there are no other questions from staff or other members, we'll proceed to a break.

Thank you. We'll see you all at 11 o'clock.

(Whereupon, the foregoing matter went off the record at 11:25 a.m. and went back on the record at 11:08 a.m.)

CHAIRMAN RYAN: Folks, if we could come back to order, please.

I've been asked by our reporter over in the far corner if you speak, please speak directly into the microphone. For the individual presenters, it's probably hard to look at your slides and continue to do that. So there's a lapel mic right there in front of Mike Boyd. If the speaker would use that

while you're giving your presentation, that would be most helpful, and I'd ask others at the panel tables to speak directly into the microphone and also for those in the audience the same. Unlike the room upstairs, these are pretty localized microphones, and it would surely help the reporter if we accommodate that need.

Thank you.

That being said, we are at the point on presentations for any public comments, perhaps questions from members of the audience. If anyone has a question or comment that they'd like to make at this point, I'd ask you to find a microphone to identify yourself and your affiliation.

MR. ANDERSEN: Yeah, I have a question, I guess, ostensibly for --

CHAIRMAN RYAN: Tell us who you are and who you're with.

MR. ANDERSEN: Oh, sorry about that. Ralph Andersen, Nuclear Energy Institute.

Starting perhaps with you, Don, I wonder if you could elaborate just a little more on this distinction between dose limits and dose constrains. I understand how they're intended to be applied, but I'm trying to rationalize in my own mind the meaning

of a dose limit in terms of protection and safety versus the meaning of a dose constraint in terms of protection and safety.

DR. COOL: Okay. ICRP's use of limit as an all source to a single individual and constrained as a single source to an individual, they've drawn a distinction simply based on whether they're dealing with a single source or whether there's all sources.

When we move to what we have to do as NRC, what you as one of your operators out of NEI, for the most part you're actually working with what ICRP would term as constraints. You have a particular source or a set of sources, small set of sources, that you're controlling and you're looking at the exposure to each of the individuals trying to provide specific protection.

ICRP would suggest that you are dealing with a constraint, assuring that that individual is receiving the acceptable protection and then designing your optimization ALARA dose reduction programs within that constraint to further reduce their exposure.

One of the debates going on last week in Beijing, in fact, was as whether or not ICRP has broadened the word "constraint," it actually became limit in the legal reference of the term. That is a

distinction that ICRP has not made, but which we will likely have to make because we, NRC, other regulatory agencies, when we use the word Limit, we're using it in a legal sense, a boundary which enforcement action is going to take place.

ICRP's use of constraint as a boundary for providing particular protection and where some action is supposed to happen, doesn't differentiate whether that action is a criminal or civil sanction or something like that, or whether the action is you have to go back in and re-review the situation or institute a new particular piece of plan or otherwise.

I think they actually would intend that it applied to both of those situations, keeping it generic, that it simply means that you have to take an action, whatever action the operator or the regulator, depending on who set the constraint, set for that particular boundary.

I don't know whether that helps you, but ICRPs, in fact, try to stay away from what a regulator might decide to do in terms of setting a hard line for an enforcement action and what a regulatory might want an operator to do in setting softer lines programmatically within different pieces of their program, each of those functions the same way.

They are a constraint. They deal with an individual and a source, and it's a boundary below which they're implementing their ALARA optimization program.

MR. ANDERSEN: Ralph Andersen, NEI.

Yeah, I'll just follow onto that to reinforce that I think you captured my question exactly. In NRC or Atomic Energy Act legal terms, it creates a quandary for me as to what constitutes an adequate level of protection. If you've got a 20 millisievert per year constraint and up to a 50 millisievert per year limit, I have a hard time reconciling what's the real safe level.

DR. COOL: I guess I would simply reflect that's a good question because, in fact, in the draft recommendations ICRP is continuing to endorse the limits from Publication 60, which for occupational exposure is expressed as ten millisieverts over five years with a maximum of five in any year.

So one way of interpreting that could certainly be that a maximum of five so long as people are floating along in the vicinity of two or less would meet their definition of limit.

There hasn't been a lot of elaboration with regard to how they might play different sources,

whether that's all of the plants that the workers might jump to in an outage year, you know, spring outage for two plants, fall outage work, two plants.

Of course from our standpoint we still regard that that individual because we're going to track them around is going to have to be within the limit. So, in fact, it's difficult for me to understand why that doesn't, when you get down to the real practical reality, meet their sort of minimum definition.

Now, one possible interpretation, the Don Cool interpretation only, is that you could take those sorts of limitation values and separately you could establish operator specific constraints within that two or less for your particular program. Every time you go through an outage, you set up goals and specific goals for each of the individual actions that you take.

All of those fit in within a structured system of a limit with constraints underneath it to make sure you don't get to that, and trying to optimize below that, and the system would still be coherent.

MR. ANDERSEN: Ralph Andersen, NEI.

More of a comment than a question, but

just for the benefit of those who aren't aware of that, in the NRC staff's efforts to begin putting together a new licensing framework for new reactors, I just want to point out that potential exposure plays a very dominant role in the framework that they're constructing. You should be aware of that.

There was a presentation, a public meeting, last month, I believe, by the research folks that are working on the new licensing framework, and it hinges almost entirely on the concept of potential exposure which is new.

The reason I call it to your attention is because in essence, ICRP points out that their discussion of potential exposure actually excludes consideration of the reactors and large facilities because of other factors that need to be considered that they really don't take into account.

But I did want to just call that to the committee's attention in terms of formulating a report or comments, that that becomes very important in regulatory space in the future.

CHAIRMAN RYAN: If I may just pick up on that and ask some of the panel members [inaudible due to NRC audio system failure]. I'm going to ask John Garrick's "so what" question.

What's different about having a dose limit? An ALARA requirement to optimize [inaudible due to NRC audio system failure] versus this what seems to me to be this kind of more complicated scheme of constraints and limits and optimization and then we've got folded onto that these low and high levels of concern based on different dose levels and, you know, putting aside, for example, the worker numbers a little bit different even though we've got the average over five years and all of that.

What do we gain or lose in radiation protection practice, I guess is my basic question, and I ask that question in two frameworks. One is for protection of workers in the workplace. Two is for protection of members of the public in the environmental facilities.

You know, I struggle in that arena, for example, in the difference between a limit and a constraint, given that not too many folks probably are exposed to more than one significant source if we leave radon and medical exposure aside.

So the "so what" question is: are we gaining anything by considering these new recommendations in terms of the fundamental radiation protection practice and safety of workers in the

public?

That's a $64,000 question, I think, but --

DR. COOL: I think you've under valued the question, and I think the pragmatic answer is not much. There's a clear recognition that radiation protection programs around the world are functioning, do seem to be providing the appropriate protection.

They are not, in fact, advertising these as numerically different changes from the recommendations that they made in 1990 in Publication 60. Numerically they're exactly the same.

They are not advertising that this is a significant increase in protection. They're advertising it as a simplification.

Now, you could put up a nice question mark behind that, and that I suppose depends on which side you're viewing it from. They would suggest to you that they've left limits in because so many people like the word "limit."

But the reality is that everybody operates with whatever word you want to use in what they call a constrained system. It's a constraint, you've set a boundary. You've given some legal or less than legal implication of that boundary, and you've constructed an optimization process below the

additional protection that can be afforded under the circumstances, period, end of discussion.

In the occupational realm, they've provided a bit of flexibility because people can bump into several different sources. In the public exposure, the maximum constraint and the public limits are exactly the same because there are a lot of circumstances where you have one dominant source, and that's the end of the discussion.

CHAIRMAN RYAN: Dr. Holahan.

DR. HOLAHAN: If I might just add briefly to that, this is a question that the Commission is going to be asking of the staff and the various advisory committees once this document has gone final because for us to do rulemaking, and that's implementing either Publication 60 or the recommendations of 2005.

For us to change Part 20 is going to require rulemaking, and we're going to have to demonstrate some sort of increased health and safety benefit to justify making that change. Basically it comes into backfit space.

And if we can't demonstrate that by adopting the new recommendations or the new methodology that will significantly improve public

health and safety, we're going to run into some significant problems with implementing any of this.

So I would ask that as these recommendations come forward, as new documents come forward, whether they be the BEIR VII report that will be available next year or other documentation, we're going to be looking to not only the staff, but the advisory committees to help us answer that "so what" question.

CHAIRMAN RYAN: That's why we're all here, Vince. We're happy to help consider it and evaluate some of these proposals, and think about that question. That's kind of why I asked it. [inaudible due to NRC audio system failure]

Any other questions or comments? Yes, Ralph.

MR. ANDERSEN: On another topic, I was very interested in Keith's presentation especially on gender specific issues, and just for any or all of you, it occurs to me that this divergence between our current U.S. legal/regulatory framework and our understanding of differences between sexes and radiation protection terms is going to create a problem, but do I have that right?

I believe that legally the regulatory

agencies are obligated to be gender neutral, and yet it appears to me that this most recent set of recommendations will highlight increasingly significant differences in terms of effects from radiation between sexes.

Is there really an issue there?

DR. COOL: I think the shortest answer is there could be. I believe at the moment you still have averaging other coefficients, and there hasn't been identified some other things, but you can see the potentials on the horizon.

Of course, as good regulatory agencies we could always default to the most conservative of the two. I was expecting the reaction, the visceral reaction that I just saw there.

But in fact, that is one of the questions. If you get to separate dose coefficients in the modeling for males and females, then you start to run into a whole new set of issues that we have not had to identify, and keeping in mind that in the broader scheme of things, while NRC is looking at byproduct materials, that it becomes an enormous issue because when you get like Ed has, the PET and the X-ray and everything else, you've got a work force which is, in fact, more than 50 percent female in its totality and

occupational exposure.

DR. POWERS: I mean there has always been a gender differential, and it causes operational difficulties and liability challenges that management just simply has to confront. So, I mean, I guess the answer is that if it came back with a set of regulations that were not gender neutral you would not be adding to the difficulties that already exist.

CHAIRMAN RYAN: One caution that I have in this area is that -- and I appreciate, for example [inaudible due to NRC audio system failure] -- I'll accept Thyroid might be different than the others, but I'm looking at other numbers ranging from .74 to 1.4. I'm going to guess they're all the same to within a certain analysis that can provide the questions.

The questions general differences I would say you know, have to be, should be evaluated in terms of a very rigorous treatment of uncertainty. Without that you're really maybe guilty of what I call numerical narcosis. You're just kind of convincing yourself the numbers are something when they might not be.

Is that a fair summary, Keith?

DR. ECKERMAN: Yes, and in fact, you know, I had mentioned that little factor of three kind of

consideration I had in the back of my mind, and that's what I was looking at in those numbers.

The other thing that one has to bear in mind is it's also a question of normalization. For example, if you looked at those numbers and changed it back to air concentration and then brought in the difference in the air intake rate, the breathing rate, some of that would disappear again.

And let me make sure also to carefully quantify those numbers that I showed you. Those were based on weighting factors averaged over the population. So if you looked at weighting factors or detriment factors that were only for the working population, things would look a little different in this calculation.

So except that ICRP, of course, in the past record has only come out with one set of weighting factors that were averaged over our entire population.

If they did some more work with respect to just workers and separated them from the population of all ages, things would look a little different as well.

So there's a lot of other issues to dig into those numbers that I showed you to look and

consider, and gender has always been one of them. Actually there are differences in the risk and the distribution of the risk across the gender.

CHAIRMAN RYAN: I guess the question that I have is when you think about gender differences, think about age differences, health status differences and other things, you could think about all of those as having an impact on one group versus another, whether it's male-female, old-young, sick-not so sick, smokers, nonsmokers, whatever you want to think about.

And I guess some of that -- correct me if I'm wrong -- kind of falls out in the epidemiology, and I think looking ahead to BEIR 7, we'll probably see some updates on those kinds of comments.

But I'm very cautious to try and interpret any one of these factors as being meaningful enough to require us to do something different in standards until you've really got the details of the uncertainty analysis and the underlying physiologic and epidemiologic issues backing it up.

Is my view fair?

DR. ECKERMAN: That's fair, and I think this is all part of that transparent process that needs to be looked at and vetted out and said.

CHAIRMAN RYAN: Okay. Thanks.

Other questions or comments?

Going once, going twice?

Well, again, we're just about at the end of our short session. Are there any questions or comments on the panel?

Dana. Lean into that microphone, sir.

DR. POWERS: Yeah.

CHAIRMAN RYAN: Thank you.

DR. POWERS: The statement was made that modification of the regulations would require rulemaking, and absolutely true, but one option that the Commission has been utilizing a lot lately to get around the question of cost benefit has been to make changes that are voluntary in nature. That is, a licensee can choose to adopt them or not, and in which case they get around the demonstration of benefit for the changes.

Has that been given consideration here?

DR. COOL: At this moment that answer is, I think, too soon to tell. Formerly with the Commission at this moment, the staff several years ago went up with several options for whether to start proceeding down a line or not.

The Commission asked us to formally wait until the ICRP recommendations were in place and then

come bring them some proposals. That's the mode that we're in at this moment.

I am expecting that the staff will be offering the Commission comments to send to ICRP on these recommendations. Once the recommendations are in place, we'll be offering them some options and recommendations for how to start proceeding.

We will have to look at that. From a historical perspective, that was one of the questions at the time that the revision of Part 20 happened in the late 1980s, which also had a bit of difficulty because we were talking about the basic standards for radiation protection. We were talking about something that was of the highest compatibility order in order to have consistent regulations across the country.

And while it has been too long for me to remember the details, there were a lot of difficulties in envisioning that different licensees could be using different sets of dose limits and standards and factors that it would be nearly impossible to try and manage a wide diversity.

The reality is we've crawled into that just a little bit by granting licensees permission to use more recent metabolic models and dosimetric information on a case-by-case basis. That hasn't

gotten too difficult because the only people who really want to use it are the folks who are dealing in uranium and thorium and a few of the radionuclides for where there was a substantial change.

A voluntary set of things will have to be looked at very carefully because there are a whole series of factors that will go into it.

DR. POWERS: Well, I understand that we certainly are getting a wide range of licensee responses and things like fire protection, perhaps in 5046 the basic reactor design basis accident. I mean, this does seem to be a trend, and it's usually based on using risk and rather than hard and fast constraints as your metric.

And you may well be moving in that direction here as well. It makes your life difficult.

CHAIRMAN RYAN: Yes, Dr. Vetter.

DR. VETTER: Rich Vetter from the Mayo Clinic.

I just wanted to make a point about adopting these and what the impact would be. Relative to adopting the limit of two U.S. units rems per year versus five, less than one percent of our monitored workers receive more than two rem. Every one of them, every one of those individuals is involved in life

saving activities every day. They work in cardiac labs, et cetera. They get high doses because that's the nature of their work.

It would be very, very complicated to try to do something about that because obviously the risk-benefit there for society is huge on the benefit side even though these workers are getting more than two rem per year. And this is at an academic medical center where we can rotate around a little bit.

At a community hospital where you don't have that option, I expect that would be extremely problematic.

CHAIRMAN RYAN: Thank you.

Other comments?

I would advise on two points. One is the Center for Nuclear Waste Research is on the phone. Welcome to San Antonio.

And with that said, I'm not going to move any talks forward because I'm trying to stay pretty faithfully to the schedule so that folks who had planned to participate or attend a particular session based on the public agenda will be able to do so.

So, yes, more questions or comment?

MS. FAIROBENT: Yeah, Lynne Fairobent with the American Association of Physicists in Medicine.

I just want to change the focus a little bit differently. We're all talking here today about the draft ICRP recommendations and how those might be implemented into the U.S. regulatory system in the future, but I know that NCRP is holding off on their action until the ICRP drafts, and I know that some of their stuff contained in the draft ICRP recommendations may, in fact, and is inconsistent with some of the NCRP recommendations.

And I just wondered if the staff could or some of the NCRP members who are here on the panel could talk to where the NCRP process is and also how the staff might resolve deciding which way to go with an ICRP recommendation over NCRP where they are contradictory.

For example, NCRC Commentary 111 versus the caregivers recommendation in the draft ICRP recommendation is an example in the medical end I'm thinking about.

CHAIRMAN RYAN: Care to respond?

DR. VETTER: Well, to the best of my knowledge, NCRP is waiting for BIER VII before they decide what to do with 116. That's their basic recommendations.

And Commentary 11 deals with treatment of

members of the public as caregivers, and I'll be making a few comments about that during my presentation.

CHAIRMAN RYAN: We'll cover that area, I think, a little bit more fully this afternoon.

And, again, looking ahead, we'll have Vince Holahan, Mike Boyd, Ed Bailey, and Rich Vetter this afternoon talking about various aspects in the EPA, the medical community, and again, the staff views on some of these other techniques.

And of course, Ed with his musical computer over there.

(Laughter.)

CHAIRMAN RYAN: Having just all kinds of fun. That's all right.

And, of course, Ed representing the agreement states' view, certainly the recipients of any changes in NRC regulations across the country.

With that being said, we'll adjourn until 1:00 p.m., and we'll start promptly at 1:00 p.m. Thank you all for your time and attention this morning.

(Whereupon, at 11:37 a.m., the meeting was recessed for lunch, to reconvene at 1:00 p.m., the same day.)

CHAIRMAN RYAN: We'll go ahead and get started if we can, please. We're going to consider now individual protection (selection of constraints) and we have several presentations, of course, this afternoon, starting first with NRC Member Vince Holahan.

Vince, welcome and thank you for being with us.

DR. HOLAHAN: Well, good afternoon. When I was putting the slides together, obviously it was in the vortex of not knowing what everyone else was going to be presenting, so you'll see a number of duplications and if that's not bad enough I was looking at some of the presentations that will be following mine and they seem to be using similar presentation slides. So we'll tend to move through them fairly quickly.

One of the things that Neil Coleman asked me to do several weeks ago is to highlight some of the changes, if you will, between Part 20 and where the 2005 recommendations are. Although we won't directly address it, we'll kind of nibble around the fringes, if you will, of the so what question.

If we had the second slide --

(Slide change.)

DR. HOLAHAN: One of the things that the ICRP reports that it wants to do is review science and technology on a periodic basis, looking for changes that might drive new recommendations, keeping in mind that they want to maintain the best safety culture as possible.

They also recognize that they want to maintain as best as possible stability in our regulatory system. As you're aware, the adaptation or adoption of the ICRP 60 recommendations by many of the European Community countries was rather traumatic and expensive. Needless to say, they are not looking for major changes and with that said, Roger Clarke has said that the recommendations that we're discussing today are meant to be evolutionary in nature and not revolutionary. That's probably an appropriate statement from the context if you're moving from the ICRP 60 recommendations to the 2005 recommendations, but not necessarily so if we're talking about Part 20.

One of the major highlights that is of interest here is the fact that they stated that they are not changing the recommendations on limits in Part 60. And for all intents and purposes, that's true.

But one of the new things that has been brought in is the concept of constraint. And as we

middled around this morning, really constraint isn't particularly new to the NRC. We have taken many of our dose limits and parsed them, if you will, so that we have source constraints.

Dr. Eckerman mentioned very briefly this morning that the radiation weighting factors and the tissue weighting factors have been modified slightly. Unfortunately, we can't get into the nuts and bolts of the tissue weighting factors because quite frankly, that's in one of the foundation documents we haven't seen. Hopefully, that foundation document will be made available as soon as possible because my understand is is that this document is over a thousand pages in length.

We've also mentioned that the nominal risk coefficients have been revised slightly. And again, these risk coefficients can be found in the data that's contained in one of the annexes at the end of the document and again, it's based on that foundation information that we don't have a chance to look at.

What I find interesting though is when we looked at those nominal risk coefficient numbers, the mortality numbers have decreased. And the reason the mortality numbers have decreased are because of improvements in cancer treatment and improvements in

detection.

And the issue that I will be looking at when we get into the foundation documents is what is that really based upon? Is that a number that we can apply globally? Is it a number that's most apropos for the U.S.? Quite frankly, I don't have an answer at this time.

(Slide change.)

DR. HOLAHAN:

So if you were to look at slide 5, it's what we call the exposure limits. And what I've tried to do is capture for you very briefly where we are in ICRP 26 which was published in 1977; the 1990 recommendations, as reflected in 60, the current draft recommendations of 2005, and part 20, keeping in mind that most of the numbers under part 20 were adopted in 1991. The Federal Register notice was March of that date.

As you see for occupational, we're looking at 5 rem in part 26 which is where we are currently today. That 5 rem number was justified originally based on risk, the annual risk of death due to exposure and it was a number that was to be comparable with other heavy industry type jobs, keeping in mind the number that was derived here, also took ALARA into

consideration.

During the 1980s, if you will, mortality among the heavy industries actually decreased below 10^{-4} per year. And the new numbers that we saw in 1990 were reduced accordingly. We've heard that that number was essentially 10 rem or 100 millisieverts for a 5-year period, giving us an average of 20 millisieverts or 2 rem per year on average over that 5-year period, keeping in mind that in any one year, we can have a 5 rem exposure.

Those numbers are also contained in the 2005 recommendation.

The impact of that number and where we are today I'll go over in just a couple of slides. If we look at the public numbers, ICRP 26 recommended 500 millirem or 5 millisievert to members of the public. In 1990, the recommendations in ICRP 60 reduced that to 100 millirem and that was actually a number that the NRC considered when it was revising at the last minute, if you will, part 20. And those were numbers that were, in fact, adopted. So we are, in fact, in compliance there.

Fetal numbers have changed. This is particularly important for the occupational worker. Dr. Vetter will actually go into a couple of slides in

his presentation, but you can see there has been a gradual reduction in the fetal exposure for that occupational worker.

In 1990, the recommendation from ICRP was 200 millirem to the surface of the abdomen during the remainder of the duration of the pregnancy. The current recommendation has reduced that to 100 millirem. Today, NRC with part 20 is at 500. Dr. Vetter, as I say, will talk about the implications of that change.

CHAIRMAN RYAN: Just a quick clarification, Vince, just so people recognize what you're talking about. It says exposure limits and that would be term of the pregnancy.

DR. HOLAHAN: That would be the term of the pregnancy.

CHAIRMAN RYAN: I want to make sure everybody

--

DR. HOLAHAN: That's correct. Medical caregivers is actually a new category. It wasn't addressed in 1977. It was briefly addressed in paragraph 194 of the 1990 recommendations, but no limit was described. And today, we actually have some quantification as we'll see in my next -- actually,

it's on this one right here.

CHAIRMAN RYAN: Could you leave that previous slide, Vince?

DR. HOLAHAN: No, I haven't left it yet.

CHAIRMAN RYAN: I'm sorry.

DR. HOLAHAN: I haven't left it yet.

CHAIRMAN RYAN: Okay. I was just going to ask you, could you help us understand the last two columns in terms of definition of a medical caregiver?

DR. HOLAHAN: Medical caregiver would be that family member that is providing comfort to a patient during their treatment. This is not an occupational exposure per se. As Dr. Cool had alluded to, if my daughter, your spouse, significant other, family member were to receive a procedure and you wanted to be with them during the course of that procedure, you would be allowed to exceed the public dose limit of one millisievert per year.

Part 20 is now 500 millirem, 5 millisievert. We were aware at the time of the NCRP's commentary. That commentary actually suggested that we consider a 5 rem exposure, essentially making the caregiver the same as an occupational worker, receiving training, receiving monitoring at the time. That was actually in a petition; we were developing

our rulemaking, one of the courses of action we considered. But the Commission selected to 500 millirem dose limit as to where we are today.

With the 2005 recommendations, it is suggested that the caregivers be allowed to receive in any occasion several hundreds of millirem per treatment with a maximum constraint, if you will, of 2 rem per year.

CHAIRMAN RYAN: Let me just kind of understand the details here. That, to me, is an interesting difference. Two rem is the annual limit versus an occasional limit of hundreds of millirem itself. At some point, caregiving becomes more of an occupation than anything else if it's multiple years, for example. Where does a holder fit into this? A family member is asked to participate and somebody holding that child, for example, during an x-ray or some other -- I'm just asking, maybe now or later. I'm just trying to probe some of the realities here.

DR. VETTER: Well, the last question, a holder?

CHAIRMAN RYAN: Yes.

DR. VETTER: Their exposure is minimal. It's very, very low because they're given an apron. They're not in the beam. They're simply holding the

child. The beam is all focused on the child, so they get some scatter. It would be very minimal.

CHAIRMAN RYAN: But they'd be in a caregiver category?

DR. VETTER: No, they're not. They're not talked about in the recommendations in that regard.

CHAIRMAN RYAN: Okay. But some states do talk about holders or others that participate, so I would just offer that as something that that's a distinction we ought to figure out. Don't step on that.

DR. VETTER: They're simply not talked about in these recommendations.

CHAIRMAN RYAN: Right.

DR. VETTER: But it's a common practice in medicine that a parent would hold a child if the child, if that was better than restraining a child in some way.

CHAIRMAN RYAN: Right.

DR. VETTER: But the parent is given instructions. They're given a lead apron and there have been a number of studies that show their exposure is minimal.

CHAIRMAN RYAN: Oh sure. That's not my point. My point is it would be, I think, incorrect to move

them into the caregiver category where there's now an applied dose limit, for example.

DR. VETTER: I follow. Yes, I agree.

CHAIRMAN RYAN: Right.

DR. HOLAHAN: Next slide, please?

(Slide change.)

DR. HOLAHAN: We have seen this slide on the maximum constraints already. I'll point out that there are three categories of maximum constraint, not four.

Mr. Mike Boyd will be discussing environmental and emergency aspects here in just a few minutes. Again, we see the maximum constraint of the 20 millisieverts here, specifically identifying caregivers in this category, again keeping in mind these are for all intents and purposes are same as our occupational exposures where we have direct benefit to the individual.

Our normal situations here, we're talking about members of the public. Again, a societal impact, but not necessary any direct benefits to the individual. And really, what's interesting is this last category here, the minimal constraint value. This is a number that has not existed for us in the Agency. We do not have a below regulatory concern

number, if you will.

What's also interesting in this number is it's also tied into those exemption numbers that we see and that's important from the standpoint that if you're below that particular exemption number, the ICRP does not consider that product or source of material to be radioactive. That's brand new. We've never seen a statement like that.

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(Slide change.)

DR. HOLAHAN: Continuing with some of the exposure limits, just to be complete. Here are some of the organ and tissue numbers. We can see for both occupational and public, the ICRP numbers are here. For the most part, part 20 tends to mirror those. But in ICRP 60 and the 2005 recommendations, we don't have an organ number any more. The reason for that is is with the weighting factors, the belief is if you can control or stochastic effects, you won't have tissue reactions or in this case deterministic effect.

One of the areas that will mostly comment on is this issue the skin dose being averaged over one centimeter, as opposed to what we're looking at 10 centimeters and it deals with the hot particle issue.

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(Slide change.)

DR. HOLAHAN: Well, what are some of the potential implications that we're looking at? Well, as I've indicated previously, the new recommendations are not as evolutionary for us as they are potentially revolutionary.

Yes, there's been some new biological material or information that's been considered, but there have been a number of publications that have been published since 1990. If you will, we're dealing with a new respiratory tract model that was in Publication 66. We have new radiation weighting factors. That's in Publication 92. New conversion coefficients for external exposure, Publication 74. We have a new reference man, if you will. We have new anatomical and physiological data, Publication 70. We have age-dependent dose coefficients for ingestion and inhalation. These are in Publications 67, 68, 69, 71, 72.

As Dr. Eckerman mentioned, the ICRP has out for comment a new human alimentary tract model. So we're talking about some significant changes the way dose is to be assessed and how effective dose is to be calculated.

I guess the question would be is what are

we going to do next?

CHAIRMAN RYAN: Just before you get there, one clarification on your slide is dose assessment methodology, just to be specific, you mean internal assessment from intakes?

DR. HOLAHAN: Yes.

CHAIRMAN RYAN: And then second, currently most of those things that I see are really not cast so much in regulation of 10 CFR somewhere as they are in implementation guidance, reg guides and NUREGs, a document to that sort. Is that a fair assessment on my part?

DR. HOLAHAN: Right now we have portions of it that are in part 20, radiation weighting factors --

CHAIRMAN RYAN: Weighting factors and the neutron quality factor.

DR. HOLAHAN: All of that is there and that basically ties us to ICRP 30.

CHAIRMAN RYAN: Right.

DR. HOLAHAN: And the methodology there. Ideally, one of the courses of action that the Commission might consider is pulling much of that information out of part 20, leaving dose limits there and put the implementation into regulatory guidance.

CHAIRMAN RYAN: But the things you've listed here, that's the only piece that's actually in there at the moment.

DR. HOLAHAN: Correct.

CHAIRMAN RYAN: Okay.

DR. HOLAHAN: So the question might be is what is the NRC planning to do? Right now, the staff is going through the recommendations. We'll be going through the foundation documents as they become available. We will be developing a list of comments for the Commission's consideration and we plan on transmitting them to ICRP by the end of the year. Clearly, we're hoping to look at any input that this Committee has, the ACMUI Committee has and the ACRS to make sure we're consistent.

We're very much interested right now in the information that you're going to be providing to the Commission, also to know if you plan on just sending that up or coordinating that with the staff.

In addition to that, as Mike will be discussing in a few minutes, we have the Federal Guidance Subcommittee where the federal agencies will also be looking at these draft recommendations and the foundation documents to make sure that we're in concert with some of our core recommendations, at

least the general recommendations.

Finally, we have an opportunity through the Nuclear Energy Agency Expert Group, to provide comments to the ICRP next year. In addition to that, we have a number of activities that we'll be looking at. First of all, we know that as far as other information, BEIR VII, should actually be published before these recommendations are finalized.

The time line that we're looking at right now with BEIR VII, Biological Effects of Ionizing Radiation is that should be going to report review within the next one to two months and we're hoping that it should be available as a final report no later than June of next year.

Dr. Ryan, you had mentioned that there were some difficulties in the basic biology in terms of bystander effects and genomics instability. Well, these are issues that DOE is also looking at. They are funding to the tune of almost $20 million a year. basic scientists to look at these issues. Both are topics that UNSCEAR will be looking at. Both are topics that we ask the National Academies to look at and quite frankly, there is no resolution on those issues today.

Once these documents are in, the

recommendations are finalized, the staff will then have to look at the so what issue. What are the regulatory options available to us, what are the costs associated with them? Based on that, the staff will be making recommendations to the Commission as to what they should do, whether they should go forward with rulemaking or not.

With this in mind, next slide.

(Slide change.)

DR. HOLAHAN: Shortly after the 1990 recommendations were published, we went through one of these type of drills. We had Brookhaven conduct a study where they looked at the impact of reduced dose limits on NRC licensed activities and asked them to identify major issues on the implementation of both ICRP and NCRP dose limit recommendation and this is an example of some of the bullets that came out of that report and because of the number of individuals involved and licensees involved, I picked the commercial power reactor section.

Now in 1995, they predicted that they had to implement a 25 millisievert annual exposure limit. It cost the licensees several million dollars per plant in capital costs, maybe half a million dollars per plant in annual costs. They projected an increase

in the collective dose of their work force, anywhere from 2 to 100 percent.

They would spread that elective dose among more workers, recognizing that these skilled craft workers were in short supply and that there was an implication that it might actually adversely impact safety at these plants.

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(Slide change.)

DR. HOLAHAN: So with that in mind what has actually happened? What I'm presenting here is some data that comes from our radiation exposure information reporting system data. We publish data annual for five different classes of workers. Here I've used 1989 as the base year. That would have been pre-ICRP 60 data. I've also included 2003 data. This is data that should be on our public website within the next couple of weeks. This is the newest data that we have available.

You can see in the two years there's been about a 10 percent reduction in the number of plants that have been on-line. If we look in the middle here, the number of workers with measurable exposures has decreased by approximately one third. But rather than a 2 to 100 percent increase in collective dose,

we see almost a two-thirds decrease. And if we look at the measurable TEDE or exposed worker, in fact, you see a one third reduction.

Currently, with the 5 rem occupational dose limit, if we had an administrative dose limit of let's say four rem, 1989, 11 workers exceeded that limit. The last reporting year, we actually had zero.

If we look at the 2 rem 20 millisievert exposure, approximately 1400 workers that exceeded that limit or that exposure in any particular year. These 11 are captured in the 1400. What we find is it's been reduced down to about 37.

This again is out of over 100,000 workers.

With the administrative limit, let's say it's 80 percent of some 2 rem, you can see approximately 10,000 workers that exceeded one rem, 1989 and today, those numbers are reduced tenfold.

Now this wasn't accomplished based on any requirements set upon industry by NRC. These were initiatives industry took themselves, looking for better practices, trying to reduce dose wherever possible.

Next slide, please.

(Slide change.)

DR. HOLAHAN: This is more of a comparison

and contrast type of situation where we're looking at radiographers. Same time periods. We have about a third-thirds reduction in the number of licensees between these two periods, about a 40 percent reduction in the number of individuals with measurable exposure. But as you can see, there's only a small decrease in a total collective dose. In fact, if you look at the measurable TEDE for worker, there's been an increase. This increase has actually been incremental from year to year. So we're finding this is the worse case situation, that is, as the number of workers were decreasing, the load has essentially shifted to the remaining workers.

If we look at the same categories, the greater than 4 rem, no change; greater than 2 rem, no change. For all intents and purposes, greater than 1 rem, there's been no change. Again, even with a reduction in the number of workers that have measurable exposures, the number of licensees.

We'll find that -- again, Dr. Vetter will talk about the medical side. He can go into that. It's most likely that there will be reductions in these numbers, that the effort that's going to have to go in there will be industry-specific. Clearly, the power plants have been on the leading edge and

aggressively been trying to deal with this for at least the last 14 or 15 years, if not longer and we'll have to see if we can accomplish the same type of things with the radiography group because that, in particular, is where we got our greatest problem.

With that, why don't I close and I'll take any questions that you might have.

DR. POWERS: I think it's worth exploring when you made your point how aggressively plant operators have sought to reduce their man-rem exposures and I wonder if you have any insights on how they have gone about achieving that?

DR. HOLAHAN: One example would be, for example, the ISOE. It's an organization, an international organization. We have a North American counterpart, Canada, the U.S. and Mexico, where they literally exchange best practices. For example, replacing a piece of equipment during an outage, how do you do it? How can I do it? How can I do it in such a way that I can keep the collective dose and the individual dose as low as possible?

These plants do get together and send representatives once a year. There's a meeting during the winter down in Florida and they literally are exchanging best practices.

DR. POWERS: I think that's correct. That's certainly one of the aspects. The other aspect is an aggressive ALARA engineering review of every activity that takes place in the plant that involves possible radiation exposure. The other aspect is that the plant's create themselves or get rated by their ability to keep not only low radiation exposures, but decreasing them, man-rem exposures. It's been aggressively pursued using an ALARA type of approach.

DR. WEINER: This is a layperson's question and it's about the medical caregiver exposure doses. If 2 rem per year is okay for a medical caregiver, why not for any adult? And this is a different situation from an occupational situation. A person goes into an occupation and takes a known risk, he or she knows that there will be exposure and says okay, I'm going to do this job anyway. A medical caregiver isn't in that situation and in theory, at least, the 2 rem is protective. You don't expect anything, any adverse effect to the caregiver for allowing 2 rem. So why not the same dose for same limit, suggested limit, constraint, whatever you want to call it, for any adult?

DR. HOLAHAN: Well, clearly there is a -- using the linear non-threshold model, a theoretical

risk. But against that theoretical risk is the perceived benefit to both the patient and the psychological benefit to the individual. And now we have identified specific individuals now as opposed to a large group, ostensibly the population of the U.S., but we can't quantify or specifically identify who those individuals are and what benefit they might have.

So go ahead --

DR. WEINER: But you're not really -- isn't the prime move for any dose constraint the health and safety of the person to whom the constraint is being applied? I mean you're not really making a cost benefit decision for any individual and so -- and also if you wanted to extend the benefit argument further, you could say well, people get electricity from nuclear power plants and therefore the truck carrying the waste breaks down in front of their house, there's a benefit there too. But that's kind of a specious argument.

My point is you're not putting the caregiver at noticeable risk. I suspect that if you were, you wouldn't make that judgment. You're saying, in effect, the risk is very small and yes, there is a benefit. But the risk to the caregiver is not

substantial.

That's the driver, isn't it? The driver is really not the putative benefit to the patient or to the caregiver for being able to take care of the patient. The driver is safety, isn't it?

DR. HOLAHAN: Well, safety and acceptability of risk. And the question is is what is an acceptable risk, what's not an acceptable risk?

As we would probably discuss with Mike here, it's been basically driven by the Courts. Right now, what is acceptable risk, 10^{-4}, 10^{-6}, lifetime risk. And you can crunch the numbers and of course, our public dose limits are significantly greater than that.

But it comes down to a matter of acceptability, what I choose to be exposed to, what I choose not to be exposed to. Granted, we're exposed to risk every day. The probably greatest single risk I put myself voluntarily into is coming down Interstate 270 to and from work. I understand the risk. I've made a specific choice there. But that would be analogous to the caregiver because of that benefit.

CHAIRMAN RYAN: Ruth, let me maybe focus here on your question by asking a second question of

Dr. Vetter.

You mentioned studies have been done for such folks like holders and others. I mean I just can't imagine where too many caregivers, first of all, would get anywhere near 2 rem. Second, that the average is probably substantially less than 100 or a couple of 100. Is that a fair judgment on my part?

DR. VETTER: Yes, that's a fair assessment. In fact, in this country, we're not allowed -- the rule is basically constructed to allow us to release a patient that would result in a member of the public getting no more than 500 millirem.

CHAIRMAN RYAN: Right.

DR. VETTER: So we're not really setting a limit on individuals, but no one, no one individual can get more than 100 millirem. So in this country, no one has exceed 500 millirem to my knowledge, with the exception of a few cases where things really broke down. But that's very, very rare.

So the practice has been going on now for several years where patients are released from the hospital, radioiodine, principally. They go home and these are patients that previously had to be hospitalized for radiation protection purposes, that is, they would result in more than 100 millirem to

members of the public. But the new rule allows us to release them into the care, quotes, of a family member and they're all given instructions and in most cases these people drive home. They stay home. They're told not to be around young children. Not hold young children on the lap, that sort of thing. So that's correct. In this country, people are not being exposed to more than 500 millirem.

CHAIRMAN RYAN: Sure. Now in the case of the other example that I asked you about earlier, holders and x-ray procedures and so forth, they're not even on this radar screen, I wouldn't --

DR. VETTER: No, no. That would be a few millirem to 10s of millirem at most.

CHAIRMAN RYAN: Right.

DR. VETTER: In those cases. In this case, it's a calculation that suggests a member of the public might get up to 500 millirem and there is some conservatism in that -- I mean it's not extremely robust, but we're pretty sure that no one is going to get over 500 millirem. And in fact, there have been a number of studies in the literature, as you well know, that demonstrate that family members are not getting more than a few hundred millirem in those cases. Family members have been badged.

CHAIRMAN RYAN: Right, exactly.

DR. VETTER: Time studies done and so forth. So --

CHAIRMAN RYAN: Thank you. I guess I just wanted to say that that rem is probably not in realm with this operation and then when you get down to the 100 millirem to a couple of hundred, then we're not too far away from what is the generally acceptable standard for exposure to the public at large anyway.

DR. WEINER: Thank you. And that is a very good clarification. I guess the -- I'll just end with a comment. The thrust of my comment -- and I'm familiar with all the risk, it's more risky to drive a car and all that sort of thing.

I've had students say to me you mean I shouldn't get an x-ray? You know, what is the risk associated with x-ray, dental x-ray exposure, which everyone gets. That kind of thing. Are you running the risk in making this limit as large as it is of saying to the public on the one hand this is a risk and because there's an associated benefit, we know you're going to take the risk, and on the other hand, it isn't so risky because we say it's okay. Are you sending, is ICRP by doing this, sending basically a mixed message, because caregivers are members of the

public. This is not an occupational exposure.

CHAIRMAN RYAN: Maybe I could ask Vince or Don or both to respond on the basis of ICRP's justification of the practice. If I heard Roger Clarke right a few weeks ago, he said that the practice justified and I think that's the question you're asking, is it justified, once that determination from societal and legislative and other drivers has been determined to be justified. That ends that discussion and then it's on to what's the appropriate constraint, if I have it right.

How am I doing?

DR. COOL: I think you did pretty well there, Mike.

Answering how I think ICRP would answer it, there are a couple of pieces to the equation. First is the degree of information that the individual has in control over what their exposure might be. And in the caregiver model they're assuming that the individual has some information. In fact, the paragraph that talks about this and suggests up to 2 rem specifically includes and are informed of the risks, so that they can make some decisions and perhaps take some protective actions or at least do this in a voluntary manner. Otherwise, the

recommendation as Vince has pointed out, was several hundreds of millirem which is not all that much different from what we have already done with patient release and ostensibly, but not terribly different, from the limit that you had placed on members of the public.

If for the moment we are assuming that we are still in a model land where any increment of dose equals some increment of risk, the desire would be to improve protection if you could. That doesn't mean that things are of no risk on any point on that curve or of some risk. It depends on what your view point is.

Yes, we are schizophrenic. We would desire in a perfect world to reduce the exposure so long as we can still achieve whatever benefit there is to it. There are obviously physical limitations to that. You can't achieve the benefit of figuring out if you've got a cavity or if you've got this or that without incurring some risk. And it doesn't matter whether it was the x-ray or somebody probing you with their finger or some other implement.

And so it goes back and forth a little bit. And as a complex mixture of what do we think the mathematical risk is, which no one really understands,

and what do we think the perceived risk is and what's our degree of knowledge that layers all of that and which most likely will drive your perception and decision in any particular circumstances.

DR. WEINER: Thank you.

CHAIRMAN RYAN: We're running just a bit over time here. Let's move through the questions and get to the next presentation.

MR. CROFF: Back to Vince, going through the list of the various impacts on NRC regulations, many of which were in reg guides and this kind of things and changes made in 10 CFR 20, then went on to occupational where I guess there was some historical claims, but didn't really prove out or in another industry may not prove out occupational dose-wise, but I'm not sure about your answer to your own question. I took away that you don't think the impacts of such a change would be terribly significant. Is that a correct impression that I have?

DR. HOLAHAN: I think the staff position previously has been implementation of the new requirements will not result in a significant increase of safety. With our current dose limits in ALARA, we're already there, that there might be some minor changes, as you would say, with the radiographers, but

for all intents and purposes, if we go through this, it's going to be very difficult to demonstrate an increase in public health and safety.

MR. CROFF: But there will be some significant effort attached to a very small --

DR. HOLAHAN: Very much so.

MR. CROFF: There will be some significant costs here.

DR. HOLAHAN: And basically, it's the cost of the implementation, whether it be writing our own regulations, internal policies, with the various licensees, changes just into the dosimetry system, the way you calculate dose. Yes, it's better science, if we could make a justification on just the science, clearly, we ought to be adopting all of the new models. But I guess the question would be, I would maybe pass this over to Dr. Powers is can we get through backfit because really, we're going to have to look at what the impact is on the power plants and will there be enough benefit to justify changing the regulations?

DR. POWERS: I certainly have not looked at it in detail, but I'm willing to bet that a reasonable analogy to look at would be fire protection. We went through an enormous effort

following Appendix R to create a training effort on the part of a licensee, tremendous training effort on the part of the NRC and their inspectors, but not an established technology that be applied by the working engineer and the operational people very intuitively. They understood what they were trying to achieve, to keep one shutdown train alive at all times, even in the face of fire.

Along came a group of people at NFPA and said gee, we can do this in a much better fashion. It will save a lot of money and it will probably make the plant maybe a little safer, but it will be a lot more intuitively pleasing, a lot more well based. And the universal reaction was well, it doesn't make the plant safer and it will cost me a huge amount of money and suddenly I can do things in an intuitive basis. I have to have punitive to do it. I don't want to do it. I've already invested heavily. It's not going to improve my plant. It's not going to generate an extra kilowatt for me. It's not going to be any safer.

What they did in a regulatory space because there are some people who would like -- and there is some benefit to it. Just make it voluntary because we have this code and standards rule coming through us, international code and standards rule.

There was a willingness to do it, but just make -- avoid the cost and still make it available to those licensees that want to do it, but just make it voluntary.

I was going to look for an analogy. It will be an imperfect analogy to be sure, but it might give you some guidance on what happens at the operational level when you get these new dictums that require a change in the technology which had spent a lot to develop and especially when it's gotten very effective where people do Appendix R evaluations in their head, because you can. You just know it so well. Similarly, you do a lot of evaluations in your head. You don't really need a computer code to do that.

When you go to more complicated systems where you do need those, there's a huge training cost associated with that.

CHAIRMAN RYAN: Just to follow up real quick, Dana. I was interested in your comments earlier about -- and recognized certainly commercial nuclear power improvement in ALARA's standpoint in safety conscious work environment, work practices, best practices. It's a tremendous lot of work. And that's in spite of a regulatory change.

When you look at a much smaller category, the industrial radiographers, it begs the question to me, well, maybe they'd be better served by thinking about risk-informed practices in the radiographer world than not.

Is there some way to use the techniques of analysis and the thinking and work practices from one industry segment to another?

DR. POWERS: Well, I think it's clear that that's the job at NMSS wrestles with enormously. Let me see if I can make the translation.

Understand that when it comes to quantitating risk analyses, a power plant licensee has an organization that is composed of people very skilled at doing that.

CHAIRMAN RYAN: I understand that.

DR. POWERS: Whereas an individual radiographer may or may not have that kind of support and generating, developing that kind of support has taken us -- depending on how you measure 25 years in the power industry to develop that technology, whereas -- and we had the advantage since they were about 100 institutions working on developing one technology whereas in the individual radiographer you might well have a thousand different technologies that you'd have

to develop and you might have one to a few people working on each one of those technologies, might be certainly challenging.

CHAIRMAN RYAN: Of course, the system is much simpler, so maybe they can --

DR. POWERS: You've got that other tradeoff. I mean there are a lot of decision making mechanisms, but even at our research reactors, we have a hard time bringing the full power of risk technologies to the fore, just because the support organizations are small relative to nuclear power plants. You just can't amortize the cost over enough people to make it justifiable.

CHAIRMAN RYAN: Thank you. Without further ado, let's move to on Mike Boyd from Environmental Protection Agency for his presentation.

Mike, welcome.

MR. BOYD: It's a pleasure to be here today and talk to you a little bit about the way EPA's standards mesh or don't mesh with those proposed by the ICRP. I'm giving, first of all, first off, I'm giving this to you today and not yesterday, as my slide says the 18th. It's obviously the 19th. But I've also given you an EPA perspective, not the EPA perspective, because we are a large -- next slide --

(Slide change.)

MR. BOYD: -- decentralized agency with 10 more or less autonomous regional offices and several media-specific program offices.

May I have the next slide?

(Slide change.)

MR. BOYD: At EPA, we were formed in 1970. We were formed along media-specific program areas and at the Headquarters level we have the office that I'm in, the Office of Air and Radiation which is the -- where the Office of Radiation and Indoor Air which is the Radiation Technical Office is located. We deal with everything related to the Clean Air Act, obviously, the emission standards for hazardous air pollutants, but we also have all of the AEA authority that was transferred to EPA, that portion of the AEA authority that was transferred to EPA is within my office in OAR.

Then you have the Office of Water which sets the drinking water standards and any standard for water quality. And then the Office of Solid Waste Emergency Response which is where the overall emergency response capabilities of the Agency are centered, as well as all of the cleanups and hazardous waste management and solid waste.

So as you'll see in a minute, each of these program area offices working under different statutes sets standards a little bit differently. After that, I'm going to talk about the role of federal guidance in setting individual standards and how that comes into play. And finally, do a quick comparison of how, what we now have on the books compares with what ICRP is proposing. It's a somewhat similar approach to what Vince just gave you.

Next.

(Slide change.)

MR. BOYD: As I said under the Office of Air and Radiation, the Clean Air Act standards set emission standards for radionuclides. It's interesting. If you've read the NESHAP, the National Emission Standards for Hazardous Air Pollutants, I wasn't around, so I don't know if it was purposeful or just inadvertent, but the standards do not cover direct radiation. It's not photons. It's actually particulates. So the particulate emission standard for radionuclides from stacks is set at 10 millirems per year. This is using the ICRP 26 definition of effective dose equivalent.

And this really is what we would consider, as many standards you'll see at EPA, we would consider

this pre-optimized. This 10 millirem was determined to meet what the Clean Air Act defined as an ample margin of safety and therefore meeting that standard is sufficient without ALARA consideration.

Under the Atomic Energy Act and related statutes which do include Uranium Mill Tailings Act, the WIPP Land Withdrawal Act, the 1992 Energy Policy Act which gave us -- told us to write the standards for Yucca and various others, Nuclear Waste Policy Act, under these, EPA has set standards, generally applicable standards that again do not require ALARA.

We typically at the Agency set a number in the Office of Air and Radiation in our regulations. It's a standard that just has to be met. There's no real discussion or has not been a discussion of optimization.

Now except for WIPP where we are the regulator, most of our standards get adopted and are then enforced by either the NRC or the agreement states. And under their programs, obviously, through the NRC part 20 regulations and others, ALARA does come into play. So even though we set a standard without an ALARA attached to it, that generally, that optimization step generally gets picked up by NRC and the states.

So I would say that in my office, the AEA type and the Clear Air Act standards that we've set don't really fit the ICRP definition of a constraint in that we think that the way we right the rule is all you have to do is meet the number.

Now you move over to the Office of Water Standards, next slide.

(Slide change.)

MR. BOYD: Under the Safe Drinking Water Act, we have set what are called maximum contaminant levels, MCLs, and we've set the -- you're probably all familiar with the man-made beta and photon emitter standard which is 4 millirem a year and this is critical organ dose. This is one of those old ICRP 2 standards that's still on the books.

We have a gross alpha standard and we have limits now for radium and uranium and I guess you know the radon standard is still being promulgated and will probably be, still being promulgated for many years to come.

But the interesting thing about the Safe Drinking Water Act, the MCLs is that there's not a sum of the fractions rule for MCLs. You are just required under the Safe Drinking Water Act's standards or under our radionuclide MCLs or any of the MCLs, again, just

to meet them, but to meet them individually. So not only is the sum of the fractions rule not applied, but again, ALARA is not applied. All you have to do is meet the standard.

So under the Office of Water standards, the MCLs, I would say here, MCLs are not constraints as the ICRP would define them.

Next.

(Slide change.)

MR. BOYD: Where we do come a little closer to ICRP's thinking is in the Office of Solid Waste Emergency Response standards which have been promulgated under the CERCLA, the Superfund law. And Superfund specifically included radionuclides as covered by the law governing cleanups and sites. And the regulations that were developed at the Agency under Superfund do include an excess cancer risk range of 10^{-6} risk, one in a million excess cancers as a point of departure, a starting point. And it says that you should not exceed about 10^{-4} excess cancers for all contaminants combined for a specific site.

This is the often called bottom-up approach where we do start at 10^{-6} and then we start applying -- it's sort of reverse ALARA, but it's really ALARA, because what you're trying to do is get

to some point at or below 10^{-4}, taking into account a number of factors.

The Superfund programs uses the term "balancing criteria, you might hear. But it really is an optimization type approach. So under this scheme, I think the 10^{-4} or about 10^{-4} is probably pretty close to what the ICRP would call a constraint. It's a level that's sort of a ceiling and you really want to stay below it if you can get there and the farther below it, the closer to 10^{-6} the better, although in radionuclide cleanups, you know, you almost never see cleanups that achieve much below 10^{-4}. Background is 10^{-4}, background radium is certainly 10^{-4}. And so this is where I think under the EPA standards you'll find something similar to the ICRP's concept there.

(Slide change.)

MR. BOYD: Moving on then to the next slide, the role of federal guidance, this was a function that belonged in the days of the Atomic Energy Commission to an entity called the Federation Radiation Council which was made up of Secretaries of all of the agencies or their designees, all the agencies that had to do with using atomic energy or radionuclides or whatever. So they were a fairly powerful group and they wrote guidance that applied.

Generally, their function was "to advise the President on radiation matters, directly or indirectly affecting the public, including guidance for all federal agencies in the formulation of standards." So this is a fairly powerful authority. It hasn't been used much at all and when we try to use it it takes a long, long time.

Don and I are currently co-chairing the Federal Guidance Subcommittee of ISCOR, so we're now still trying to get out the federal guidance for the general public. But this authority does have the potential for allowing us to bring some consistency across federal agencies in the way radiation protection standards are issued.

(Slide change.)

MR. BOYD: The old issues, the next slide, the old standards, the old guidance,I'm sorry, the old guidance that's still on the books, and I'm using -- I've been trying to use the word standard. I don't know if I've been totally consistent, because I don't think that a lot of what we've done at EPA fits what you would call a limit or a constraint, so I'm just being generic there.

But in the federal guidance we have used the term limit. And in the 1960 guidance issued under

President Eisenhower, we had a public dose limit of 500 millirem and this does meet the ICRP's current definition of limit because it was from all sources to an individual, member of the public. And as far back as 1960 we acknowledged in this guidance what the ICRP is now acknowledging that you can't always know where all the sources of exposure are coming from to an individual, and in 1960 they said when all the sources of exposure are not known, then the per capita dose should not exceed 170 millirem and they also advise that individual doses should be as far below this guide as practicable.

So I think you're seeing there something like what the ICRP is calling a constraint, even as far back as 1960. But the individual limits should be some fraction of 500 and that what we now call ALARA should be applied to that number. So those -- as you know, the -- most of you I assume know the 1960 guidance for the general public is still on the books. It has, in practice, been superseded by all of the major players, the NRC, the DOE and most of the states, adopting the 100 millirem and I'm here using the traditional units just for ease of comparison.

So it's in that sense then made somewhat obsolete, but it's still an existing guidance and it

is still often referred to and is frequently to the embarrassment of the Agency. So we are trying to revise that.

(Slide change.)

MR. BOYD: In 1987, next slide, we did revise that part of the 1960 guidance that pertained to workers. In the 1987 guidance we adopted the limit which was actually, I think, to be called a constraint of 5 rem per year committed effective dose equivalent. The guidance also recommended that fetal doses and if you had a worker younger than 18, both of those should be held to 500 millirems. The 18 would be 500 millirems in a year. The fetal dose, 500 millirems during gestation.

This 1987 guidance specifically required ALARA, but what it did not do is define the way NRC's part 20 does. It did not define a radiation worker. You could read the 1987 guidance and people have read the 1987 guidance and ICRP guidance as well, too, to say that anybody can get up to 5 rem if the source of the exposure occurs while they're earning a salary, regardless of what their employer's responsibility is for the source of that dose.

In other words, if you had a flower shop sitting on top of an old TNORM site, you know, maybe

you could get 5 rems and that would be fine because that would be occupational exposure. That, I think, is being -- to use Vince's term about nibbling at the edges, I caught a few sentences or at least one in the 2005 language where the ICRP is actually talking about separating those workers who are not what NRC would call radiation workers, but are employed by, for example, a nuclear utility, and applying the public dose limit to them. Maybe a secretary in an administrative building in a nuclear power plant would not be subject to the 5 rem occupational limit.

I have to admit that if you read EPA's current federal guidance, you might draw a different conclusion. So I think there's a place where some clarification is useful and also, OSHA has raised the same issue in relation to the -- sort of the "dirty bomb" discussions, when you can let someone go back to their office after a terrorist event. Can they go back to work when their office is giving them 2 rem a year, 5 rem a year, 500 millirem a year, 100 millirem a year. So there's a lot -- there is a need, not just a perceived need, but a real need, I think, to sort of clarify what doses apply to what people under what circumstances, when it's a radiation worker and when it's just a member of the public.

Next slide.

(Slide change.)

MR. BOYD: We are working, we've been working for 15 years, I'd say on at least revising the federal guidance for the general public. We are at a point now where I think we're very, very close. We have been in discussions with the major agencies, EPA, NRC, DOE and now Homeland Security. And we're -- the current thought is that we would propose federal guidance for the general public with two options. The first option which is -- which was an initial attempt at a compromise that didn't quite work out, but we're going to leave it for the public to comment on, would be an option that doesn't specify any numbers. Instead of ICRP's sort of confusing what a public dose limit and what an individual dose constraint is and coming up with the same number for it, we wouldn't have any number. We would say that it's up to agencies in a specific situation to determine what the appropriate number would be in that situation. So there would be no limit as defined by ICRP and constraints would be pretty much site specific.

Not surprisingly, NRC and DOD and the folks at DOE could see it both ways, but there were some real concerns about not having a public dose

limit in the federal guidance. So Option 2 is now proposing in the current draft which has not gone to the Federal Register yet, but this is almost certain to stay in when it does, a proposal that would have the public dose limit set at 100 millirems which is consistent both with the 1990 ICRP and 2005 recommendations. Both of these options, 1 and 2, stress that optimization is the key to radiation protection, but we don't in either option beyond specifying public dose limit, we are not specifying any values for individual source limits or as the ICRP would say, constraints.

So the current thinking on new federal guidance is we would say that you start at 100 millirem and you apply optimization to come up with a source specific limit.

This is kind of, I guess, skipping a step because it's not setting a constraint and then doing ALARA. It's depending on how you view it. I mean you could view the 100 millirems as a limit below which you need to set a source-specific constraint or you could use the 100 millirem as the source-specific constraint. So there's some fuzziness there, I'd say still.

Finally, let's do some comparison of the

EPA standards with what ICRP is proposing. Looking now at just those four numbers, the ICRP constraint which included the constraint for emergency responders at the high end was 100 millisievert and 10 rem. The 10 rem is actually lower than what we currently have in our protective action guides which says that for life saving, you can go up to 25 rem and you can on a voluntary basis, even exceed 25 rem, but this is strictly voluntary.

I would say other than the lifesaving number being higher, the 10 rem is otherwise not inconsistent, that's sort of one of those fuzzy ways of saying it. It is mostly consistent, but it depends on how you write all of your background materials supporting it and who your first responders are and who you allow to get these kinds of numbers.

So we're a little higher there and I think the important thing to remember about emergency response is that we at EPA, and NRC as well, set limits and standards and constraints and whatever you call them, assuming particularly for workers a sort of on-going lifetime scenario where this limit isn't just something you will get this year, but it's something you will get every year that you're in the work force or might.

In an emergency response situation, you have to really think through whether that guy that gets 25 rem is going to be asked to do that a second time in his life and if this 25 rem is a one-time exposure, then maybe it's not so out of line with the 10 rem annual dose for life saving. Just an editorial aside there.

The ICRP worker constraint at 2 rem, you've already heard that our -- the federal guidance limit is 5 rem plus ALARA. That's still the number that's on the books at NRC and in the agreement states, I believe.

Next.

(Slide change.)

MR. BOYD: The -- back one, I'm sorry.

(Slide change.)

MR. BOYD: The ICRP 60 public dose limit which has not been retracted, I would say is consistent with our federal guidance for the general public option 2 which is 100 millirems. This -- if you call the 100 millirems of public dose limit, then we're consistent. But if you call the 100 millirems of source constraint, then we're probably not consistent because EPA tends to set source limits that are typically well below 100 millirems, typically

around 15 millirems down as to heard 4 millirems. Those are numbers that aren't constraints in the sense that you -- all you have to do is meet them.

CHAIRMAN RYAN: Mike, it would be helpful if you could maybe give a couple of examples of those individual source constraints.

MR. BOYD: Right. Well, I think they're not constraints again because we don't require optimization below those numbers. But source limits, if you would, --

CHAIRMAN RYAN: Sure.

MR. BOYD: -- would be the drinking water limit at 4 millirem, the high-level waste limits for -- I think WIPP and Yucca have both been at 15 millirem, if I recall correctly. So numbers that are generally --

CHAIRMAN RYAN: Would NESHAP fall into that category as well?

MR. BOYD: Yes, it's in there, exactly.

CHAIRMAN RYAN: That is one probably that affects the broader number of licensees or NRC agreement state folk.

MR. BOYD: Right. So that is where we have actually set a limit that would be if you view 100 millirem as a source constraint a little

inconsistent with where EPA would set source constraint. I am a little hesitant to use the word "constraints" again because of the fact that we generally don't require optimization below a standard.

Okay. As far as that fourth number, just as has been said, we haven't yet adopted a minimum constraint either. I think there have been a lot of discussions. We are -- is it collaborating agency? -- whatever you call it on NRC's clearance rule activities. We are working with the IAEA and others. So we are very familiar with the idea of the one millirem concept, but as yet, there has been no action at the agency to put this into guidance or rulemaking.

Finally, there is a table, which I don't really think has been referred to except briefly by Don this morning for those exclusion levels. And these are levels where if you're below, you sort of fall out of the system of radiation protection.

This last slide is basically a little exercise I did just in the last few days looking at our own regulations and comparing them to those activity concentrations.

What I found was that in most cases, what they're calling exclusion levels are below levels that we have set in our existing regulations. So it's not

going to put us in conflict for the most part in saying you're excluding something that we would otherwise regulate. But it's pretty darn close.

The second bullet here, we have a memorandum of understanding between the two agencies that we call "triggers for consultation" when the final cleanup at an NRC decommissioned site if the concentration of a radionuclide there exceeds these numbers that are in our appendix, the table that is appended to that MOU. We agree to talk about it because that means that it is slightly or on the verge of exceeding the EPA's risk range.

Well, the artificial beta/gamma exclusion level in that table works out -- it's .1 becquerels per gram. That's 2.7 picocuries per gram. If you look at that appendix, you will see quite a few radionuclides that are 3, 4, 5, 6 picocuries per gram, pretty close, 2.7. I think that niobium-94 actually is a 2. So that is sort of a sore thumb sticking out there.

So it's just worth commenting, I think, that they're setting an exclusion level that if applied to broad areas of contamination, infinite plane, infinite depth, could get you pretty close to EPA's risk range. I think the exclusion levels

typically are applied more to maybe sod materials, not large, infinite quantities of them but just wanted to bring that up.

Finally, that K-40 number just has me scratching my head because that is the 10 becquerels per gram. That is 270 picocuries per gram. I don't know where you find K-40 at those concentrations in the environment. If they were there, I don't think I would want to be there, but that is just something to try to do a little more investigation to figure out where that number came from.

That's it. If you have any questions, I'll be glad to take them.

DR. CLARKE: I do have one question, but it may not be a fair question for you, Mike, --

MR. BOYD: Okay.

DR. CLARKE: about the EPA's work within the Superfund Program.

MR. BOYD: Right.

DR. CLARKE: This morning we heard that one of the aims of the ICRP is to look at radiation protection now for non-human species, --

MR. BOYD: Right.

DR. CLARKE: -- which would require multiple issues and possibly multiple endpoints. The

EPA has developed guidance for ecological risk assessment, trying to do the same thing for hazardous chemicals, non-radionuclides. I wonder if there is anything that came out of that program to pass on here, lessons learned.

MR. BOYD: Well, lessons learned and I can also tell you where we are in regard to responding to the environmental protection issue. I think we have learned, first off, the ecological risk assessments have often, I think, and, again, in a decentralized enforcement scheme. Where you have ten different regions setting different ways that standards are enforced, you can find great variability. But I think in general, you find that ecological risk assessments have often been given short shrift, that in almost all cases, it's the human risk assessment that has driven cleanup decisions.

One example where it is sort of the flip side is that oftentimes when the human health risk assessment is marginal, maybe you should clean it up because it's right on the borderline.

You could use an ecological risk assessment to defend not cleaning up because if there aren't many people living there and you are going to destroy a sensitive habitat, then the ecological

damage from doing site remediation can be far more serious than cleaning it up to achieve a slight reduction or a slight improvement in public health.

Remediation is a messy business. You generally end up taking down trees, taking topsoil, and pretty much destroying a habitat. So I think, particularly for radionuclides, that ecological risk assessment more often than not will lead you to declare an area a wildlife preserve and not remediate it because you are hurting the species otherwise.

But, having said all of that, -- and that's editorial, too -- we are working very closely with several of the workgroups. We have just recently through the Interagency Steering Committee on Radiation Standards, ISCORS, formed a new environmental subcommittee that is going to be an interagency effort to track what the ICRP's proposing.

Before we did that, we had a little informal group, NRC, DOE, and EPA, that was doing somewhat the same thing. We have helped support the development of the RESRAD biota code, which is moving the DOE's biota dose assessment protocol into a RESRAD platform.

We think that is a pretty good dose assessment model, certainly very conservative, and

will be a useful tool. The graded approach that they are proposing and the tool that they have developed will we think prove to be quite useful in determining compliance with wherever the ICRP or IAEA end up on this.

We think -- in fact, I think that everyone in the U.S. that I have talked to among the agencies is almost certain that the only place where biota would not be being protected is where you have them exposed and man is not present in the environment, maybe in marine lakes, in ocean bottoms, or maybe in deep geologic disposal if you happen to have biota down there, but I don't think you do, but those situations where you have high doses and critters are getting it, but people aren't around. And so that is a very small subset of the biosphere, where we think we'll end up concentrating our activity.

We are not opposing the efforts. We think research is fine. We are interested in what the European Union is doing, what Canada and Sweden are doing, but we don't see ourselves embarking on a big regulatory or even guidance effort here any time in the near future and probably except for those very small subsets probably never. I may have just gone over the edge there, but that is my perception.

DR. CLARKE: Thank you. That's been my experience as well when the ecological risk assessment [Inaudible due to NRC audio system failure.] added through the balancing criteria look at the impact of the mediation [Inaudible due to NRC audio system failure.].

CHAIRMAN RYAN: Thanks. Go ahead, Ruth.

MEMBER WEINER: Your CERCLA standard is actually risk-based.

MR. BOYD: Yes.

MEMBER WEINER: Why aren't your other single source standards risk-based?

MR. BOYD: Well, I would say that they were all health-based with the exception of radon or they were mostly health-based, but many of them predate CERCLA. The original high-level waste standard, 40 CFR 191, the uranium mill tailings standards, all of those came about before CERCLA and really before the science was there to give us the ability we now have to do incidence and mortality risk assessment.

I would say most of those numbers, again, with the exception of radon had their genesis in a health-based consideration.

MEMBER WEINER: Ten millirem per year?

What is the health-based, risk-based estimate supposition or theory for ten millirem per year --

MR. BOYD: I think it was --

MEMBER WEINER: -- or 15? I mean, take any number.

MR. BOYD: Right. Well, 15, actually, using some risk numbers for external, low LET, which we had at the time we were trying to do a cleanup rule, that happened to be about where you would come out at 3 times 10^{-4}, which is about as about as we were willing to go in terms of exceeding 10^{-4}.

So that is the 15 number. The 10 I think was a separate determination that it was considered. And I don't know the history of it. There are probably others in the room who can correct me, but I know that that was meant to satisfy the court's definition of an ample margin of safety below a health-based action level.

MEMBER WEINER: I think you have just given me the answer, which is that those very small numbers are based on at some determination or some estimate of ample margin of safety.

MR. BOYD: Right.

MEMBER WEINER: That's rather than being specifically risk-based on quantitatively risk-based.

Would that be a correct assumption?

MR. BOYD: I would probably go with that, yes. I only hesitate because we do try to tie everything to a risk determination now for [Inaudible due to NRC audio system failure.] scheme of things. But certainly when the ample margin of safety rule came out, I think we were considering that to be safely below sort of the health-based action level.

MEMBER WEINER: I am just curious. How do you determine that the constraint or standard of 100 millirem per year for a member of the public from all sources has been met?

MR. BOYD: I don't know how you can do that except Mike Ryan said earlier that most people aren't likely to be exposed to more than one major source of ionizing radiation. If that is the case, you for most people, probably for 90-95 percent of that population, you can make that determination, but globally, I mean, how do you know that someone didn't -- for example, I like to use the follow the waste truck from a nuclear power plant in New York down to Barnwell, you know, tailgating the whole way.

So there are always those exceptions you can dream up, but in general, it's hard. And I think the ICRP has recognized that it is almost impossible

to assure that a public dose limit is being met. Another aspect of that is you are also dealing intentionally with different regulators, different licensees, and how do you apportion who gets what among that public dosing?

MEMBER WEINER: Then if your dose limit for the public is 100 millirem per year and you're assuming that most people are only exposed to one major source, shouldn't you rethink your single source limit somewhat? I mean, right now they are right around 10 or 15 percent of that. And if that is all a person is exposed to, you are well below 100.

MR. BOYD: I think Vince hit on this earlier. At EPA, under the current regulations that were derived from CERCLA, we have set an upper limit of the risk range. And that pretty much constrains us to the 10-15 millirem.

MEMBER WEINER: Thank you. Just very quickly [Inaudible due to NRC audio system failure.] do you consider "very conservative" the same as "pretty good"?

MR. BOYD: No.

DR. POWERS: You are really going to get in trouble answering that one.

MR. BOYD: Right.

MEMBER WEINER: Thank you.

CHAIRMAN RYAN: I can answer the Barnwell question. The drivers are actually trained to observe and make sure they are not being followed routinely. So that would be reported to the police very soon.

Mike, one last question -- and that is, it seems inherent in all that you have said that listed in everything is the linear no threshold theory that any increment of dose, even at the very small levels, like 4 millirem a year or less or whatever, are assumed to be cumulative, additive, and follow that theory. So inherent, as I read it, in the EPA standard-setting activities is this inherent I believe to be a conservatism [Inaudible due to NRC audio system failure.] recognizing that that is an assumption setting these values. Is that a fair summary?

MR. BOYD: That is fair. We do apply the dose and dose rate effectiveness factor of two that sort of cuts the slope of the curve in half, I guess.

CHAIRMAN RYAN: Right. But still, I mean, there is a conservatism still built in because you do accept --

MR. BOYD: Right.

CHAIRMAN RYAN: Did you have one last --

DR. CLARKE: A quick question. Again under Superfund, you have developed a process whereby doses can be converted to risk through cancer slope factors of radionuclides. Would there be any impact from these regulations on [Inaudible due to NRC audio system failure.]?

MR. BOYD: I think there are several things that are going to impact. Keith has worked very closely with Oak Ridge, Keith and Rich, down there on generating the slope factors.

There are several things coming. There is the BEIR VII, which will probably change the underlying risk estimates. There is every time the U.S. health statistics are updated, that changes the risk. And so we now I guess either do or are about to have 2000 numbers, so the life table analysis, the survival functions there.

The biokinetics that are used by the ICRP in generating the dose conversion. And, actually, the organ dose, I should say, will definitely be a part of what goes into any new revision of the FGR 13.

I think the new Hiroshima dosimetry, the BEIR VII, the 2000 health statistics, and the ICRP biokinetics are all going to factor in [Inaudible due to NRC audio system failure.] risk coefficients will

probably -- you know, that takes at least three years, right, Keith? There may be four or five. So we would probably be looking at as early as 2008, more likely 2010 or so before we will be updating this coefficient.

DR. CLARKE: Thank you.

CHAIRMAN RYAN: Without further ado, let's press on to Ed Bailey from CRCPD.

MR. BAILEY: Thank you very much.

6.3) PRESENTATION BY EDGAR BAILEY (CRCPD)

MR. BAILEY: Mike, you really have an easy job at EPA. You only have ten semiautonomous regions to deal with. We've got 51 very autonomous states and the District of Columbia and a couple of territories that we have to try to have a somewhat uniform pattern of regulation. And it's not always possible.

I am just rambling now while they get the slides up there.

There is one state that on the public dose limit because they were an agreement state adopted 100 millirem per year for radioactive materials and because they had a strong medical lobby, I presume, left the public dose limit from X-ray at 500 millirem per year. So there can be some weird things that happen in the states. And that wasn't California.

Okay. Dr. Ryan mentioned the Conference of Radiation Control Program Directors. And it's really an organization composed of the radiation control program directors and staff members in the 50 states, D.C., and U.S. territories. I put a small fourfold in front of each of you at your place and a card that if you are SI-impaired, like I am, you can use to --

DR. POWERS: Bless you, sir.

MR. BAILEY: -- translate rapidly and not look quite as uninformed.

These 50 state program directors do include, of course, the directors of the 33 agreement states. The states do almost exclusively regulate X-ray usage in approximately 80 percent of all of the radioactive materials licensees in the United States. I don't know the total number of X-ray facilities in the United States, but I know in California, we have over 30,000. So they are a major source of radiation exposure to individuals.

Next slide. I would like to speak a little bit -- and my presentation will probably be quite a bit different from other people. I want to talk about terminology. The first bullet there is something that I think is very important when we are

trying to express what is going on in radiation protection. Changing terminology does not necessarily improve the understandability of what we are trying to say.

I would challenge any of you to go to one of our public meetings in California and in the 15 or 30 minutes we gave you convince or inform the audience of, 100 percent inform, the difference between a constraint and a limit and so on and so on.

Changing terminology always involves reeducation of the workers and the regulators. Now, when I said we had 30,000 X-ray facilities, it is going to be a job to get out there to those 30,000 and educate them on what we are trying to do if the terminology and so forth is adopted.

The last one is that the terminology may improve the understanding for the developers of the terminology but not necessarily for the users and regulator.

I used dose in parentheses because I think we have done ourselves a great disservice. When we go out and talk to most people, we start talking about effective dose and this dose and that dose, they're completely lost.

I think we should have settled on the

common phraseology to be dosed and then have all of these other doses as subparts of it so that when you are going out talking to the public, you talk about dose, which is really what is the important thing.

When we change acceptable doses, those changes are perceived as radiation being more hazardous than presently thought. On the example we're talking about here, I think it is going from 5 to 2 rem.

And those changes are widely used to discredit both users and the regulators by the "antis." You didn't know what you were doing five years ago. Why should I believe that you know what you are doing now?

And although it probably won't be too significant, the use of incidence of cancer, instead of mortality, will make some differences. Those, too, will be pointed out as another mistake that we have made.

Next one. Dose reductions, if they have to come about, will result in increased shielding new designs and a question about existing facilities. When we went from 500 millirem to 100 millirem, we had a major turmoil going on about existing facilities. These were primarily that 30,000 category I'm talking

about and not in the total in the United States of 10,000 or so radioactive materials used. And, likewise, we will have increased controls on emissions.

I remember what we went through when the ten millirem came out. Everybody went into a fury trying to prove that the ten millirem to the maximally exposed off-site individual was not a lower dose than compliance measured at the stack under an NRC regulation. So we need to make sure that we are very careful however we institute these new recommendations.

Next, please. I think potentially the biggest problem is in the cost of decommissioning or the impact on decommissioning. When I look at the table, it talks about 100 millirem for the general public, and I already know that we have a variety of sources that are either constrained or limited -- I'm not sure which exactly -- to 25 millirem a year, such as low-level waste site uranium mill, a decommissioned site.

We are going to see an argument -- I know I will in my state, at least -- that we should go down to the one millirem level for a decommissioned site because nobody is getting any benefit, either direct

or indirect, from going to 25 millirem.

As we decrease the cleanup standard, in particular, the costs go up dramatically. And we have seen this, at least in California and in some of the other states, where the 25 millirem suggested by NRC -- or not suggested, I guess, adopted in the regulation -- is deemed not to be acceptable because they do compare it to the 10^{-4}, 10^{-6} range. And 25 is considerably above 10^{-4}.

Generally we hear the thing touted one in a million, one in a million, one in a million. That is apparently the safe level in a lot of people's minds, which, roughly translated, is about one millirem.

When we go to do cleanups and we go below, say, 25 millirem or any other number, we have a lot more costs in characterization, cleanup verification, the sampling, more sampling, more surveys, more lab analysis, all of which are expensive.

I will say that since the court threw out our 25 millirem a year cleanup standard and we have sort of been in limbo, we have released for unrestricted use over 300 sites.

The vast majority of those because, again, the technical people wanted to be sort of precise have

said it's indistinguishable from background. These may even include sealed source sites because the purists would want to say, "Well, maybe that source didn't leak at the legal leakage rate, but they may have put out a few atoms here and there."

But we have had very few sites released that exceeded one millirem per year. So it may beg the question. The ones that have proven to be the most difficult are the agricultural sites, agricultural, experimental stations, where they deliberately used in most cases carbon-14, which has a very long half-life. So it hangs around.

And those doses depending upon the model you used -- and we tend to use the farmer scenario because if you're talking about an ag station that's suddenly shutting down into something, it's probably going into agricultural production after that. So those we have seen can cause big problems how you word whatever regulations come out as a result of these recommendations.

And, as you are all aware, I believe, hopefully on the Waste Committee, as the level goes down for cleanup, the volumes go up geometrically. So you have got the problem of waste disposal.

Certainly at 25 millirem, there is a lot

less waste than there will be at one millirem or whatever. I think that these are issues that need to be looked at when you implement any of the recommendations, sort of look at some of the fallout of what the recommendations of the implementation is going to be.

Next. Flora and fauna. I guess my original reaction is that one really scares me. It can be large problems depending upon how it is decided to implemented by NRC and EPA. It can be possibly small problems.

I would find it very difficult for us to resist the argument that doing an EIS, that we had not evaluated the effect of radiation on an endangered species. Never mind that it's not one of a bottle species to be considered.

I remember when we were doing the Ward Valley waste site. One of the items of a great deal of concern to everyone there was the desert tortoise. I would bet, although I am not a biologist by any means, that the metabolism of some radioactive materials on a desert tortoise are really different from those in a tortoise you find in the Southeast, down around South Carolina, particularly in the metabolism of water. So that I think that this could

prove to be a very contentious situation if this were not clearly spelled out how it is going to be enforced.

And I would hate to bring up the last point, but it is a wonderful opportunity in my humble opinion for a continuation of NRC-EPA disagreement on how you enforce recommendations of a national and international body.

Just to sum it up, I think we have to be very careful in adopting new systems that are going to apply to a lot of people. The flora and fauna issue, I was just reminded of another incident. I understand that NRC has a complaint now that there is a radiography firm that is exposing rabbits to extremely high levels of radiation and, therefore, they should be stopped by doing the industrial radiography, I presume, along a pipeline because of the bunnies that are hopping along by the pipeline.

There would be a situation most of us wouldn't think of. I praise the ingenuity of the person that came up with this. We could have a lot of these things come up with beginning to look at the impacts of radiation on flora and fauna.

I would be willing to bet that 25,000 of the facilities that we have that use X-ray would not

be able to guess what the word "optimization" means other than you get the best picture you can.

So with that, I will leave it for questions.

CHAIRMAN RYAN: Ed, when I think NRC licenses under the Atomic Energy Act, I think about registrants with medical X-ray equipment, and I think about states' authority to regulate NORM and TNORM. What do you think about particularly the medical area and the NORM and TNORM?

I guess I think we all recognize that in terms of exposure to the public, it is radon NORM and TNORM and medical exposure that are driving the bus.

What I'm driving at is, could you talk about how agreement states deal with AEA-regulated material versus non-AEA-regulated material and how you would try and make a coherent hole out of new guidance in this area?

MR. BAILEY: Okay. I can tell you that the majority, if not all, of the agreement states treat NORM, naturally occurring and accelerator-produced radioactive material, in the licensing and inspection process exactly like they do AEA material.

The problem comes in when you are looking

at NORM and TNORM. It's what has to occur to get it into the regulatory scheme. I have a large rare earth-producing facility, which has fairly high levels of naturally occurring radioactive material that we still haven't got a handle on. Certainly radon is the big one that stick out to the side. Very, very few people are regulating radon in any way comparable to the dose the way they regulate other sources that give the same dose.

The oil and gas field TNORM waste, which is primarily pipe scale and that sort of thing, is very diversely regulated among the states and, of course, not at all by the federal government.

So the short answer is we tend to view -- and I'll use a quote from one of my colleagues. "A rem is a rem." We don't care where it comes from. But in practice, it's very difficult to get at some of these diffuse NORM sources that have been in the environment for years and years. You have to figure out how to get into it.

In the medical area, there is no consistent uniform system of regulating the X-ray sources other than the suggested state regulations for control of radiation, which CRCPD sort of shepherds and so forth.

Those are purely voluntary upon the part of the state, whether they want to adopt them or not. So many times many states will lag far behind what the current standard is. States will go off on divergent paths.

The state I mentioned, where they decided they would leave the public dose from medical X-ray at 500 millirems seems totally inconsistent with the general philosophy that it apply equal regulation to equal doses of radiation.

So, like I said, EPA has it easy. They only have ten regions.

CHAIRMAN RYAN: Let me ask you the now inflated dollar-value question, the $128,000 question. Do you --

MR. BAILEY: Okay. If I answer it correctly, do I get that or --

CHAIRMAN RYAN: I'd rather owe it to you than have you not have it owed to you.

MR. BAILEY: Okay.

CHAIRMAN RYAN: Do you see these new recommendations offering states, agreement states, either on the AEA side or the non-AEA side, an improvement in your radiation protection practice? Do you see any real benefit to what is being offered or

what the new advice is shaping up to be, recognizing we have got consultation papers and so forth coming? Do you see it as a help, a benefit, or ultimately neutral?

MR. BAILEY: I think the using of new scientific methodology is certainly a scientific improvement. The others, though, to me are almost a political decision. And, as we often see, the political decision always has at least two sides to it.

And so one has to be careful, for instance, going to the two rem. Certainly it would offer more protection to a limited number of our workers. I don't know that that would offset the bad press you get, again, as I mentioned, for, hey, you were wrong again. Why should we believe two rem is "safe"? Why don't you go to 100 millirem per year for occupationally exposed people? It's going to vary from place to place.

CHAIRMAN RYAN: You didn't mention costs, but there would be a lot of costs.

MR. BAILEY: Generally cost doesn't come up except in a negative way. The only reason you don't want to go to the 100 millirem or to the 2 millirem or whatever is because you don't want to

spend the money to protect your workers. I mean, that is the way it usually comes out, not the other way, as we think about it.

CHAIRMAN RYAN: Any other questions or comments?

(No response.)

CHAIRMAN RYAN: Thanks, Ed.

Let's turn now to our last presentation in this group, Dr. Richard Vetter from the Mayo Clinic. Dr. Vetter, welcome.

DR. VETTER: Thank you very much, appreciate the opportunity.

6.4) PRESENTATION BY RICHARD VETTER (MAYO CLINIC)

DR. VETTER: I will just preface my remarks by saying that what I am about to tell you is based on my own knowledge and experience and input from ACMUI, the Advisory Committee on the Medical Use of Isotopes. It's not a formal position in any way of the Advisory Committee.

Next slide, please. My first several slides go over some stuff we have heard before, but I just wanted to underscore a few things. One is that the recommendations talk about sources of exposure. I just wanted to point out that source does not necessarily mean a physical source. It could be the

Nuclear Medicine Department. It could be the hospital, et cetera. So we are not necessarily talking about a physical radiation source here. And that is important when we start talking about constraints and limits.

And relative to judgments, responsibility for justification for most of these recommendations would fall on governments or government agencies except for medical. I want to point out that medical here means the patient. It does not mean the activities within the hospital. It does not mean exposure to the public in the waiting room, et cetera. It means only the patient.

Next slide, please. Justification for medical exposure, then; that is, the patient, falls outside of the realm of government. So we perhaps don't need to talk about it very much here. Justification of the practice lies more with the profession.

And justification of the procedure; that is, whether or not you had the procedure done on you, falls on the practitioner. So it's a discussion between you and your doctor whether or not you get that CT.

I would point out, however, that

government has entered into the quality of these. There are a number of recommendations, especially from FDA, that deal with quality of medical procedures. So while it might be justified and while exposures might be determined pretty much by the procedure, government does enter into it to some degree.

Next slide, please. I will just point out that there are classes of exposure. Occupational is obvious. Medical. Again, I mentioned that was for the patient, refers to the patient. There are no constraints relative to the patient exposure. Everything else is public. So all other sources that we are talking about here deal with public exposure. And that does become an important item for medical centers.

Next slide, please. I would also like to point out that for classes of exposure, there is individually related exposure and source-related exposure. For individual-related, this has been pointed out by a number of the speakers here today. For example, using the public as an example, an individual may be exposed to several different sources: hospital, emissions from a power plant. You name it. And so the assessment of total exposure must be attempted, medical facilities simply being one of

those.

Next slide, please. Now getting to the business of the constraints, ICRP defines a restriction on dose as a constraint. ICRP 2005 says that these are obligatory. In other words, they almost say it's a limit. But you are obliged to meet that constraint.

They also say that if you fail to meet the constraint, your program has failed. The input I received from a number of people has suggested that that is very strong language and could actually be counterproductive. We don't need to talk about that in detail, but failure is a very, very negative message.

We think failure if you're going to use that word in recommendations or in regulations, that should be reserved for a limit, not for a constraint. Perhaps this comes from our background in ALARA, where we set goals and when we fail to meet a goal, we investigate.

But failure to meet a goal doesn't shut our program down. We don't get cited by the NRC for having violated regulations because we missed an ALARA goal. They might ask us how well we're doing, if they notice that, and what are we doing to follow up on it,

but we don't get cited for it. It's not a failure of the program to miss a goal.

But in the 2005 recommendations, it is considered to be a failure, which implies that there is some punitive action there, punitive measure that could occur as a result of that. And we just think that is pretty strong.

Next slide, please. Okay. Dose constraints are intended to provide protection to the most exposed individual within a class from a single source. So this would be the most exposed individual who visits a waiting room in a hospital. This is a very small population, a fraction of the population.

And, in fact, if you go to a hospital and you look at the people who are visiting that hospital, you will find that -- this is anecdotal. This is just based on observation of this and not based on any kind of formal survey or measurement, but I think you will observe that most of the people there are older people.

Now, I know we averaged all of this out into a single risk officiant, but the risk to these most exposed individuals is actually quite small. So I think the feeling that I have gotten -- and, again, this is anecdotal -- from physicists, in particular,

is that the constraint in this regard probably should be based on the probability of exposure, rather than the most exposed individual. What is the probability that an individual will receive the 100 millirem, not what is the dose in a particular case to the most exposed individual, which in the hospital's case is going to typically be someone who is considerably older.

Also, within the description of these populations, I must confess I don't quite understand how this applies to constraints, but within the description of these populations, ICRP says that we should consider the mean characteristics of these subpopulations.

If we do that in a hospital, it's an older population that is being exposed. That is, this is the members of the public are an older subpopulation.

Next slide, please. Now, we have seen these numbers also, emergency situations. I'll use U.S. terminology, ten rem. The current U.S. limit is five rem.

Now, it's interesting that I think this creates some confusion in the minds of many who read these recommendations. The dose constraint for an emergency situation is ten rem, but the limit is two

rem. So obviously it becomes confusing when a constraint is supposed to be a fraction of the limit. It might be 100 percent of the limit, certainly can't be more than the limit, but in this case, it is. So it's not really constraint. It's exception to the limit. Maybe it's just the way I read it. I get confused when I read this.

Apart from that, this does make sense, emergency situations having a higher limit than what you would normally expect for a limit for the occupational worker. For that member of the emergency room who might be involved in dealing with a few hundred patients from a radiological dispersion device, it is reasonable to allow in that particular circumstances higher limits, higher doses for those people who are involved in that emergency.

Now, that being said, it is pretty unlikely we will see those kinds of levels in a hospital because presumably these people would have been decontaminated at the scene and they would have at least gone through one decontamination prior to arriving at the hospital unless they're really critical and they're wrapped in a blanket and hauled to a hospital immediately. It's pretty unlikely, we think, that we would see those kinds of doses.

Nevertheless, philosophically it makes sense that for emergency situations, you allow higher doses.

Now, how does that differ from the standpoint that we can't plan these things in advance? We will find out the moment those patients show up. And so we can't do a planned special exposure. So that makes sense to us.

The direct or indirect benefit refers to occupational exposure and cares of radionuclide therapy patients, the maximum constraint being two rem. The current U.S. limit -- and I have missed one. I left a line out there. The limit is 50 millisieverts or 5 rem for occupational and 5 millisieverts or 500 millirem for cares of the radionuclide therapy patients.

We have talked about this before. There are measurements that have been published in the literature that demonstrate that hospitals are meeting these limits, that the guidance that is provided by the NRC works, that hospitals are able to meet this limit. Nevertheless, there are situations where patients could result in numbers in doses to members of the public that are higher than this.

The example that ICRP uses is a child who is treated with radioiodine therapy or some other

radionuclide therapy who if the parent is involved or family members are involved in caring for the patient, the dose might go higher than 500 millirem.

We have those situations here in this country today. The way we handle that is we don't allow the child to go home. The child has to stay in the hospital. The interaction between the child and the parent is observed very carefully. The parent is instructed as to what they can do to help care for the child. And they can't sit right next to the bedside because they would get more than 500 millirem. So in those cases, the child has to be hospitalized.

We have seen similar cases where a parent, an older parent, requires some additional care or the family desires to provide some care for that parent. And the parent can't be released because it would result in more than 500 millirem to members of the family.

In that case as well, the child or the adult child who is caring for this aged parent has to be instructed on how much time they can spend in the room, what they can do, what they can't do, and so forth.

In cases such as that, it makes sense to the medical community that a higher limit be allowed

so that the family member can provide more care if that is what they desire. This would have to be done under very carefully constructed conditions and monitored in that case. But it does make sense that in special situations like that, that a limit to that care-giver of more than 500 millirem be allowed.

This actually, as mentioned earlier, was recommended by NCRP Commentary 11. They recommended as high as 5 rem or 50 millisieverts. And, again, this would be in very, very carefully selected situations. It wouldn't be normal.

Next slide, please. The ICRP 2005 does talk about the exposure of women as not necessarily a special subpopulation but potentially a special subpopulation. They normally would see no reason to distinguish women from men in terms of how you control occupational exposure unless the woman is pregnant.

Once the pregnancy is declared -- underscore "declared" -- it is the same in this country. The woman must declare. If they don't declare, then we are not knowledgeable of the pregnancy. But if they do declare, then we need to take appropriate precautions to make sure the fetal dose is kept under 500 millirem in this country. ICRP is recommending that that limit be 100 millirem, 1

millisievert, during the remainder of the pregnancy after the pregnancy is declared.

We took a look at our exposures at Mayo of the results of monitoring regnant workers. And five percent exceed one millisievert. So it's not a large number. Most of them are under 100 millirem. It's only a small number that is above 100 millirem. And we do, by the way, rotate those employees out of the higher exposure jobs.

For instance, we would move a PET technologist to general nuclear medicine in that case. We would move a nurse from the radionuclide therapy floor to some other area in the hospital.

We could do this fairly easily because we are a very large academic medical center. So there are lots of opportunities to move people around. But what do you do in a small community hospital? That becomes very, very difficult for them.

In addition, the handwriting is on the wall. Tech is going to increase considerably over the next number of years, general nuclear medicine. That is, the use of technetium-99m is going to decrease. The use of positron emitters is going to increase. Positron emitters 511 keV, about 4 times the energy of technetium-99m, exposure, likewise, goes up. So this

will become increasingly challenging for the medical community, in particular, community hospitals, where it is very difficult to move people around.

Some have suggested that this could be counterproductive in that it creates an opportunity to discriminate against hiring a young women; in particular, if she appears to be pregnant. If you have a nuclear medicine technologist who is pregnant and interviewing for a job, there is some worry that there could be some discrimination. There shouldn't be, but there is some worry about that.

We also have to be a little bit careful in medicine about what we do about people like that. That is, how much do we move them around? The precedent is the Johnston Controls case, where Johnston prevented women from working in a particular area where the risk from lead was higher. It turns out the salaries were higher in that area as well. And they prevented women from working there. And, therefore, they were discriminating against women.

So in medicine, the same deal. If a technologist for some reason were paid more than general medicine technologists and we move that technologist out, we either have to protect the salary and promise they can move back or we can't move them

out or something. We have to be very, very careful not to discriminate against that pregnant employee.

Next slide. I took a look at typical radiation doses received by women in medicine. In addition to the data from my own institution, I looked anecdotally at data from other institutions. And in a cardiac lab, typical doses run from a few rem to more than five rem, to the whole body badge.

Now, they're not exceeding a limit because they are wearing a lead apron. The apron will stop about 95 percent of the radiation dose. Only about five percent penetrates.

In addition, in some cardiac labs, you get pull-down leaded plexiglass shields. There are lots of ways to protect people. Nevertheless, if you are simply wearing an apron, the dose under the apron in these same people is going to be somewhere in the neighborhood of a couple of hundred millirem to more than 500 millirem depending upon how busy and how many cases that cardiologist is working.

In PET, the badge readings run from less than one to two rem to the badge, to the whole body badge, per year. Now, you can't provide a lead apron here. We're talking about 511 keV. Lead apron won't do anything to that. So typically we would expect in

that case that the dose to the abdomen is going to be more than 500 millirem.

So, consequently, if there is a pregnant technologist who works in PET imaging, we've got to watch that very, very carefully. And in great likelihood, we would probably have to move that person out of that area at some point in time.

In general nuclear medicine, the badge doses tend to be considerably lower, generally between 105, 100 millirem a year. So that's not such a big problem, although, once again, the dose to the abdomen would be over 100 millirem or 1 millisievert.

Next slide, please. So, just in conclusion, about that last slide, once again, I will point out that in a community hospital, they don't have the flexibility to move people around. And that becomes very problematic.

Medical exposure. As we mentioned earlier, there is no limitation on dose. ICRP makes it very clear they do not intend to limit this dose to the individual patient because it could reduce the effectiveness of the diagnosis of treatment. So that's totally between the doctor and the patient at that point.

Next slide, please. But there are

constraints that apply. Within the discussions of medical exposure, there are constraints. But they apply to workers and members of the public.

So ICRP says a constraint of a few millisievert is reasonable but should not be used rigidly. And this applies to care-givers for radionuclide patients, radionuclide therapy patients. [Inaudible due to NRC audio system failure.] mentioned this before.

Current NRC regulations do allow release of patients. And we in hospitals are able to live within that. One other thing I wanted to mention in this regard is that as our population gets older, the probability that more people will be treated with radioiodine increases, not only for thyroid disease but for other disease conditions; for example, there is a protocol now that has demonstrated very clearly in animals -- and they are moving toward some human studies shortly. They can take the receptors from the thyroid, put them in the prostate, and treat the prostate with radioiodide. You will see all kinds of things like that where they are using new and novel techniques for using radionuclides for therapy.

Next slide, please. ICRP says public constraints are not appropriate for individuals who

volunteer for research studies. So, in other words, humans who participate in these studies are basically considered patients. And also all of this falls within the ethics and controls of the institutional review board, where these doses are very highly controlled.

ICRP also says discharges to sewers and airborne effluents should be assessed. I would point out that there are a number of publications in the literature that show that both have been done. Both have been assessed. And discharges to the sewer result in minimal exposure to employees in the sewage treatment plant. And hospitals typically use the EPA comply code to demonstrate that their effluents are less than ten millirem. So this is being done on a fairly routine basis.

And exposures in the waiting room are -- the word they use is adventitious. In other words, we don't need to worry about that except for radioiodine.

Next slide, please. Recommended dose limits. So now we will move from constraints to dose limits. Currently in the U.S., the dose limit for occupational is five rem, ICRP two rem. Now, this isn't new. ICRP isn't recommending anything new. This was ICRP 60 as well. I just wanted to point out,

however, that this would be reducing the limit in this country from five rem to two rem would be problematic for hospitals; in particular, small hospitals and, in particular, for very small categories of workers.

For example, I know this isn't regulated by the NRC, but if a limit is adopted by EPA-NRC, the feds, the states will be forced to adopt it as well. And they will apply it across the board.

The people in the hospitals that get these high doses work in the cardiac lab or in the electrophysiology lab, where the doses, where their badge doses, are high, not everyone, but there are some who are high. We just need to be very cautious about what we do that reducing a dose doesn't become counterproductive.

These people are involved in lifesaving activities. Some of these patients go into that lab. They're failing all medical treatment. And they're going to die. They come out of the lab with some cells in the heart ablated that are causing the heart to beat inappropriately. And they live for many years after that.

These cardiologists are saving these people's lives. The cardiologists are getting doses higher than two rem per year, but in my opinion and

the opinion of many physicists and others in medicine, this is highly justified. So I think we just have to approach this very, very cautiously.

We are not talking about a large number of people either. In terms of the total detriment to the population, it would be a very small impact or it is a small impact. This would be in a larger academic medical center, it is a little easier to move these people around if that becomes a problem. But in a small community hospital, once again, that would be very, very difficult.

Relative to public exposures, the constraint of .3 millisieverts per year would be problematic. Let me just reflect briefly on the history of how X-ray shields are designed. It wasn't that many years ago, in my lifetime anyway, 20 years ago, that X-ray shielding was designed with a public dose limit of 500 millirem.

In other words, on the outside of the shield, you had to achieve 500 millirem. And so you would calculate. You go through this calculation and determine that you had to have a certain thickness shield in order to achieve 500 millirem.

After you designed the room and built it, you would put a badge out there to make sure you

achieved 500 millirem. In most cases, it was not measurable. And that is because the methodology is very, very conservative.

Then what was it, about 1990 or so, the dose limit for members of the public was dropped to 100 millirem. The methodology didn't change. It didn't need to. You plugged in one millirem, but you basically calculated the same thickness for the shield. You remeasured. And, again, it was a very, very low number or zero on the other side of that wall.

So now they are suggesting a constraint of .3 millisieverts per year in the case of multiple dominant sources. So now should we incorporate .3 into our calculation? I guess that suggests that that is what we should do.

If, in fact, we are measuring almost nothing outside the shield, what I am struggling with and what we are struggling with is how do you apply the constraint basically?

Did you have a question?

CHAIRMAN RYAN: Yes. It's on that exact point. I am struggling with considering that exposure outside an X-ray room to a member of the public is going to be routine.

Now, if you are considering a secretary who is at a desk somewhere on adjacent parts of an X-ray department, member of the public, I guess that would be 2,000 hours per year.

But I struggle a little bit with, first of all, that whole concept. I think most folks, a large percentage of individuals, that go in and out of an X-ray room are there hopefully never and hopefully as a minimum number of times possible, either as a patient or a care-giver.

The patients, those sitting in the waiting room, are dwarfed by what they get once they're examined. So I am not worried about that so much. I am just thinking about this in terms of practical radiation protection practice.

And then for individuals that could receive exposure at 100 or up to 300 in a workstation that is not a radiation worker job, I think that is probably something that radiation protection practice probably ought to look at anyway.

So multiple sources, I guess I am struggling with who is in this category. I have challenged lots of folks that say, "Give me an individual or a class of folks or a group of workers who are multiple source exposed."

Nuclear power in my view is out of that picture because of the constraints that are on that. We know that it is a very small fraction of total background exposure. The nuclear industry workforce relative to [Inaudible due to NRC audio system failure.].

So I am trying to find the intersection where multiple source is a meaningful thing for us to figure constraints on that. I haven't come up with it. Have any of you?

DR. VETTER: Well, let me just make a comment. And then I think others may wish to chime in here, too. Relative to whether or not this is a routine practice routine, it is a routine practice, but whether or not an individual would be routinely exposure, the answer is no.

Now, we do take that into account, at least partially, by using something called an occupancy factor. What is the fraction of a time someone might be there? But what we don't do is take into account the probability that it is the same person.

And that's why earlier in my presentation, I suggest that, instead of looking at this in terms of the most exposed individual, we should probably look

at it in terms of the probability of any one person exposed. So I would agree with you in that regard.

CHAIRMAN RYAN: That's my point. Ed?

MR. BAILEY: The NCRP confused it even more by recommending 25 percent, that you consider that there were 4 sources and not 3 sources, basically, that could impact at the same time. There is a new commentary coming out on whether or not that should apply to X-ray facilities because this was a great concern in redoing the shielding report for NCRP.

The question that you raised was about where that could occur. The most common example of where it would occur would be in a place like Oak Ridge. By the way, that one-fourth came out of the commentary on clean air emissions, where you had perhaps four plants pumping stuff out that basically stayed in the environment, as opposed to --

CHAIRMAN RYAN: Where are those plants in Oak Ridge, Ed?

MR. BAILEY: I don't know. That was just an example that was given.

CHAIRMAN RYAN: Ed, that is my point.

MR. BAILEY: Right.

CHAIRMAN RYAN: People can theorize cities

like Oak Ridge or Hanford or somewhere else, but in reality, I challenge anybody to show me somebody that has three or four significant sources exposing.

You know, I am not disagreeing with you or challenging you, but I think this might sound like a nice construct if there is more than one source significant.

But, again, radon is a big one. Medical exposure as a patient is the second. And everything else is a distant third, is a collective. So, in practice, we are talking about creating a structure to regulate the distant third group. Yet, we just kind of blow by the two big ones. And radiation protection risk management is, by the way, integral of everything that is regulated and unregulated.

So I'm struggling with, is there an example where you can say, yes, this group has three major sources of exposure? I don't know. I wrestle with that. Maybe there isn't an answer here today, but I think that is a challenge we have to think about in trying to figure out, does this sort of a recommendation make sense? If I am wrong, tell me, but I am struggling with that.

Sorry for the interruption, Richard.

DR. VETTER: No. Fine. I appreciate the

interruption because that is exactly the point I was trying to make. From the hospital perspective, we have been designing these shields to meet 100 millirem.

The methodology is very, very conservative. When we measure out there, we don't get that. And that's fine. We're happy we're not getting that. But the point is if we have to apply this constraint to that methodology, now we have to add shielding. So we will get even lower doses out there.

CHAIRMAN RYAN: By calculation?

DR. VETTER: By calculation. So it's a little bit confusing at this point as to how this would be applied. Since we're not doing it to ourselves, if this is going to be done, this constraint is going to be applied by the government.

And so I just want to leave that with you that that would be -- we're confused about it, number one. It would be problematic, number two. And then, number three, if you are going to apply this, do you apply it to existing facilities? Do we have to go back and re-shield hospitals? A lot of them will go out of business before they did that. So, anyway, it's very problematic and I think requires some discussion if we are going to go forward with it.

Next slide, please. So this more or less is the beginning of my concluding remarks here. Dose constraints and limits for pregnant workers in this country if we applied one millisievert as a limit, that would be problematic.

I'm not saying it couldn't be done. I'm saying it would be problematic. It would be very difficult for community hospitals. And there are some thoughts that it could lead to some discrimination in order to make it work.

Workers, 20 millisievert, problematic for select individuals. Here again, there have been some suggestions that some people would simply stop wearing their badges.

Public, one millisievert limit is probably okay. The limit, underscore "limit," is okay. We're living with that now. It's the constraints that are a problem for us. If we had to design our shields to meet .3 millisieverts or, as Ed mentioned, using the NCRP methodology, they don't exactly say 25. They say 25 percent. They use a percent, don't they, of the limit? That would be problematic.

The cost of applying these constraints would be significant. In particular, if you had to begin to retrofit hospitals, it would be constrained,

very expensive.

Next slide, please. Just to mention waiting factors, that has been discussed already. We have very, very few internal updates in hospitals. Even in nuclear medicine, where the dispensing radioiodine, if you do it properly, the technologist is not going to get [Inaudible due to NRC audio system failure.].

Where these factors are used is in medical research. So this could affect the final dose that is calculated for a research subject who is getting a particular radiopharmaceutical.

So it could affect -- in fact, ICRP has, I think it is, 53, report number 53, that has a whole bunch of radiopharmaceuticals, where they have calculated the dose. If you want to simply use that as a reference, you can use that to help evaluate the dose to research subjects.

This would change those numbers. Exactly how it would change it would depend on the biokinetics of the particular radiopharmaceutical. I do not envision that this would be a big deal. We would simply calculate the new dose, inform the patient accordingly, and continue the work.

Next slide, please. I just said that.

Next slide, please. So, in summary, constraints for public exposure from facilities, from medical facilities, we think are problematic, especially for X-ray. Now, I know NRC doesn't regulate X-ray or EPA doesn't either, but if you begin to regulate it, it will filter down to X-ray.

Limits for occupational exposure of the fetus are problematic for selected personnel, the proposed limit. You know, in the large facility, you can reassign workers in a small when you simply don't have that luxury.

Limits for occupational exposure are problematic for the proposed limits. The proposed limits are problematic for select personnel.

So, with that, if there are any questions, I would be happy to try to answer.

CHAIRMAN RYAN: Let me start with just one quick one on ALARA in the medical setting for workers. You know, you mentioned a few. For example, invasive cardiologists, perhaps a couple of other categories will be at or near that two rem and up to five rem. Occasionally the whole body badge outside of the shielding apron will be even above that.

When you get that circumstance where an individual practitioner or perhaps a particular room,

how do you deal with that from an ALARA standpoint? Is that a part of your program? And how does it work?

DR. VETTER: Right. Medical facilities, if they are a materials licensee, they have to have an ALARA program and in some states perhaps even to use X-rays. I'm not sure.

In the state I am from, use of X-rays doesn't require an ALARA program, but we have a materials license. So we simply apply it across the board. So it would apply to cardiology as well.

So we have what we call a derived investigational level. It's a level based on what we think is achievable for the average cardiologist. And anyone who goes above that, we investigate. Usually people who go able it, it is because their patient load is high or they had a complicated case or something of that sort. So there is not much we can do.

Now, initially there were things we could do. That was to institute the use of pull-down shields, shields that are mounted from the ceiling, you know, these ergonomic kinds of things where you pull it in front of your face so you can shield your face, in addition to wearing the lead apron.

For other personnel on their own, there

are portable plexiglass panels that can be moved around, lots of things that can be done. And I think the ALARA program helped us to figure all of those out, and they have reduced doses in those environments.

So any time anyone exceeds a derived investigational level, we take a look at what is going on, what's the reason for this. Maybe the machine is going bad in putting out too much dose or something. You know, we want to know what is going on. Usually, as I mentioned, it is caseload.

If someone goes over the limit of five rem to the badge, then we use the NCRP methodology. NCRP report number 122 says you can calculate the effective dose under the apron and use that for your effective dose as the assigned dose for that individual.

And I am probably fairly safe in saying that most states allow that. Certainly our state does. They simply allow us to do it. They recognize that we're using an approved methodology in accordance with an NCRP standard. And so we assign a dose.

If they don't go over five rem, we don't assign a dose. We simply put in their file that their badge dose was whatever it is. And then we don't assign a dose. The reason we don't assign a dose is

because the badge is less than five rem, they're within the limit, we can calculate an assigned dose depending on what the current approved methodology is for doing that.

Twenty years ago, it was effective dose equivalent. Today it is effective dose. Tomorrow it is different weighting factors for effective dose. So we don't calculate it on a routine basis.

MEMBER WEINER: I just have one comment. I wanted to thank you, Dr. Vetter, for recognizing the problems with applying these doses to pregnant workers. And I think they would also apply not just to medical workers but to students and graduate students under these constraints. I could not have done my graduate work.

DR. POWERS: I will simply acknowledge that the pregnant worker or potentially pregnant worker is an intractable problem, even under the current regime, whether or not you can reassign without [Inaudible due to NRC audio system failure.] of benefit, you simply run into the problem they refuse. And then you have a legal liability problem that just is impractical.

CHAIRMAN RYAN: Anything else?

(No response.)

CHAIRMAN RYAN: Okay. We are at a point [Inaudible due to NRC audio system failure.] discussion for comments from members of the public. Any comments?

7) PUBLIC COMMENTS

MS. FAIROBENT: Lynne Fairobent with AAPM. Vince, your industrial radiography slide, was that only NRC licensees or did that include all industrial radiography, NRC and agreement states, in your numbers?

DR. HOLAHAN: I believe all of the licensees with the agreement states are required to submit annual reports to [Inaudible due to NRC audio system failure.] reports are due annually [Inaudible due to NRC audio system failure.] time frame.

MS. FAIROBENT: Okay. And I would just like to follow up a document that Ed and Dr. Vetter made on perhaps the need to increase shielding. The industry did a workshop a couple of years ago -- well, I guess a year and a half ago now -- taking a look at it because NCRP was proposing a reduction in the shielding report, which was the revision 10 CRP 49. That's I believe at the printers now.

And we did do an awful lot of cost estimations and impacts on existing facilities, on new

facilities. And it was going to be drastic for industry.

NCRP backed off from that in the new report for both the diagnostic X-ray facilities and the therapy facilities from shielding is going to come out at the 100 millirem.

If, in fact, now we get into a situation -- and I know this may not directly apply for NRC, but it certainly applies for some of our other regulatory counterparts to NRC -- where if the ICRP recommendation of .3 is adopted, we are back into that same situation. And it's not a trivial impact on the community.

And, as Dr. Vetter said, I'm not sure that it really provides any increase of safety to the public or to the worker in this case as it would be applied.

So keep that in mind as we look ahead to potential regulatory impacts on adopting these constraint values.

CHAIRMAN RYAN: Thank you.

Any other comments or questions?

MR. ANDERSEN: Ralph Andersen, NEI.

I will just start with a question for any of the panel members. Can you tell me in regard to a

constraint what a source is in regard to application of a constraint? You have read the ICRP recommendations, as have I. Is it crystal clear to you what a source is?

Dick, for instance, you use a lot of different stuff at Mayo, X-ray machine and a nuc med source. Are those two sources or is that one source?

DR. VETTER: Those would be two sources. When you say, "What is a source?" it depends. I think you have to identify the population first. And then you identify the source, my impression from reading the recommendation.

So if you're talking about a worker, there are two different sources. If you're talking about a member of the public who is visiting that facility, I would interpret that to be one source. That is, whatever exposure the member of the public gets while in that facility, the facility is the source.

MR. ANDERSEN: Any other takers?

(No response.)

MR. ANDERSEN: Okay. That is an area that I suggest we really need a lot of clarification on.

MR. BOYD: I think that is true, Ralph. I think the way I red the ICRP, you could certainly consider an entire facility as a source, but the other

interpretation is equally valid.

MR. ANDERSEN: Also, I just wanted to make a couple of quick comments on the dose at nuclear power plants and ALARA programs. First of all, how did we get there? Vince showed, I believe, 1989 data and 2003 data.

A couple of comments that may or may not be shared by other industries. First of all, we have a very robust infrastructure who as part of their design is to accomplish that kind of result, institute a nuclear power operations, does routine evaluations to bring it down. I believe that Dr. Powers had asked, you know, how did we get there?

So they evaluate programs on a routine basis and also facilitate that sharing good practices, but we also have a strong arm of technology development through EPRI and technology transfer, the point being that Vince had put up some comments about what is it going to take, what is it going to cost.

Those numbers or statements that were generated in 1995 actually were lowballs. We spent more than a couple of million dollars per facility and more than $500,000 a year in O&M costs to get there.

Now, the driver really was to improve productivity. That is really the point. ALARA at

nuclear power plants is really integrated into production because it is really an efficiency program, streamlined work processes, shortened job time, shortened stay time in radiation fields, and so forth. So you get dose down.

I don't think that would be generally applicable to many other endeavors that use radiation, industrial radiography being an example. So they would lack that economic driver that we have in our industry.

Also, because of nuclear safety considerations, primarily we routinely engage in that transfer of information, transfer of good practices, and technology transfer that includes ALARA practices. What we found interacting with other industries is typically and especially where you have competitors interacting with each other, that is not the case. It is very difficult to create that kind of culture of sharing.

So I just wanted to respond that for communities like the radiographers, it might be much more difficult than you would first think for them to accomplish similar types of results.

CHAIRMAN RYAN: Thanks. We appreciate that insight. It reminds me [Inaudible due to NRC

audio system failure.] the comment that Dr. Vetter made that somebody might decide not to wear a badge. I would venture to guess that a worker who decided not to wear his badge at a nuclear power plant wouldn't be there very long based on that culture.

MR. ANDERSEN: Ralph Andersen, NEI.

Actually, you made me think of one other comment that I totally overlooked. There are really two. One is that in looking at the numbers of workers and doses, keep something in mind. If you tell me that you would really like to see most workers or all workers stay below two rem as a goal, I can do that.

If you tell me that if one of those workers gets two rem plus one millirem, that will be a regulatory overexposure. I'm going to keep all workers below about 1 or 1.2 rem. And that is going to be much, much more difficult because then I will have to build in a large margin.

For information, the routine administrative dose guideline we use in our industry as sort of an upper bound is about two rem a year. Then we make exceptions to go above that when we have a special skilled worker that is needed for a certain application.

That is 40 percent of the existing limit.

So we would actually have to change our culture and accept a much reduced margin if we were suddenly dealing with a two rem a year limit.

The other comment I wanted to make goes to the .3 millisievert or 30 millirem a year possibility within constraint. Even though the maximum constraint is recommended as 100 millirem, the fine print -- and you really have to look carefully to see that -- suggests that lower constraints are appropriate for many applications.

For mining, milling, power operation, -- those are ones I'm familiar with -- 30 millirem is virtually impossible to demonstrate. You can somewhat do it by calculation, but the uncertainties are very large.

And that is one of the concerns we have always had about something below 100 millirem. That is just about as low as we can go and still demonstrate that on a practical basis.

I am not talking about members of the public off site. I am talking about our non-radiological workers that are on site.

CHAIRMAN RYAN: Ed?

MR. BAILEY: The biggest factor in reducing overexposure to both industrial radiographers

and to radiologists probably was doing away with a 1.25 [Inaudible due to NRC audio system failure.] exposure limit and simply going to 5 rem a year because it gave people time to react and move people around or restrict their work.

So it is very important how you write the [Inaudible due to NRC audio system failure.]. It's not just the number that makes a difference.

CHAIRMAN RYAN: True. One small point on worker exposure, and I guess either Vince or Don can address it. And nobody has touched on it. There is a special case that is allowed in 10 CFR 20 for planned special exposures where an individual can be exposed up to one time the [Inaudible due to NRC audio system failure.] limit on twice during their lifetime. That dose [Inaudible due to NRC audio system failure.] apart from their lifetime occupational record.

So, just for the sake of completeness, I wanted to mentioned that even the current 10 CFR 20 has a different [Inaudible due to NRC audio system failure.] it's a limit, right? Based on that exception, twice and a worker might [Inaudible due to NRC audio system failure.]. Is that right?

DR. COOL: That's true.

CHAIRMAN RYAN: I don't know how many

times it's been done.

DR. COOL: I don't think it has ever been used that I am aware of.

CHAIRMAN RYAN: I don't think I am aware of any, but it is still in the code.

DR. COOL: Right. And there is no similar thing in the ICRP recommendations at this point.

CHAIRMAN RYAN: I just want to be a little bit more precise in comparing [Inaudible due to NRC audio system failure.].

With that, we are at a point where we are scheduled for a short break. And we're close to the time. So why don't we come back right at 5 minutes to 12:00, which would put us a few minutes behind our agenda schedule. And we'll press on with the discussion of optimization.

Thank you all for this very informative session and good discussion.

(Whereupon, the foregoing matter went off the record at 3:41 p.m. and went back on the record at 4:00 p.m.)

CHAIRMAN RYAN: We have two additional presentations scheduled and time for discussion and question and answers and then a wrap-up discussion and public comment period. So we'll bring all those

things together. I think at the end we're going to ask our panel members to stay around, as the Committee may deliberate for the benefit of the audience and try and arrange some themes and key points that we heard today as part of the entire day's activities. And that's a preparatory activity in thinking about structuring a letter that will offer our views and comments to the Commission.

Without further ado, let me turn to Don Cool who's going to lead us off on the discussion of optimization and protection, and he'll be followed by Dana Powers, a member of the Advisory Committee on Reactor Safeguards, is also going to provide us some insights from the ACRS point of view. Don?

DR. COOL: Thank you. I don't hear this echoing, so I hope I'm picked up, Madam Recorder. Microphone's gone. Get this up fairly close to my throat in hopes that it can pick up and we can proceed, and you should be able to hear me.

I wanted to address quickly the questions of optimization. We've touched on them briefly this morning in our introduction, so what I would like to do is give you a fairly quick overview of the things which are in the ICRP dropped recommendations and then introduce a couple of topics where I think some

discussion may be warranted.

First and foremost, optimization, a fundamental principle of radiation protection that hasn't changed. As envisioned by ICRP in these recommendations, not only is it dose reduction but it would incorporate other things that go into a broad definition of protection, for example, avoiding accidents and potential exposures, minimization of waste. Although the words aren't in the draft, you can read other things, perhaps such as securing facilities and doing other sorts of things like that.

In addition, the ICRP suggests that it's consistent with the adoption of a safety culture. We'll talk a little bit more about the relationship of that in a bit. We can go on to the next slide.

Characteristics of an optimization process. A forward-looking process, so this is not a retrospective, go back and try and prosecute the innocent type of approach but rather a forward-looking iterative process that's continually looking to try and determine if the best protection is being afforded under the prevailing circumstances.

In that respect, it ought to be systematic and structured, go through in a very logical sort of manner. One of the things which is emphasized more

now than in previous ICRP documents is that it has both the qualitative and the quantitative judgments. Those familiar with the ICRP's publications will note that several in the past, ICRP Publication 37, for example.

There have been discussions on optimization with very nice mathematical formalization most around collective dose to get some sort of valuation and figure of merit, which would then be used to decide whether or not you had optimized the process. This included alpha and beta factors that allow you to weight collective doses and get a cost/benefit ratio comparing with how much it cost to do something with the benefit that would be derived.

In these 2005 draft recommendations, ICRP is both acknowledging and in fact pushing more of the qualitative attributes that have also been part of the day-to-day activities that most operators actually have but which actually haven't had a formal place within the recommendations. In that respect, part of what they're trying to suggest is that it is a frame of mind that I've put out there to continually challenge whether or not there is the best protection being afforded.

I will grant you will observe that most of

the chapter in the draft recommendations is written at a very high conceptual level and appears to be written in the context of a very large decision-making process like an environmental remediation or the introduction of a whole new facility.

In the discussions which have gone around and around us within ICRP, I think it is envisioned in a more broad context and this is intended to include things like local work groups talking about ways that they can improve activities, the work planning that would go into each specific job in a nuclear power facility, the technicians in a pharmacy suggesting a better way to shield the syringes and all of the other little practical, some might even call it, seat-of-the-pants activities that forms the real heart and core of improving a day-to-day radiation protection. We can go on to the next slide.

ICRP has always had this bit of tension between what's optimization and what's ALARA. And what they will tell you, or at least what I have heard Roger Clarke tell you on several occasions, is that optimization and ALARA are not equivalent. In fact, as the process was going through over the last few years, they wanted to eliminate the word, "ALARA," and there was a great pushback from many folks, certainly

within the industry and otherwise, that ALARA is a very recognizable term and graphically describes exactly what we want to do with doses, okay? Point taken. However, optimization, as viewed by ICRP, includes not only dose reduction, which is what the ALARA means, but also all of the other factors such as the waste disposal, the potential for accidents and all of the balancing factors.

So if you will, you are both right, if you are talking to the advocates there, ALARA is equivalent, and ICRP that says ALARA is not equivalent to optimization. ALARA is a part of optimization when you are dealing with the specifics of dose reduction. What ICRP would wish for everyone to remember is that you ought not to simply be fixated on dose reduction if that means that you're doing some other things that are kind of stupid and reducing number of surveillances and other things, which may push up the potential for accidents or other problems which are also involved in overall protection of the source. We can go on to the next slide.

They talk in general terms about roles and responsibilities, suggesting that regulatory authorities, competent authorities, government agencies, would generally be looked to to establish a

clear policy and requirement on operators and users of sources for their to be optimization. For the most part, they would assume that the actual responsibility for optimization is with the owners, designers, users of the facility to have gone through and done the analysis. They would have expected that regulatory authorities and others would be looking over their shoulder but not likely doing it themselves. So, again, as Mike Boyd noted a bit earlier, there are some differences with at least some corners of the regulatory world where the regulatory authority, in and of themselves, will assume some measure of the optimization responsibility. That's not how ICRP has normally laid it out.

ICRP uses constraints as the boundary for optimization, and we've already had quite a bit of discussion around the constraints. Let's immediately go to the next slide.

People are always looking for a way to use a graphic to try and explain what's going on. This happens to be a drawing that got tossed up on the board in Beijing last week. I'm not advocating it as good or bad, but this is a polar representation of the world of dose. That would be the perfect world of zero right there in the center, and everything that

you do to try and reduce exposures are moving from a greater dose outside towards the center and the polar plat.

ICRP would represent the relationship of optimization and dose reduction with constraints as being the constraints forming a ring and there might be multiple rings, as we've talked about at various times. In a normal situation for a practice, something that you had under control, you would always assume that your optimization process, the nice little arrows on this chart, start inside the circle and move towards the center.

ICRP also recognizes that while a constraint is supposed to be a boundary for optimization, if you're in a preexisting situation or you're dealing with an emergency type of situation, you may have something where the dose starts outside the boundary of where you would like to be. And thus the objective of the dose reduction and optimization is to try and move it in; first, ideally, to get you inside of the constraint and then to further reduce the exposures.

One of the conflicts which is not clear within what is written, at least in the present time, is the fact that in the normal definition of

constraint -- I see my laser is dying -- a constraint is supposed to be a boundary to optimization. And one of the difficulties that gets associated with this is how you deal with a constraint in that definition and at the same time acknowledge that there will be situations where you will be outside of the constraint at the starting process. And does that mean you have the wrong constraint or does that mean that the definition of optimization also needs to include situations where the constraint is something other than an external boundary within which you're always optimizing. I point this out as one of the definitional inconsistencies that's there.

This also raises something which Dr. Vetter very appropriately noted: They use the word, "failure." And failure is a very nasty term if you come across a preexisting situation which is already out there and you sort of run into the fundamental question of who failed at that point. So there are some issues associated with the definition of a constraint versus the definition of optimization always being bounded.

Move on to the next slide and raise another one of the issues that is floating around, which is the role of collective dose. As I mentioned

a bit earlier, previously within the ICRP system, collective dose and a mathematical quantitative approach to optimization, which is what had been discussed. In these recommendations, ICRP is backing away from collective dose in a very significant manner. They are indicating, and there are many who would agree, that the double integral over all space and time is maybe a very nice number but doesn't tell you very much in terms of actually making any decision, because it basically adds up everybody who could ever possibly have gotten a dose and whatever that dose is, down to the microfempto, whatever, very, very extremely bits of dose, and adding them all together for a single figure of merit, pointing out that that really doesn't help you in the decision process. So it's not terribly useful on its own for making decisions.

The alternative recommended is something that's gotten nicknamed dose matrix. Matrix, I grant you, also implies a mathematical construct. I'm not sure that that's actually what they mean in all circumstances but rather a way of representing a wide variety of informational needs and attributes that goes into making the decision. We can go ahead and have the next slide, and of course I did that just as

she moved over.

There are a variety of attributes which they would suggest ought to form a matrix that allows you to understand the information that's available. Those might be organized under the classic questions, who, what, where, when, why, how in asking who got the doses, where are they, what are their characteristics, what are their ages, what are their genders, what were the number of people, where were they located, when did they get exposure, was it today, is it spread out over the next 50 years or is it 10,000 or 100,000 years from, what other considerations may come into play in this in terms of the types of values that people may place on this, what technical and other economic considerations may be part of this discussion and to use that combination of attributes in presenting the information to the decision makers and other individuals who are involved in the decision process to help make that decision. We can go ahead to the next slide. And in fact I'm going to ask you to go ahead to the next slide after that.

Another discussion which comes into the recommendations for the first time in a really significant way is the role of stakeholders. ICRP, if you go back to some of the documents that have been

published recently, has been acknowledging the issue of stakeholders, but this lays out very clearly that ICRP believes that there is a role for stakeholders, there's a recognition that stakeholder processes have wide varieties of kinds of processes and level of involvement. It would be nice if there were some words that sort of implied that the stakeholder process ought to be sort of graded to the level of decision and the level of risk. I don't actually find those words in the current document. Again, that's something which is a point we might wish to note.

Certainly, we here at the NRC have a very strong view with regards to stakeholder involvement being important and trying to grade the relationship of what you're trying to do and the risks that are involved and what you're trying to accomplish to both the processes that you use and the individuals that you involve in the process. If you stand back, take the 35,000 foot level view on this, again, this means that you involve the workers in the decision in how they're going to improve their work activities. And if you're dealing with a large environmental construct of how you're going to decommission a facility or remediate the territory, that you ask the people living in the area and get their input in the

discussion of who's involved and what their characteristics may be. All of that would be incorporated within this role of stakeholders. We can go to the last slide.

I will raise one other point of very interesting discussion. It doesn't get much text here, but it is a whole new attribute that has been put in. And as I mentioned in my talk at the beginning of the day, that is the mentioning of the best available technology approach within the construct of optimization. Depending upon how you choose to read the words in this draft report, it is not clear whether the ICRP means that the best available technology not entailing excessive costs is something which would be equivalent to optimization or might be part of optimization.

Certainly, I think that we would hold a view that they are very different in their underlying basis. Optimization, even as ICRP would have put it, looking at the best available protection. Best available technology, at least as I believe most people understand it, is a technology base -- what's out there and what is possible to do, what can you implement, does it necessarily look at whether a new technology makes a substantial improvement in the

protection or whether it's just a new technology that moves the decimal point over a little bit. Again, this is an area that does not have much within the text. I know because of meetings last week in Beijing that it is a point of discussion to determine how it should be playing with regards to the whole issue of optimization.

And with that, I'll complete my quick run through on identification of several issues that we have started to identify within the optimization process. Questions?

CHAIRMAN RYAN: I go back to ICRP, I think it's 55, is that right, where there's a little bit more meat on how do you do an optimization considering engineering controls and work practices and level of risk and all those kinds of things. That struck me as being a little bit more focused on exactly what you should do if you're a practitioner thinking about optimizing some practice or activity.

I read this and I see some interesting conundrums here. First of all, it's only for control of emissions. I would think that best available technology might be for exposure to workers too. So why they pick on emissions and why they pick up that. And if it's an optimization, how can it always be the

best? That just seems to me to be a conflict in the words chosen. And it leads me to the theme of some of the optimization discussion, which in a lot of ways it's interesting discourse but when I think about, well, how would I apply that as a licensee, I struggle with how I would get there. So in a lot of ways, it seems very detached from what a practitioner could actually put to good use, if you will. Is that a reasonable conclusion on my part?

DR. COOL: I think it is a reasonable conclusion based on the material that's currently in the draft. My observation, better than a hunch I think, is that a lot of this in fact is being driven by again a lot of the environmental protection concerns, issues that are being raised particularly in Europe, and I would note that a lot of things -- Mike, you can correct me if I'm wrong -- but a lot of the things in effluence and releases to the environment, not just in radiological concerns but for sulfur oxides and a variety of other things from various plants, have looked at best available technology. In fact, I think our friends at EPA have been known to fight more than a few lawsuits on whether they're using that approach or otherwise.

This, in one sense, may be an effort to

try and draw some nexus between the two. Whether it's a good nexus to be drawing or not and its implications for other things are two very good questions.

CHAIRMAN RYAN: Well, and I think you've brought out the real decision of what is the appropriate use of that terminology is really not something that's settled in a recommendation or fundamentally in a regulation. The EPA case is certainly one, but ultimately gets fleshed out in the courts and in the details of court cases that examine it case by case, and then after a while you see the pattern. But I just wonder how this fits in a radiation protection practice, how it improves where we are now in terms of environmental protection.

DR. COOL: Unfortunately, what's in the ICRP draft doesn't help us other than to speculate, as we are here.

CHAIRMAN RYAN: Okay. Thanks. Jim, any questions? No? Ruth?

DR. WEINER: I have a couple. You pointed to this information as forming a decision matrix or that that's what the proposal is; is that right? In any kind of decision making, there is usually an element of prioritization, and in this case it would be the prioritization of these information needs.

What does ICRP intend -- who do they intend would do this prioritization? Is it ICRP, is it the emitter, was that discussed, is it the receptors?

DR. COOL: They don't say.

DR. WEINER: Do they recognize that all of these information needs are not equally important?

DR. COOL: Yes. In the text, there is a discussion of weighting, which is in fact a mathematical term for giving priorities and relative weight in the decision-making process to certain of the elements.

DR. WEINER: Right.

DR. COOL: So that recognition is clearly part of the draft, and I can probably pick up a paragraph here if you give me a minute or two, but I know that is in the draft.

DR. WEINER: That is but they don't say how the weighting is done.

DR. COOL: They do not give a specific suggestion on how the weighting is done.

DR. WEINER: Why is zero risk considered a perfect world?

DR. COOL: Well, that's probably also a good question. From a philosophical standpoint, and I probably overstated that particular where we wish we

could go back and delete the transcript, but for a graphic moving towards that direction and being consistent with their underlying philosophy, all kidding aside, that if you assume linearity for the purposes of establishing a dose control framework, then if you can move to a lower dose, that ought to be a good thing.

DR. WEINER: Well, this does raise a question, and perhaps, again, it's a question about the linear non-threshold theory or in general it's a question. We know we are not going to move to zero dose. Everybody gets some anyway from background. Why not at least use -- I mean I admit that there may be an optimal dose or a minimum dose or something or a minimum dose over background or something like that. Was there some reason for stating this as zero dose rather than acknowledging that there is some minimum.

DR. COOL: I don't think ICRP actually uses the word, "zero."

DR. WEINER: Oh, that was your word.

DR. COOL: And the other thing that I think is an important clarification, and I'm not sure that it's in the written text in discussions like Roger Cleric a couple weeks ago, Roger is usually pretty careful to talk about this as a dose increment

above natural background and trying to reduce the increment, acknowledging that there's no such thing as a zero, as you correctly pointed out. So you're talking about dealing with incremental additions or reducing incremental additions.

DR. WEINER: Okay. Thank you.

CHAIRMAN RYAN: Ruth, let me add on to that and ask you a question or ask you and Don a question. It seems to me that if you think about this fundamentally, and leaving apart the linear non-threshold theory, I think that's a much maligned radiation protection theory for the purpose of standard setting that gets beat up inappropriately when people want to pick on something, but if you think about managing risk, you can manage risk by things and spending money and having activities, and if you keep trying to lower that risk, you end up turning 180 degrees around and ending up with more impacts on a lot of human activities.

For example, building a bridge. How many deaths does it take to build a regular bridge versus some new spectacular whiz-bang bridge in terms of bringing materials to the site and truck accidents and all the rest when you think of that bridge as a system?

If we think about activities and radioactive material or sources of radiation as a system and really think about it from soup to nuts, beginning to end, design to cradle to grave kinds of thinking, I think you've got to recognize that there is an optimum point where you've squeezed out as much dose reduction or risk management as you can and you've optimized it. Because if you spend more money and do more things, you might actually back up.

So that's something that I think doesn't really seem apparent in their optimization discussion that it can turn around on you if you're not careful. Is that a fair comment?

DR. COOL: I believe that's a very fair comment and true. You find -- what I think ICRP would probably argue is, yes, we agree with you precisely. That's why you find words about economic and social factors being taken into account. You don't find it perhaps as clearly as you might have wished it to be said, but I believe that they would agree.

CHAIRMAN RYAN: Well, that's fair. They didn't say if you don't taken them into account, you'll back up. That's really what I'd like to add to that comment is that you really will back up if you keep trying to overmanage the risk.

DR. WEINER: You mentioned that they're considering best available technology, which is in fact, as I'm sure Mike Boyd can attest, is a concept that comes from air pollution control, basically. And in air pollution control it almost always does mean less emission. And I guess my question is does ICRP recognize that in radiation protection it does not -- the analogy may break down? It may not always mean better protection.

DR. COOL: There's nothing in these words that allow me to say yes or not.

DR. WEINER: Okay. That's good. Finally, everybody talks about stakeholder involvement. Does ICRP -- does the document mention how stakeholders are identified?

DR. COOL: No, it does not. And my understanding of the foundation document, it describes some of the groups or individuals who might be involved, but it in fact does not attempt to get into either specific processes or specific identification approaches, recognizing that those vary almost as much as the kinds of decisions that are made.

DR. WEINER: Thank you.

CHAIRMAN RYAN: Dr. Powers?

DR. POWERS: Do you want me to comment

extensively or just interrogate the speaker?

(Laughter.)

CHAIRMAN RYAN: All of the above, sir, at your pleasure.

DR. POWERS: I'll comment. Mr. Cool and I find ourselves of like mind on a lot of these things, so don't really have much of an interrogation for him. I really don't want to talk about the deep philosophical underpinnings of the concept of ALARA. Certainly, I agree with anyone that tells me that optimization and ALARA are not identical. Optimization is clearly distinct. ALARA is a different process.

What I would like to focus on are the practical aspects of ALARA engineering. I do so only because Mr. Cool asked me to do so, but episodically I get to audit lots of ALARA engineering reviews. They're fairly routine aspects of operational activities at any nuclear facility. They are qualitative. Very seldom is any computation done. If it is, it's algebraic computation on the back of an envelope. By the time you get to the ALARA review, you're assured of falling below regulatory limits or constraints as you choose your language.

Quite frankly, I find these ALARA reviews

impressive for the number of things that people that operationally have to carry out an activity can identify that people that design an activity never even thought of. I see the ALARA is absolutely crucial for the maintenance of flow worker doses and even falling worker doses. Mr. Holahan certainly showed us some impressive results, and I'm willing to assert that substantial fractions of those came from ALARA and ALARA-like activities. Certainly, INPO, one of our speakers has mentioned, has been enforcing an ALARA culture within licensees. Similar enforcement exists within DOE facilities.

ALARA really is possible because of linearity. Engineers function best in linear worlds, and though the world may in fact not be linear, the truth is we can capture a huge amount of technology with linear models. And anything that you do that's going to make ALARA non-linear is going to have a negative effect on its effectiveness. So when you see signs of non-linearity creeping into things like taking into account social and economic factors, anything that makes the problem multi-variable, it is something really that becomes distressing. Quite frankly, as practiced now in a linear concept, ALARA is very well established, it's very well understood

and it's very functional, and you should not be complicating.

Now, I suffer the frustrating of nearly all of our speakers here in that the document they've given us is long enough but it lacks enough detail to comment on any one item very authoritatively. And so when you look at the plain text of the words associated with ALARA, first of all, you find there's not a great deal of text associated with it, and they look fine. It says go forth and do ALARA.

When you look at the interpretation of those words by others that have had longer to examine this document than I have, you find things that are distressing. Certainly, in some of the NEA analysis, they find this concept of best available technology not intending excessive costs. They associate that with ALARA, even though the plain text associates it with emissions to the environment.

Whether one associates it with ALARA or with the emissions to the environment, I think as a regulatory body, NRC has to be very careful of this concept of best available technology. I think some of those points have been made here. It's not the use of best available technology that we want to achieve. We want to achieve an adequate level of protection, and

it is seldom that we find the best available technology is the only way to achieve an adequate level of protection. I think the history that Ms. Weiner brought up, that of for best available technology shows that to be the case, that anytime a regulatory agency comes in and prescribes how an engineering organization carries out its job it in fact is probably interfering with the execution of that job.

It certainly becomes a problem for a regulatory agency that's charged with providing adequate protection of the public health and safety instead of the best available protection of the public health and safety.

ICRP does seem to associate this safety culture with optimization. This is an area that the ACRS has been extremely interested in. We find within our group many people with many definitions of safety culture. I think some of our speakers at lunchtime decided that any time you collect six people together, you will have probably 12 definitions of what safety culture is.

What we do know is that it's extremely difficult to monitor and measure safety culture, and it becomes a concept that's not regulatable. I think

ICRP would be far better off if it identified the attributes of safety culture that it wants to be incorporated into its document, including its ALARA practices, rather than calling out safety culture itself.

There also seems to be in the document an air or an aura of what I would call continuous improvement. I'm sure that continuous improvement is a laudable characteristic of an owner/operator organization, probably one that should be included. It is a major problem for a regulatory agency charged with providing adequate protection of the public health and safety. And we can see object lessons in comparing things that go on within government-owned facilities and those in commercial facilities to understand what continuous improvement can do for you.

Continuous improvement can lead to a focus on the minutia because you can get improvement by looking at things that are familiar and small, whereas things that are big and difficult are tough to improve on. And I think we need to be very careful trying to regulate for continuous improvement rather than regulate on minimization of risk, because we really want people to go after the big things that are big contributors to risk and not go after the minutia.

Well, I think that concludes everything I wanted to say. My comment on ALARA is KISS, keep it simple stupid. It's got to be a linear, single-objective function that's comprehensible and can be carried out routinely. This is especially true when we have a quantitative measure of what reasonably achievable is, as we do. Introducing best available technology into that is a route to assuring we'll stop doing ALARA.

Now, Dr. Weiner will promptly ask me why I would want to continue to have organizations knocking themselves out to reduce a dose that's already very small, and I think I would agree with one of our speakers here that a lot of the motivation for ALARA is not just to reduce the dose to the workers, it's to improve the efficiency of operations.

Dr. Weiner doesn't let up. If any of you know her, she's very tenacious and she'd say, well, why should I care in radiation protection about whether the work goes very efficiently? Isn't that a management function? Well, quite frankly, what has impressed me most about ALARA activities is the number of times that in the ALARA review the potential for accident has been identified and subsequently avoided because of the ALARA review.

And so it is not, Dr. Weiner, because we're trying to reduce the dose alone, that's certainly a motivation, but we'd also like to have further check to make sure that we're not leading ourselves into an accidental dose that of course could be well above the limits. With that, I'll stop.

CHAIRMAN RYAN: Thank you, Dana. Jim? Dana, a couple of thoughts that I'd like to pick your brain about. One, I couldn't agree with you more that the ALARA review process, if done right, addresses chemical, electrical work practice, material management, lots of other safety concerns besides radiation safety. So if it's integrated like that, you can sure get a lot more out of it than worrying about a few extra millirem.

DR. POWERS: It's becoming such a familiar and easy process that integrating itself is very, very natural.

CHAIRMAN RYAN: And that to me is the transition from an ALARA process to a safety culture is when that all wraps together seamlessly within an organization.

Don mentioned a step that ICRP is kind of drifting away from collective dose. On the one hand, I think that's great because collective dose as a

measure of public risk doesn't mean much, particularly if you're multiplying a pismorem, which is the smallest unit of radiation dose you can talk about yet get paid times a gazillion people. You get a big number and you can calculate lots of cancers but it's meaningless at the end of the day because the structure of it falls apart.

I do know, though, that in my own experience in the low-level waste industry, and I'm sure it's true in power plants from what I've seen of activity in power plants, there's a lot of focus on, let me call it, man-rem calculations for lack of a better term, and I guess that's an example where the number isn't so important as an absolute, I guess in my own view, but comparing scenario A man-rem versus scenario B is a metric that helps you in decision making. Could you just a comment a little bit more and expand on that for us?

DR. POWERS: Yes. It's an area that's not just in radiation protection but in worker safety all together, that what we call the societal risk, the society of worker risk, arises a lot because it's difficult to predict where individuals will be at the time of events. And so you'd like to use a more collective smeared out measure and it's used exactly

as you describe. It's not so important what the actual number is, though if it gets very big, certainly you'd worry about that. But you'd like to use it as is doing things this way better than doing things this way? And you'd like to work with a number. As I said, engineers are very linear people and like linear models. And so you use a single metric that has some linearity.

This has been made a technology, I would guess. A codification of it has come out of Dupont for the safety analysis of chemical processes where they use what amounts to a societal risk to the working population. And it has subsequently been adopted into the Department of Energy and some of its analysis of its facilities. I guess it's now into the regulations on nuclear facilities by the NRC and has a value to it because of uncertainties about small populations of workers in the event of hazardous events. It has a good history within the chemical industry for avoiding worker hazard.

There are some who view it as competitive to the quantitative risk assessment. I think from my point of view I look at them as two sides of a similar coin.

CHAIRMAN RYAN: I think Don had a comment

on the first point. Don?

DR. COOL: Yes. I think there are a couple of things that are important within this. Yes, a collective dose calculation has been used as a measure of performance metric. One of the things that's immediately important about that is that's not a unbounded collective dose. In most cases, you know who, you know what, you know when. It was for a particular task at a particular facility, and you use that as a measure of performance to see if a similar task at another facility, at least on that metric, was better or worse. And that actually fits within ICRP's definition, because then you've defined some of the who, what, where rather than simply being in double integral over all space and all time.

What they would then caution you is that it's probably still not good enough to give you all the information to actually know whether the protection was better in one case or the other because there will always be other factors -- the size of the facility, the layout of the rooms, other things that were going on at the time -- that may mean that even though the collective dose in Case B was a little bit higher than the collective dose in Case A for this other plant, they may have actually done a better job

over here in Case B because of other things that were going on.

CHAIRMAN RYAN: If I heard Dr. Powers correctly, that gets back to ALARA engineering, because the engineering part kind of takes in do I have a big enough room to have shielding, am I height-restricted, all those practical things that have to be considered. Dr. Weiner?

DR. WEINER: I was going to make a comment about the collective dose concept. It does have -- you use it in calculating transportation -- risks of transporting of radioactive materials. In the absolute, it doesn't mean anything, of course. I mean you are multiplying zillions of people by nano millirems and pismorems. But in comparing the risks along one route with another, it does have a certain utility. You can say this one -- and you can fold a lot of other things into those risks, like accident rates over certain parts of the route and so on.

So there is a utility in comparing. It's just that in the absolute it's difficult to keep reiterating that the absolute number of person-rem or man-rem is not a particularly significant figure if that number involves a very small dose.

DR. COOL: Yes. That's very, very true.

CHAIRMAN RYAN: We are magically on schedule to hear other comments for these last two presentations. We're now at a point where we could entertain other input from members of the audience, folks that might want to make additional comment. Ralph?

MR. ANDERSEN: Ralph Andersen, NEI. I just wanted to reinforce what I thought was a very important point, and that's the notion of maintaining the single objective focus and not mucking it up with a whole bunch of other variables. It really goes to comments that Dr. Powers as well as Dr. Cool.

Yes, when you make a comparison there are often different factors that you can rationalize to say, well, okay, A was better than B or B was better than A, but as an industry, a lot of our success has been in deciding not to make that rationalization. That is, we challenge ourselves to say, well, the fact that it can be done for this less dose proves that it can be done for this less dose. My job is to go figure out how to take care of these other extraneous factors and get it done. But it says single-minded focus, and so I just really want to reinforce that, because I think that's precisely where it transitions to safety culture.

CHAIRMAN RYAN: Well, thanks, appreciate that point. Any other comments, questions? Yes. Tell us who you are.

DR. HAMDAN: Latif Hamdan, ACNW staff. This is for Don Cool. You know, there will be scenarios, as has been mentioned, when ALARA may not be compatible with optimization, just like best available technology. And so the question is in the draft, in the ICRP, did they discuss this? They left a lot of adjectives and they have the optimization. Did they address this that they may not be compatible? And in these scenarios when this situation happens, then what prevails?

DR. COOL: I think the answer to the first question is, yes, they address what ALARA is and go on to address the broader view, to use their word, that optimization has to include a variety of these other factors. I don't think they give a particular break point for what is or what isn't beyond their recommendation that it be optimization and that unless three is a unique circumstance where dose reduction is the only factor that whoever is conducting the analysis be keeping in mind the potential for accidents, the reduction for waste and the other factors that may be important.

As Dr. Powers noted, a lot of what happens in these analyses is you come across things -- this is a real dangerous spot, this or that can happen. That then becomes more than an ALARA review. It becomes closer to what ICRP is talking about in optimization because it's identifying other factors that are important for protection and making sure that the overall protection is the best under the circumstance.

CHAIRMAN RYAN: Yes, Ralph?

MR. ANDERSEN: Ralph Andersen, NEI. A statement made often in many of the presentations by Roger and others accompanying the new recommendations is the change in philosophy to the idea that if you protect the individual, you have in fact protected the population. If that premise really is underlying the new recommendations, then my view is it's a very short step to imply that collective dose has no relevance in ascertaining the quality of protection provided, that that really continues to come back to a determination of whether you've protected the individuals. Is that notion consistent with the philosophy that underlies the recommendations?

DR. COOL: Well, that's a very interesting philosophical question. I'm not sure I could speak authoritatively for ICRP. They are certainly leaning

that direction but have not completely walked away from the fact that the number of individuals exposed and other factors are also important, that it isn't simply the magnitude of each individual dose. What they have taken a significant step back from is that that collective number is not by far the most important factor, that it is the individuals and then how many of them did you get?

CHAIRMAN RYAN: Anything else? Yes, please, Mike?

MR. BOYD: Is this working? Maybe not.

CHAIRMAN RYAN: It's fine.

MR. BOYD: Just a couple of thoughts on utility of collective dose, and I think that it's generally thought of as being useful in managing worker doses, worker scenarios. It occurs to me that there are two other important examples. One is it has great utility when you define collective dose in space and time, not when it's truncated, for doing the kinds of regulatory impact analyses that we're require to do when we issue new regulations to help us estimate the actual number of lives, the cancers averted or lives saved or whatever. So it does have some utility there.

And it had had -- when the world of

increasing use of nuclear power and nuclear applications seemed to be an ever-expanding universe in those bygone days, we worried about long-term persistent radionuclides accumulating, both in the environment and particularly in the stratosphere, and that's why we back in the '70s, I guess it was, set limits on noble gas emissions, looking at some equation of what we thought would be a continually expanding universe and not wanting to -- even though the doses to individuals would be very small, over time they could be build up. And collective dose is another tool for helping you gauge that. Now, obviously, you can be wrong, as we were at the time, but I just wanted to point out those two uses.

CHAIRMAN RYAN: Well, I think I understand the second whereas to metric.

MR. BOYD: Yes.

CHAIRMAN RYAN: I disagree wholeheartedly with the first. When you multiply those trivially small doses by some risk estimator and say cancers or deaths occur as a result, I think that does not properly account for the conservatism in the model under which that calculation was made.

MR. BOYD: There are many conservatisms in the model, but I guess the only counter argument is

that in some cases we're required to do that, we have to show --

CHAIRMAN RYAN: Even if it's statutorily required, I appreciate your obligation to do that, I think scientifically it's at risk of being just flat out wrong.

MR. BOYD: I think it is important that you truncate it in space and time.

CHAIRMAN RYAN: Absolutely. And I think also, as Milt Levenson, a former member of this Committee, would point out, if something is four or five or six orders of magnitude conservative or some huge conservatism, it's not conservative, it's wrong.

MR. BOYD: Right.

CHAIRMAN RYAN: So I just recall that we have to be careful that as a metric, in a lot of circumstances, whether it's the workplace or in a truncated assessment or to meet a legal requirement, there is utility. But I think we've got to be very careful not to allow it to be used in situations where it is going to be interpreted numerically and success or failure would be judged by the numerics when in fact the numerics don't mean anything as an absolute quantity. That's the point. Thanks. Thank you for that clarification. Anything else? Any other

comments?

Well, that being said, we're at the part of this meeting where we can, I think, work together to draw to a close. What I'd like to ask our members to do, including our consultant and ACRS participant, is summarize for everybody here what points they might think are summary points that would give us the kind of start-up for our letter writing session, which will occur on Thursday morning at about 8:30 we'll start the letter writing session formally. So without further ado, let me start first, Dana, with you.

DR. POWERS: Well, I've written out seven areas that I thought you might address in your letter, and many of them I've talked about up to now. One I have not. One is that especially in the numerics and any new recommendation I think it's imperative that eventually there would be a document which allows somebody to trace where the number came from and exactly what data it's based on very specifically. I think that's an essential thing that will have to appear.

The other comment that I have not spoken to I think you may want to consider recommending to the Commission that they defer action in this area until they have the advantage of having to BEIR VII

report available to them to augment what they have here.

And another recommendation you might want to consider is that the staff cast as one of the options for the Commission to consider is adopting the more modern ICRP recommendations, not as a mandatory change to the 10 CFR but as a voluntary change to the 10 CFR. That seems to be a trend we're adopting when we're having challenges associated with the cost/benefit ratio.

CHAIRMAN RYAN: When you say adopt the more modern recommendations, could you be a little bit more specific?

DR. POWERS: Oh, ICRP 60 and these 2005 recommendations. That's what I meant, more specifically.

CHAIRMAN RYAN: Okay. Great.

DR. POWERS: Now, they're associated within a lot of documents and whether you endorse those in the 10 CFR as part of the rate guide, I mean that's a judgment somebody else has to make at the appropriate place to do that, not do that. But especially when you're wrestling with dealing with established licensees who clearly are -- what they're doing is safe enough but you want to bring new

technology to them, better sciences, better methods and things like that, this option of doing it voluntarily I think has some attraction to it. I pointed out the example of fire protection where you've done that. We've also done that in revised source terms for accidents. We're looking to do it in revised definitions and design basis accident. There's some attraction to doing that and what not.

At any rate, I've written these notes out for you. I'm not going to be able to participate in the Thursday session, but --

CHAIRMAN RYAN: We have your input.

DR. POWERS: -- for whatever they're worth.

CHAIRMAN RYAN: We appreciate your participation, Dana. Thank you very much.

DR. POWERS: Let me say that I have thoroughly, thoroughly enjoyed this. The speakers were excellent, the information was excellent. Reading the documents was a very worthwhile effort on my part, and I hope to continue to interact with you as you develop your work in this area and what not.

CHAIRMAN RYAN: Wonderful.

DR. POWERS: And I'll do my best to try to summarize this for the ACRS as a whole. I know

they're interested. It's not a regular part of their agenda, but they like to be kept up to date on these things.

CHAIRMAN RYAN: Okay. And if we can help you in any way report back to the ACRS, we'd be happy to do that.

DR. POWERS: Thank you.

CHAIRMAN RYAN: Thank you. Ruth?

DR. WEINER: I think I've gotten it all in the questions that I have. I think we should -- I think in our -- a theme that keeps running through this, I have to agree with what Dr. Powers just said, and that is that recommendations could be adopted as a voluntary alternative, because to continually adopt these new recommendations is going to create some hardships. And they're not necessary hardships. And I hope that we keep that in mind what other fallout there is from wholesale adoption of ICRP recommendations when there is no tangible improvement, in some cases, to safety.

CHAIRMAN RYAN: Okay. Thank you. Allen?

MR. CROFF: First to say something that I think has been implied by both Dr. Weiner and Powers is we can't treat this draft report as a monolith. After listening today, it's very clear that some parts

of it are maybe not too bad and some parts are giving some significant heartburn. My sense is things like tissue and radiation weighting factors swell. If you go to the overall methodology, there may be some impacts there, and, as it has been suggested, there may be some methods to sort of work around that to start to get to the more modern methods without really forcing it on everybody in a crash basis. And then we get to some of the dose limits constraints and some of those seem to be potentially causing some significant difficulties, and those will have to be treated in their way.

I'm a little concerned, especially on the limits and constraints, whether at this point we know enough about why the ICRP or its working group did what it did enough to really comment well on whether that makes sense or not, and with these foundation documents seemingly coming out very slowly, the ICRP comment deadline approaching, if not extended, of course, how far we can go in saying what we recommend as being right and wrong or anything in the middle.

So I hate to say this, maybe we're going to end up with a couple of letters in time, the first letter commenting on some things we do know and we think we're confident about and then some explanation

of why we can't comment on other things and await the rest of the foundation documents, maybe the BEIR document at the same time as part of the whole package. With that, I don't think I'm going to go into any specifics.

CHAIRMAN RYAN: Okay. Great. Mark?

DR. CLARKE: A couple of things. One, picking up on one of the questions that Mike Ryan asked, and I'll just pose it as a question: Will the foundation documents speak to the uncertainties so that any recommendations for new standards can be what I guess I'll call uncertainty in form? I think that would be pretty important. We're in the position of having the recommendations but not the foundation documents. It seems to be kind of like a strange juxtaposition.

I was very intrigued by one of the comments that Ed Bailey made and that also poses a question: Do dose reductions encourage the perception that risk is more dangerous than we thought? I guess we had hoped new science would take us the other way. With that event, I think the scientific basis for any changes just needs to be very understandable and very transparent.

And then, finally, I think the EPA

experience with the ecological risk assessments experiment, the issue about non-human targets.

CHAIRMAN RYAN: Thanks, Jim. I guess my largest point is that when I asked my $64,000 or $128,000 question, I got a pretty uniform answer and I didn't hear any dissent, and that is that adopting these recommendations would be not helpful, they'd be at best neutral and in some cases, as Dr. Vetter pointed out so well, problematic. I see some nods, and nobody's saying, "Oh, that's all goofy." So I think that's a very important major point from our discussions today that should make its way into our letter.

I do think on the positive side there are some very important things that are elements that are quite good, and that is that we have made substantive improvements in the underpinning of the science in terms of internal dosimetry. We have, in some cases now, 50 years of modeling activities and study to improve our models of the human body and models of radioactivity movement in it and through it. So that's something that I think needs to be recognized as something to bring forward from the exercise.

In addition to the basic radiation biology, I think there are some physical quantity

issues -- the improvement in proton and neutron radiation weighting factors and also from the epidemiologic evidence -- and we know that's in progress, as has been pointed out, that we ought to think about this BEIR VII as it's coming along something we should wait for. It sounds like a pretty reasonable thing given the timing, that the epidemiology evidence has resulted in the improvement of organ risk factors and has for all practical purposes confirmed our overall risk estimators which is the underpinning for everybody's radiation protection practice at the end of the day. So there is, I think, three or four very positive things that we need to grasp that are very good.

Now, I asked Vince the question of what gets into a regulation and what gets into a guidance document or a NUREG. I think it's something that the staff has a better feel for how to best communicate it to licensees as advice or guidance or requirement. Vince, you mentioned something interesting, for example, that maybe the weighting factors should come out all together and become a guidance document to make them easier to address should that evolve in some way. So that's certainly something I think we should consider as we make recommendations that maybe that's

the direction to think about.

But I think, in my own view, I kind of agree now with what Roger said, that this is evolutionary rather than revolutionary, and it's incremental, in my view, in terms of where I judge it as how does it improve radiation protection practice? Is it a tremendous step forward in that regard? And I guess I see it as, at best, neutral and perhaps creating some problems with some segments, taking note of the fact, for example, that the power industry has accomplished great things in dose reduction and plant management and across the industry has done a very good job under a static set of basic fundamental requirements. They didn't need the further guidance to do well, and there are examples where things haven't gone in the best direction possible. Though possibly compliant, they could have gotten better perhaps or so on. So I wonder what we would get in trying to adopt it.

I'm troubled by the language issues, and I think Ed Bailey pointed out that constraint, limit, requirement, recommendation, I mean all of these are kind of very special words in the regulatory world, and I'm not sure that what the ICRP has in these recommendations matches up with what is our lexicon

here in the U.S. system. It's hard enough to teach students about the Federation Radiation Council and the Atomic Energy Act of '46 and what's not regulated by either one let alone trying to say, "Let me tell you what the word dose has meant over the last 50 years and what it means now." So I think that's an aspect of adopting regulations that there is a cost and an implementation hurdle to get over if we saw great merit in these recommendations. So I think that's there.

And, again, I'm a little bit troubled by the fact that really there's not much huge difference in what ICRP is recommending as limits versus what we have in the U.S. I think we had several charts and tables that showed that they were more or less fairly well aligned, whether it's the generally applicable public protection standards that the EPA has responsibility for or the workplace or public exposures from licensed activities that the NRC has responsibility for or the agreement states have responsibility for. It's true that there is general agreement. There are a couple of exceptions that I think Dr. Vetter and others noted, but we're not wildly different.

And, again, I come back to the idea that

do these offer significant advances in radiation protection practice or incremental advances? And, again, I separate the basic recommendation aspects from the things I mentioned as the positives, like the dosimetry modeling and practices that if adopted might make it more uniform for licensees to calculate internal dose and so on and so forth, or might make it better for future regulatory activity at the NRC to have all of that dosimetry available and so forth.

So that's kind of my bullet points. Hopefully, I'll be able to recreate those as I start to tap on my computer to write all this out. But I'd be happy to have any of the panel members' reaction to what you heard as the major points. Did we miss anything? Did we catch it all? What do you think?

DR. ECKERMAN: I thought that Vince Holahan made a good point that we need to keep in mind that we're still back at ICRP 26 and when you've gone through the discussions, I mean in the dosimetry we've already gotten into using information in later documents, but in point of fact what's really adopted in our recommendations is all the way back to 1977 and '79, ICRP 30. So there are a number of years that have gone by that we need to keep in mind on that.

CHAIRMAN RYAN: And that's why I

mentioned, Keith, that updating the dosimetry might in fact be a step where we could get internal dosimetry assessment methodology. You know, licensees have access to that now if they solicit to do that or request to do that, but maybe formalizing that -- that was my point is to agree with what --

DR. ECKERMAN: Right. And that I also think is very important, because just as we had mentioned here that in some of our ALARA activities the important thing is probably the prevention of or staying on top of the accident situation and the potential for. And in the dosimetry, much of what we do in routine dosimetry also has to be brought into bear on dealing with actual heavy exposures that we might be facing and so forth so that there is a need to not lock ourselves down into that earlier dosimetry system that may not serve us well under those situations. And that's what you're alluding to there --

CHAIRMAN RYAN: Exactly. And you did a good job of --

DR. ECKERMAN: -- as some of our other needs. That ICRP dosimetry system, for better or for worse, it's probably the only game in town for a lot of dosimetric questions.

CHAIRMAN RYAN: Oh, sure. And there are parts of 10 CFR that go back, so bringing that forward is a positive step. Any other reactions, comments, questions? Vince, did we do a good job of summarizing?

DR. HOLAHAN: Well, I think you've done a good job of summarizing. The biggest thing we have to make sure we do is we will have a single set of comments going back to ICRP from the staff. Those comments will be sent up to the Commission. We have to make sure whatever is in our comments that this Committee's comments are also recognized, whether they are embedded into our comments or are two parallel documents or however and make sure the Commission recognizes that there has been an iterative process going on.

CHAIRMAN RYAN: Well, I think what we will report in our letter is also in fact to call the participants by name and organization and, as we usually do in our letters, describe the activity for the day and then provide our summary of what we heard and what was reported to us and then offer our comment on it. And that goes to the Commission. And, again, we will try and get that letter writing session accomplished Thursday. You're all invited to attend

that and if there's some particular phrasing that we've done that's not exactly representative of what you wanted to say or what we heard, there's an opportunity to have interchange at that point. So I think we'll accomplish the goal of open communication about it, but our letter will go to the Commission in time for your knowledge of what we've set up and then your comment thereafter. Dr. Vetter?

DR. VETTER: I guess I'd just like to support what Dr. Croff said, that's it not a monolith. There are some good things about it, some neutral things, some bad things, and whether you structure your letter in that regard or not, I think we just need to be cognizant that there are some things about these documents that do lead us forward.

One of those I'd like to support is the advance in internal dosimetry. Just relative to a medical environment, we have very few -- as I mentioned, very few internal exposures. That's pretty rare, occupational exposures. But it's very common to do dosimetry or human studies. And we basically have to use the latest. We're not necessarily tied to do anything in particular or any method in particular, but we basically have to use the latest that's out there. And so when this dosimetry goes forward, new

weighting factors and so forth, we will be adopting those.

CHAIRMAN RYAN: Thank you. Keith, any additional comments? Mike?

MR. BOYD: Just one quick one. Coming in here I think I had seen the recommendations as being not terribly incompatible with the way we do business at EPA. I mean the dose numbers that were there wouldn't really cause us any problems except for potentially the emergency worker PAG issue that I raised. But I've sort of been enlightened, I just wanted to say, by Dr. Vetter's comments about the medical aspect, which I frankly hadn't focused on. And I just wonder if it's a problem for us, which I agree it appears to be, think about those third world countries that are using our old uncollimated x-ray machines and what they're up against. That's it.

CHAIRMAN RYAN: Well, that is an aspect that I think Dr. Clarke mentioned is that we sometimes think of them in terms of just the application here and they are making these recommendations to every country. So that's an aspect of it we have to think about. Ed Bailey?

MR. BAILEY: I don't think I have anything to add.

CHAIRMAN RYAN: Well, thank you for coming. And, finally, Don Cool.

DR. COOL: Just stand back and make the observation that I think in one sense we have revalidated that we have, the United States has a well-functioning radiation protection architecture in the regulations and how our licensees use it. And much of what I think we ran into today was the question of terminology and description, either changing terminologies or inconsistent uses of a word or multiple instances of a word meaning different things. And we're struggling with how that helps to actually improve a well-functioning protection system.

And part of what we're going to need to do is evaluate that and improve both in context of are we making an improvement to the actual exposures of the individuals, and are we improving our ability to explain it to ourselves, to a user who has to implement it or to someone out on the street who asks why are you doing what you're doing?

And as rightly noted here several times, there are some pieces of this which do help us, and there are a number of components of this where it either isn't clear that it helps or it's pretty clear that it does not help us, at least as presently

drafted.

CHAIRMAN RYAN: Okay. Thank you. Any other comments from the audience or other participants today? Yes, Ralph?

MR. ANDERSEN: Just a couple. To add on to Keith's comment, actually, by regulation, our 50 licensees are required to use ICRP 2 to calculate dose numbers of the public. It creates an interesting dilemma when we get a Master's or a Ph.D. student in health physics that comes to our site to start work. The first thing they say is, "What the heck is this? I have never seen this in my life." Not to mention that you can't buy ICRP 2 anywhere. So I really endorse the notion of voluntary compliance concept.

I would just note, though, that if -- reinforce what Vince said. I think considering putting that type of thing in regulatory guides which creates a lot more flexibility is a smart move, but what you might want to do is consider that if you're going to offer a voluntary option is to make the only option to either use what you're currently using or use the most advanced methodology so you don't have people choosing options in between.

The other comment I'd make associated with that, which I've always seen as problematic, is

actually under accident conditions at a nuclear power plant. In our transition from routine operations to an emergency plan, we actually change from the ICRP 2 base ideally to an ICRP 60 base, because actually the PAGs drive us from the point of the offsite recommendations. And you actually contrive some scenarios whereby you would declare yourself into a condition and then run the calculation in a different base and find that you're not there yet, which would be at the least embarrassing in a public communication concept. So there are some very legitimate reasons for bringing us up to date and up to a fairly common basis.

Finally, on the environmental radiological protection area, my simple comment would simply be despite the fact of sitting through two years of interactions with the ICRP and reading the most recent recommendations, I still can't find where they made the case for the need for a new stand-alone framework. And most of the other comments I have about that flow from that basic case. I don't understand what the problem is that we're trying to solve.

CHAIRMAN RYAN: Ralph, that last comment actually stimulated my memory to talk a little bit about that aspect of it as well. In my own view, I

have not seen any evidence or heard anybody say in peer review publications or whatever that there is a case that needs to be solved. Second, I haven't really seen anybody say that the principle that if you protect man, the environment is also protected is invalid either in a given case or across the board. So I'm waiting for that evidence. Third, and most importantly, I think my own view is that what has been offered is at best a logical construct of some sort for a system without any real anchor to it. I don't know how I would calculate dose, for example. I know how I would calculate absorbed dose to a reference of species or a bumble bee or whatever it is, but I would have no idea what that meant in terms of any one of the half a dozen dose-equivalent concepts we've rattled around today. And I don't even know if that kind of number would be even meaningful in that sense.

So without -- my own view is that at the end of all of that, until I see some evidence that there is a problem, as you pointed out, and, second, that there's some end point of interest or there's some reason to press forward or a framework to press forward with the science of it, I remain yet to be convinced or yet to see more from whatever the Committee is working on. I think the important point

from the Commission's point of view -- I mean the Commission upstairs, not the Commission of ICRP -- is that without further substance to all of that, it just doesn't seem like pushing it forward or saying much of anything about it is meaningful or helpful. I just don't see the meat on the bones of this logical construct. So that's my own view.

Anything else? Any other comment, question?

Well, with that, I think we can certainly close for the day. I want to thank each panel member for their time and energy and preparation. I want to thank again Dr. Powers from ACRS for being with us today. I look forward to the opportunity to have him participate in the future and maybe join him in an ACRS meeting. So thanks again.

DR. POWERS: I can't emphasize how much I appreciated being here and appreciated the speakers.

CHAIRMAN RYAN: Well done all around. Thank you all very much, and to our participants from the audience, I also want to say thank you very much.

And with that, we're adjourned.

(Whereupon, at 5:24 p.m., the ACNW meeting was concluded.)

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