UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001

September 4, 2013

MEMORANDUM TO: ACRS Members

FROM: Derek A. Widmayer, Senior Staff Scientist **/RA/**
Technical Support Branch, ACRS

SUBJECT: CERTIFIED MINUTES FOR THE ACRS RADIATION PROTECTION AND NUCLEAR MATERIALS SUBCOMMITTEE MEETING, APRIL 27, 2012 – ROCKVILLE, MARYLAND

The minutes of the subject meeting have been certified on June 6, 2013, as the official record of the proceedings for that meeting. Copies of the certification letter and minutes are attached.

Attachment: As stated

cc w/o Attachment: E. Hackett
C. Santos

UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001

MEMORANDUM TO: Derek A. Widmayer, Senior Staff Scientist
Technical Support Branch, ACRS

FROM: Dr. Michael T. Ryan, Chairman
Radiation Protection and Nuclear Materials Subcommittee

SUBJECT: CERTIFICATION OF THE MINUTES FOR THE MEETING OF THE RADIATION PROTECTION AND NUCLEAR MATERIALS SUBCOMMITTEE, April 27, 2012 – ROCKVILLE, MARYLAND

I hereby certify, to the best of my knowledge and belief, that the minutes of the subject meeting on April 27, 2012, are an accurate record of the proceedings of that meeting.

/ RA / 06/06/2013
Michael T. Ryan, Chairman Date
Radiation Protection and Nuclear
Materials Subcommittee

Certified On: June 6, 2013
Certified By: Michael T. Ryan

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
RADIATION PROTECTION AND NUCLEAR MATERIALS
SUBCOMMITTEE MEETING MINUTES
April 27, 2012
Rockville, MD

The Advisory Committee on Reactor Safeguards (ACRS) Subcommittee on Radiation Protection and Nuclear Materials (RPNM) met on April 27, 2012, at 11545 Rockville Pike, Rockville, MD, in Room T2-B1. The meeting was convened at 8:30 am and adjourned at 11:41 am.

The entire meeting was closed to the public to discuss pre-decisional materials. Mr. Derek A. Widmayer was the cognizant ACRS staff scientist and the Designated Federal Official for this meeting. Since the meeting was closed, there were no requests for time to make an oral statement or written comments received from the public concerning this meeting.

ATTENDEES

ACRS

M. Ryan, Chairman
D. Skillman, Member
H. Ray, Member
S. Armijo, Member
S. Schultz, Member
D. Bley, Member
D. Widmayer, ACRS Staff

NRC Staff

D. Cool, FSME/DILR
V. Holahan, FSME/DMSSA
D. Jackson, FSME/DILR
A. Huffert, RES/DSA

SUMMARY

The purpose of the meeting was to review and discuss the Draft SECY Paper, **"*Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance.*"** The Draft SECY Paper contains the staff's recommendations on conforming the NRC's radiation protection requirements and guidance to the latest International Commission on Radiation Protection (ICRP) Recommendations concerning radiation protection (Publication 103, 2007). The Subcommittee planned to gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee at its June 2012 Meeting.

SIGNIFICANT ISSUES	***Reference Transcript Pages***
Dr. Ryan, Chairman of the Subcommittee, introduced the topic of the meeting and the presenter from the NRC staff	1
Dr. Donald Cool provided the FSME staff presentation on the development and contents of Draft SECY Paper, "*Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance*." The presentation included a brief history of the ICRP publications and NRC implementation of the recommendations, summary discussions of each of the major revision efforts proposed by the staff in the Draft SECY Paper, and discussions about the stakeholder workshops held to discuss the revisions and main points brought up by stakeholders in these meetings.	2 – 150 (Slides Pgs 151 – 185)
Members of the Subcommittee brought up the following issues during this presentation from staff:	
- Clarification that the regulations that would be revised if the entire effort discussed in the Draft SECY Paper would principally be Part 20 and Part 50, Appendix I (Schultz)	10
- Clarification that natural background radiation is not to be included in exposures to the public as well as medical diagnostic or therapeutic radiology when determining whether the 100 millirem/yr recommended dose limit is being reached. (Ryan)	40 – 43
- The bases for some of the empirical data used in studies on doses received and how they vary according to societal factors. (Ryan and Armijo)	46 – 49
- The inclusion of accelerator-produced materials and the doses from them into the items regulated by NRC. (Bley)	56 – 59
- The questions around the options for lifetime exposures and the pros and cons or methodologies to keep records. (Bley and Skillman)	64 – 68
- Whether there is a "safety" benefit from adopting the international terminologies when you update the dose calculational methodologies to be consistent with the rest of the international community (Ryan and Skillman)	74 – 77

- Whether there is a real scientific justification to make changes to the allowed dose to the lens of the eye (Ryan and Bley)	97 – 101
- The possible difficulties and options associated with changing the requirements for protection of the fetus and embryo (All Members)	101 - 111
- The impacts of updating the terminology to use SI units (Ryan)	115

ACTION ITEMS	***Reference Transcript Pages***
Staff is asked to provide a briefing, if appropriate, on the contents of NUREG/CR-6112, "*Impact of reduced dose limits on NRC licensed activities. Major issues in the implementation of ICRP/NCRP dose limit recommendations*."	124

ATTACHMENT

Official Transcript of Proceedings, Meeting of ACRS Radiation Protection and Nuclear Materials Subcommittee [CLOSED], April 27, 2012, Rockville, MD.

Document Provided to the Subcommittee:

1. Draft SECY Paper, "*Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance*" (including Appendices) (Pre-decisional-Official Use Only)

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on Reactor Safeguards
Radiation Protection and Nuclear Materials

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Friday, April 27, 2012

Work Order No.: NRC-1581 Pages 1-149

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON REACTOR SAFEGUARDS

(ACRS)

+ + + + +

RADIATION PROTECTION AND NUCLEAR MATERIALS

SUBCOMMITTEE

+ + + + +

~~CLOSED SESSION~~

+ + + + +

FRIDAY

APRIL 27, 2012

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

The Subcommittee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B1, 11545 Rockville Pike, at 8:30 a.m., Michael Ryan, Chairman, presiding.

COMMITTEE MEMBERS:

MICHAEL T. RYAN, Chairman

J. SAM ARMIJO, Member

DENNIS C. BLEY, Member

HAROLD B. RAY, Member

STEPHEN P. SCHULTZ, Member

GORDON R. SKILLMAN, Member

NRC STAFF PRESENT:

DEREK WIDMAYER, Designated Federal Official

DONALD COOL

VINCE HOLOHAN

ANTHONY HUFFERT

I-N-D-E-X

P R O C E E D I N G S

(8:30 a.m.)

CHAIR RYAN: The meeting will now come to order. This is a meeting of the Advisory Committee on Reactor Safeguards, Subcommittee on Radiation Protection and Nuclear Materials.

I am Dr. Michael Ryan, Chairman of the Subcommittee. ACRS members in attendance are Sam Armijo, Dennis Bley, Gordon Skillman, Harold Ray and Steve Schultz.

The purpose of this meeting is to discus the draft SECY paper recommendations for policy and technical direction to revise radiation protection regulations and guidance.

The draft SECY paper makes recommendations on conforming the NRC's radiation protection requirements and guidance to the latest recommendations of the International Commission on Radiological Protection.

The meeting this morning is closed in order to discuss pre-decisional policy information so I want to correct that. I told one person it was open, but it's closed.

Derek Widmayer is the designated federal official for this meeting. The Subcommittee will

gather information, analyze relevant issues and facts, and formulate proposed positions and actions as appropriate.

The Subcommittee plans on proposing a letter on this matter for consideration at the full Committee at the upcoming June meeting. A transcript of the meeting is being kept and will be made available on the web.

It is requested that speakers first identify themselves and speak with sufficient clarity and volume so they can be readily heard. Thank you very much.

We will now proceed with the meeting and I call upon Dr. Donald Cool, senior adviser on radiation safety and the international liaison in FSME, to open the proceedings. Dr. Cool, welcome and thanks for being with us today.

MR. COOL: Thank you Dr. Ryan, Mike, members of the Committee. I am glad to be here. It's been a little while since we have come and talked with you about this, but certainly not the first time over the process that we have been working over this.

The pre-decisional paper, which was provided to you several weeks ago, was the version of the paper that was going into the office concurrence

process. There have been as usual a number of editorial changes. Probably the most significant changes was a refinement related to the resource section actually adding an enclosure related to the resources to lay out some more details in that area. It did not change any of the staff's recommendations that were discussed in that paper.

I do not have the numbers to replace that XXXX for the SECY but I can tell you its date is April 25 of 2012. It was signed on Wednesday. I just haven't heard from SECY what number they have assigned yet. But this paper has now or is at this moment in the process of going to the Commission.

The staff's, one of the staff's recommendations in that paper was that the Commission make it publicly available during their consideration process. That requires a specific Commission action so we will see at what point they make it available to the public.

The paper, in its final form, as it went up to the Office of the Secretary, is a total of 68 pages, 15 pages of the Commission paper itself and some 53 pages of the various enclosures.

An outline of the paper and indeed an outline pretty much of the discussion that I have for

you this morning to be able to answer your questions, some background discussion of all of the various things that we heard from the stakeholders on the wide variety of issues, the policy options that sort of wrap up all of the details of the individual technical issue recommendations that we have made, and then the enclosures deal in considerably more detail, as you might expect, with updates in the area of radiation risk, indeed, a summary of the stakeholder interactions, which is principally a listing of the wide variety of places that I and others have had the opportunity to be over the last couple of years.

Enclosure 3 is the major enclosure, which is a technical issue by technical issue examination of what we started with, some background on that issue, what we heard during the discussions, and then our analysis leading to our conclusions for that particular technical issue.

It's also supported by enclosure 4, which is an examination of some of the international and international impacts done by the staff in our office of research, working on several different things under a User Need Request that we prepared. We will talk about that a little bit later, and also some resource estimates.

So, the purpose of the paper, besides the fact that the Commission asked us to come back, was to first summarize the interactions with the stakeholders. We have been at this for three years.

It is to specifically request approval of recommendations in terms of the policy and technical directions for further development of the detailed regulatory basis. I want to emphasize that these are recommendations for the directions to proceed in continuing with the detailed development of a technical basis. We are not, in this paper, asking the Commission for a final agreement on any particular regulatory language. I'll explain a little bit further as we go along.

We have a good idea of what we believe are the appropriate directions to proceed, but we do not have the information that would be necessary to do an appropriate regulatory analysis, backfit analysis, or some of those other things at this point, because the interactions that we have had thus far were very broad and wide-ranging, starting with what is Part 20 for some people, and the major options and differences, and in that kind of discussion, not surprisingly, you don't get to the level of detail which would be very useful and is necessary of specific words of what the

regulation might say, specifically what the guidance might say to implement that and it's really important, when you finally decide what you want to do in a proposed rulemaking action.

The paper also is to request the Commission's approval to develop in parallel a regulatory basis for revision of 10 CFR Part 50, Appendix I, the criteria associated with ALARA for effluents from the power reactors. So, in --

MEMBER SCHULTZ: Excuse me --

MR. COOL: Yes sir.

MEMBER SCHULTZ: Don, I just wanted to get clarification on that point. You are -- you are looking for concurrence that you will be directed to address both of those documents at this time, versus one and then the other?

MR. COOL: Correct.

MEMBER SCHULTZ: Okay, thank you.

MR. COOL: The recommendation is to work on both of them, to work on them in parallel, but not to actually try to do them in a single package. We will talk about that a little bit after a while --

MEMBER SCHULTZ: Okay, so there's a timing difference?

MR. COOL: There could be some timing

difference, but they are linked in a couple of the issues and then they each have their own separate issues, which is why we don't want to have them completely locked.

CHAIR RYAN: Picking up on Steve's question and your answer Don, I guess I take away that you are not married to the idea they have to be issued on the same day but you don't want them to be months and years apart?

MR. COOL: Right.

CHAIR RYAN: Okay.

MEMBER SCHULTZ: Thank you.

MR. COOL: Okay. So, a summary of what you are going to hear today. We are recommending to the Commission that: we proceed with the detailed information that would allow us to update the scientific information and models for expressing, calculating radiation exposures -- that particularly deals with a lot of the models for internal exposure, not quite so much for external exposure but in fact the units apply to both; to update the terminology -- we will go through each one of these in detail so I am just going to briefly tell you where we are headed on this; we are recommending to the Commission that we develop a detailed basis to reduce the occupational

total effective dose-equivalent limit; to reduce the limit for the lens of the eye; to reduce the limit for exposure of an embryo or fetus of a declared pregnant female; to explore the implications and issues around increasing at least the recognition if not the use of the SI units -- before we started we were having an interesting discussion on what a becquerel versus curies and millicuries; to --

MEMBER BLEY: Don, I can't imagine you haven't been exploring that for some time. I am curious about why, in the paper, this is an explore item rather than a recommendation.

MR. COOL: There were two reasons for that. One, that issue didn't actually derive out of this set of ICRP recommendations. Two, the Commission has an existing policy statement which in fact says at the end of it that it did not intend to revisit it unless there were significant implications that needed to be reconsidered.

This was actually put on our plate by the stakeholders for us to -- is this the time to do this along with some of the other interactions, and we have not, jumping momentarily, had -- looked at all the implications, because there are obviously some positive aspects in terms of talking in the same

language as everybody else. There were clearly those sets of issues in the Fukushima response, for example, where everything over there was in becquerels and grays and sieverts and millisieverts, and over here, there was the busy scrambling around of trying to do the translation of quantities, which made things a little bit difficult. Quite interestingly the press very quickly started to use all the SI units, because that was what they were being fed over there, and that made it more complicated over here.

So there were a variety of things that might be positive. There were also some huge implications for the exact same thing: you screw up one of those exchanges between what's a becquerel and how many picocuries it happens to be and you can be in big trouble really quick.

MEMBER BLEY: And on the other side of this equation, what's the downside of this switch?

MR. COOL: The downside of this --

MEMBER BLEY: I assume it wouldn't be tomorrow. It would be, like, over the next 5 or 10 years we would make the transition?

MR. COOL: For quite a while. The downside of this is getting everybody to actually talk in the units, change records, forms, all of the --

variety of training and other things that are all there. There's a lot of infrastructure which is all written.

MEMBER BLEY: Of course I assume now, and I wonder if it fits in part of this cost-benefit evaluation, that everybody out there who is hiring new people out of school, have to retrain them on the old units, which they probably haven't seen.

MR. COOL: Yes, the simplest answer. If they are trained here in the United States, they have probably been exposed to both. If they are trained anyplace else, they have only been trained in SI.

CHAIR RYAN: Dennis, I will just tell you and the rest of the Subcommittee that the medical profession in the United States has pretty much adopted SI units. So it's almost exclusively licensees in the Agreement States or the NRC and there are others that have not, but the medical, physics community, nuclear medicine and all that, have switched over.

MEMBER BLEY: Has the Navy rolled over?

CHAIR RYAN: No.

MEMBER BLEY: Okay, they are still -- okay.

CHAIR RYAN: They are still using film.

Go ahead Don.

MEMBER ARMIJO: Don, before you go -- on the occupational limits, those three categories, is that basically the recommendation to adopt what the ICRP recommends, or to -- or the U.S. or the NRC to evaluate their recommendation and come up with something of our own that we believe is appropriate? I am just trying to understand what reduce means as opposed to, you know, adopt.

MR. COOL: In each case, it is not identical to the ICRP recommendation and we'll give you the specific recommendation as we go through them. In each case it is a reduction but in each case it is not an exact mimicking of the current ICRP recommendation and we'll tell you why.

MEMBER ARMIJO: Okay, yes, for example, and this is not my area so -- but I know we have the Health Physics Society in the United States, which I thought may have a different view on these limits and do their -- first of all, do they have a different view, and if they did, how would they -- you would incorporate their view in your process?

MR. COOL: The Society, as a whole, as well as lots of the individual members, have been participating in these dialogues and discussions.

Mike, correct me, I don't think there's actually a published position statement related to the limits. There is a published position statement now on the use of SI, that just came out a little while ago. There's one on patient release which came out earlier this year and the number one related to radiation risk and some other things.

I don't think they have actually put out a separate position on the limits themselves.

CHAIR RYAN: But I think the other reason they have not is that they quite frankly are waiting for this to come out so at they won't be endorsing, you know, what they believe to be on track without delay so I think they don't want to get out ahead of -- because there is nothing at this point to endorse. So I think that's -- that will be shortly forthcoming after this is public.

MR. COOL: We have benefitted greatly from lots of discussion with a wide variety of the folks within the health physics community.

CHAIR RYAN: I might point out that some of our other observers in this meeting are members of the Health Physics Society and experts within the radiation protection staff at NRC, so there's quite a lot of overlap in that area.

MEMBER ARMIJO: Okay.

MEMBER SKILLMAN: Don, a question on TEDE. Is there any particular industry that pushed back on reducing the TEDE limit? Unless most of the nucs are going to --

MR. COOL: It is actually more simple to answer the reverse question. There was no industry that did not push back on it, at least to some extent, including the nuclear power industry.

MEMBER SKILLMAN: Really? And the reason for -- you said did not push back?

MR. COOL: Did not push back, yes. Yes. They all pushed -- they -- we will get there in just a moment or two because --

MEMBER SKILLMAN: They're trying to hang onto flexibility?

MR. COOL: So, we'll talk about that. There are some where there are significantly greater issues in dealing with the reduced limit than others.

MEMBER SKILLMAN: I'd like to hear about that.

MR. COOL: Yes.

MEMBER SKILLMAN: Okay. Thank you. Thanks.

MR. COOL: Dropping back to this quick summary of the recommendations. To explore adding additional categories of licensees that are reporting their occupational exposure. Most people, you have worked in the Navy or you have been in the nuclear power industry or something, reporting was the way of life. Not the case for all types of licensees.

And just as a little prelim, there's this big group of folks who do not have to report any of their exposures: medical. We do not have occupational exposure data from anything except the nuclear pharmacies, which are the one limited group who are engaged in the production of -- I'm not going to be able to quote the words -- but radioisotopes under Part 35.

So, under than some folks working at the nuclear pharmacy, we do not have information on occupational exposures from those categories of licensees.

So, then there are some others, and there are several other facets to that particular recommendation as well, and then lastly, we are recommending to align the Part 50, Appendix I methodology to the updated scientific terminology and modeling. That is the connection between the effort

of looking at Part 20 and the efforts that will be looking at Part 50, Appendix I.

So, not knowing who all we might necessarily have here in the background, ICRP, the International Commission on Radiological Protection, has been around since 1928 or so. They have published various statements of things, the first recommendations publication itself, Publications 1 and 2, 1959, then the revision of that in 1977 which was Publication 26, the revision and update of that was Publication 60 in 1990 and their latest revision and update consolidation was 2007.

It was announced on December 15th or so of 2007. Those who get their lovely printed hard copies of that didn't -- they didn't actually show up in the mailboxes until March or April of 2008, but we had the document available so that we could start working on our analysis.

So they announced their new recommendations. We were, as a promise to the Commission back in 2001, immediately prepared to start looking at some of the issues that were associated with it.

The last revision of Part 20, a major revision, was finally published in 1991. There was a

three-year implementation date so its final effective date was in 1994.

The ICRP recommendations in Publication 60 came out in 1990. As I think you probably know, rulemaking is not a fast process and there are a variety of legal considerations that we have go into, one of which is that you have to have notice and comment on any of the possible revisions that you might wish to make.

We did not have the information in ICRP Publication 60 related to occupational exposure and the changes in the dose limits in time to do anything associated with that rule.

There was actually a conscious decision made to go ahead and put the rule out and implement the rule because it already made a huge number of changes and issues: that was the whole move from maximum permissible concentrations and body burdens to a concept of effective dose equivalent as it was called at that time, which allows you to add internal and external exposure.

So there was a lot of things that happened. We chose to move forward with that and said we'll come back and look at it.

2001 we went to the Commission and said,

okay, it's been 10 years, there would certainly be some things to look at but ICRP is already talking about things that might be in its next possible update of the recommendations.

At that time there were some rather interesting discussions going on from Dr. Roger Clarke who was at that point the Chairman of the ICRP. They were talking about whether there needed to be even things such as limits and other things.

There were some pretty wide-ranging discussions and the staff recommended to the Commission at that time that instead of starting a rulemaking process, which might be done about the same time perhaps as another set of ICRP recommendations came out, and therefore be behind yet once again, that we simply wait, that we participate actively in the ICRP's dialogue, and that we look at what would be the right things to do once ICRP had put out their new set of recommendations.

So that's what we did. Our analysis went up in December of 2008, the SECY paper 08-0197. The Commission approved of what we suggested to do, which was to go out and engage the stakeholders and initiate the development of the technical, now called regulatory basis in April of 2009, so just about three

years ago.

One of the things I point out there, initiate development of the technical basis. When the Commission told us to interact with ICRP, but not to do rulemaking, they told us not to work on any technical basis development activities.

So things that would be done that would be looking at potential impacts, classes of licensees, dose distributions and things, were not being done until starting in 2009. So we have been working on a variety of things, not just out talking to people.

But we did talk to a lot of people. I put this together basically as three phases, I've sort of nicknamed them. Phase I was a lot of presentations to organizations and groups. We basically tried to get us anyplace they'd let us in the door to talk to them about it, to try and start getting people aware of what was going on and start getting their feedback.

We did have a Federal Register notice that was inviting input on some of the key issues from that SECY paper, 08-0197. That's the way that we could have the appropriate docket and everything set up so we could keep track of the comments.

We pulled that stuff together and put out a second Federal Register with a whole series of

specific issues and questions which served as the baseline for three facilitated, roundtable workshops that were held in late 2010, in Washington, in Los Angeles and in Houston.

We tried to have a table about three or four times this size with representatives from all of the different kinds of uses. So sitting around that able we had everything from well loggers and radiographers and gauge users to power plant rad protection officers, to medical physicians, the whole gamut of things.

In Washington, we put some extra focus, and in fact a whole extra day, into the reactor area and the discussion of the issues associated with Part 50 Appendix I.

In Los Angeles, we rather deliberately stacked the deck in the direction of medical so that instead of a couple of representatives amongst the 30 or so people around the table, we went looking and were successful having essentially a representative from every single major modality type of use around the table.

In Houston, we flip-flopped that and went looking for extra participation from the industrial side, radiographers, more gauge users, source people

who are working in the change-out and a variety of those other sorts of issues.

So each one of those meetings had very active discussions, lots of interesting back and forth, some common themes and obviously some differences leaning sort of in the direction of medical or in the direction of industrial or in the direction of reactors.

Not quite a year ago, ICRP put out a statement regarding the lens of the eye and some other non-cancer effects. That was supported by what was at that point a draft report with lots of details on the non-cancer effects of radiation exposure.

That statement included ICRP's recommendation that the dose to the lens of the eye be reduced. The limit was 15 rem, 150 millisieverts, per year.

The new indications were that while they still believed that was somewhat of a deterministic effect, that that effect was being seen, cumulative doses of around 50 rem or 500 millisieverts.

So as -- the math doesn't add up. It doesn't take all that long if you are running at the limit to start to get up into an area where you could potentially have the induction of cataracts.

Now I will go ahead and say right now we have only had one case that I know of where the lens of the eye limit has actually been exceeded.

MEMBER BLEY: For the proposed limit or the existing one?

MR. COOL: The existing one.

MEMBER SKILLMAN: Over what time span Don?

MR. COOL: Tony that goes back to what, '93 or so?

MEMBER SKILLMAN: One incident in 20 years.

MR. COOL: One incident in 20 years or so, at 15 rem.

MEMBER SKILLMAN: At 15 rem. Yes. Thank you.

MR. COOL: We are going to need to have some microphones turned on.

MR. HOLOHAN: Just to clarify, that's the data that's in the REIRS system, so not all licensees are reporting to us and not all workers, whether they be interventional cardiologists or industrial radiographers, if there is a grievance, do they report to us.

Vince Holohan from FSME.

CHAIR RYAN: And define REIRS in the REIRS

system.

MR. HOLOHAN: That's the radiation exposure incident reporting system, and that's reported annually in NUREG-0713.

CHAIR RYAN: Thank you.

MEMBER ARMIJO: If you go into a nuclear plant and you have got a dosimeter and you get an exposure, how do you differentiate between your dosimeter exposures that you are carrying around and dose to the eye?

MR. COOL: That is a good question.

MEMBER ARMIJO: You know, is it the same number or is it a big --

MR. COOL: It is, if you have a uniform whole-body exposure. If you do not have significant variations or significant shielding the numbers will be similar, not identical, but similar, because the dose to the body, what was called the deep dose equivalent, measured at one centimeter depth in tissue. The lens dose equivalent is measured at 0.3 centimeters depth, the depth for the lens of the eye. But absent significant shielding one way or another, or a very asymmetric dose field, the two numbers are roughly the same, and in fact most all of your dosimetry processors will give you this nice little

thing, buried inside that little chip are a series of filters and otherwise and they have algorithms which allow them to take that badge reading and do a calculation for a lens dose equivalent 0.3 centimeter depth, as well as the deep dose equivalent, to look for the various types of radiation.

MEMBER ARMIJO: So, would this new limit, would that be the, truly the limit for your, the whole -- the most constraining limit if you are working in a power plant, or is -- what would be --

MR. COOL: That is exactly one of the issues that was raised and one of the considerations that we will talk about a little bit more when we get back there.

MEMBER SKILLMAN: Okay. Okay. Sam, in the early entries that we made at TMI2, we had our dosimetry in the center of a body and we also wore a dosimeter taped on up here to try and catch the eye and we had one down on our extremities, so --

MEMBER ARMIJO: And that was specifically because of the concerns about the eye.

MEMBER SKILLMAN: And the real issue was the HP personnel knew that we were going into those areas and they were very sensitive to being able to discriminate between the lens of the eye, the

extremity and the whole body.

CHAIR RYAN: It also tries to account -- or you try to account as best you can for a radiation quality and radiation type. Lens of the eye, you know, electrons losing their energy in the lens of the eye, is probably a lot more important than one interaction of a gamma ray, where perhaps most of the energy is deposited somewhere outside the eye.

So it's a very specific --

MEMBER ARMIJO: Kind of radiation.

CHAIR RYAN: Kind of situation where you have to assess the individual's dose based on a particular radiation --

MEMBER ARMIJO: Okay.

CHAIR RYAN: characteristics and type and quantities.

MR. COOL: There may well have been beta fields and other things, because the beta radiation, not nearly as penetrating, doesn't give you nearly as much in the deep, but it would get to the lens of the eye.

MEMBER SKILLMAN: But my real point is, at least in that instance, and I've got to believe it's probably how the health physics community functions, if there is great uncertainty as to what the

individual is going to be exposed to, the HPs are very aware of the need perhaps for additional monitoring to make sure that they can really point to the difference between extremity, whole body and eye --

CHAIR RYAN: And that is not done in a vacuum. If there's any concern about what is the radiation field we are going to, there will be a lot of pre-survey work done to better assess these questions and you know, parameters that people will be going into.

MR. COOL: So, following the ICRP statement, with their recommendation, we put out a third Federal Register because that topic had not been in the discussion to date. It was not a topic in the facilitated workshops that we had had a few months prior.

So we opened up yet again for additional comments on that, as well as anything else that people wanted to put on the plate as a result of thinking about that you mentioned the question of does that become the --

CHAIR RYAN: Don, is it a fair statement on my part to say that in the comment period up to then and even through now, that you have received comments from all the significant organizations, like

Health Physics Society, ANS, EPRI, INPO, on down? I mean, is there anybody that hasn't commented and you wish they had, or that we have covered the field pretty well?

MR. COOL: The only area in which we have not had the kind of participation that I would have liked is actually the NGO, more environmental groups, because most all of this discussion was focused in occupational areas. It was not focused in the public exposure area. There was no discussion -- we made it very clear this is not something where the staff is going to reopen quantities for clearance of materials or otherwise.

And so while we had a number of more individual discussions with individuals from that community and we did get a few comments, we didn't have the same degree of participation.

CHAIR RYAN: And just, I think, for the other members' benefit, I believe this is still true, that these regulations are not aimed at, in any way, to limit diagnosis or therapeutic uses of radioactive material, because the dose of the patient is something not regulated by the NRC.

MR. COOL: That is correct.

CHAIR RYAN: Okay.

MR. COOL: The standing Commission policy, that we do not intrude into the practice of medicine, holds.

CHAIR RYAN: I just wanted to make sure that everybody was up to date on that.

MR. COOL: And, while the official comment periods on the Federal Registers have closed, we'll still take comments. People talk to us and otherwise we keep adding them to the record, just for no particular reason, to close it off.

CHAIR RYAN: And I guess just for our, just, nuclear power industry, the NEI in particular, Ralph Anderson has been very active on commenting on this and participating throughout this time period. Is that --

MR. COOL: NEI has commented on each of the Federal Registers. They were one of the participants at the table in each of the three facilitative workshops. And we have been invited to address each of their radiation protection forums over the last several years, and in fact, they have given us significant blocks of time to do what amounted to a miniature version of facilitated workshop with all of the reactor radiation protection measures sitting in the room.

So we have had a lot of participation from those folks. Yes. We got a total of 59 comments docketed, not an extraordinary number given, perhaps, these kinds of issues, hundreds and hundreds of pages of transcript of meetings and other things of course.

The general view was in two pieces. First, general support by most folks that we should be doing changes to reflect the current methodology for calculating dose, the current ways that we talk about dose, that could change a little bit. We'll talk about that some more in detail.

So, that part of it, yes we should be moving to the current scientific calculational methodology. On the flip side of that, the question that you asked a moment or two ago, the general view was that there was no reason to change limits, ALARA or anything else.

One of the things which perhaps in retrospect would have been more helpful, we did not spend significant time in the facilitated workshops talking about the information that was available on radiation risk.

And one of the things that many stakeholders said was a generalized statement that we don't think radiation risk supports the changes that

you are making.

We asked on a number of occasions for them to try and help us understand more specifics that were associated with that. They did not give us specific, more detailed comments and explanations of why they thought it was. But it's a pretty consistent theme, particularly from folks in the medical community, who quite frankly have a different view of radiation risk than some others.

They are used to talking about doses that are hundreds and thousands of times greater than these regulatory limits and that's what they pump into a patient to achieve what needs to be done for them medically.

So there are some differences in views and it's understandable why that is. There was a generalized view that the impacts would be unacceptable. It was a little bit like deja vu all over again, not at all unlike the kinds of comments that the NRC got in 1986, the last time there was a proposed rule for a major revision, because that rule was suggesting that instead of a maximum dose of 12 rem, as in three rem per quarter, up to a maximum of five N-18, where N was the individual age in years, it was proposing a single limit of five.

And there was a considerable reaction that oh, it's going to be horrible, we are not going to be able to do this, that's long ago, forgotten, everybody has functioned happily with it, there hadn't even been any particular request to use additional dose.

The first time I ever heard of someone using a planned special exposure, was during the Houston workshop. It was the first time I'd ever heard of where they had set up the planning and actually had to use a dose greater than five rem.

The third view, which was a rather interesting sort of view, mentioned more than once, was that the things that are done in the United States and the kinds of sources, the quantities, the activities that are used, were different from what was used in the rest of the world, and that therefore that should justify a different set of units for radiation protection.

MEMBER BLEY: You will tell us more about that?

MR. COOL: I'll tell you a little bit more about it.

MEMBER BLEY: Thank you.

MEMBER SCHULTZ: Don, this was one discussion in one workshop or --

MR. COOL: No, this actually showed up in at least two out of the three workshops, in Houston and Los Angeles. I don't remember that that statement was made in Washington. I'd have to go back and look up the transcripts of course. But --

MEMBER SKILLMAN: Were these three sub-bullets that you have here, expressed against a, if you will, a financial backdrop? Was this all about money?

MR. COOL: It is about money. When you translate, I might need more people to do a particular job, or I don't have the additional people to do the job, as in physicians have to be trained and specialized in their area, and as one person actually said, Dr. Cool, so if your mother is coming in and needs cardiac surgery now, and my cardiologist is approaching the limit, say, oops, sorry, we are going to have the intern do it today, is that what you want us to do?

I mean, they were very bold, in-your-face statements associated with that. And yes you can translate that to money, but a lot of that translates to numbers of individuals who are available or would be needed to do the same kind of work in the same sort of way that it is done now.

MEMBER SKILLMAN: Okay, let me kind of flip the question. In the same workshops, were there individuals from other cultures who did not push back and who thought this is a pretty good idea?

MR. COOL: We did have some international folks there. They did not participate as actively, but did note on several of the occasions that things such as this were already being implemented in their countries.

We did not have international insights from the medical community, for example. The folks who were at some of the workshops were more from the reactor community, and the medical and industrial areas is one of the areas -- we'll talk about this in a little more detail perhaps later as well -- where there's been an ongoing question just, so how is the rest of the world living with the reduced numbers? It proves to actually be incredibly difficult to get a handle on that, because everyone's focus of information has been the reactors and when you start to say, well, what about these other folks, the amount of data goes right sort of underneath the table, and unfortunately, the same sort of statements which border on allegations, as in the doctors just leave the badges back on the desks, we really don't know,

there's a fair degree of noncompliance, so we really don't have a good idea for what the actual occupational exposures are, was heard in the international community as well as from here in the United States.

MEMBER ARMIJO: Well, that's counter-productive if people would -- if the changes would make you make a response, what I'd consider a responsible M.D. leave a badge on a desk in order to do his job. You don't want him to do that.

CHAIR RYAN: I would say that this change is not going to change the degree to which that happens already.

MEMBER ARMIJO: Well, it just shouldn't be happening at all.

CHAIR RYAN: I understand that Sam, and don't disagree with you, not even a little, but the fact of the matter is that those issues come up all the time.

MEMBER ARMIJO: Yes, but you know, how do you answer, respond to the view that the risk doesn't warrant the changes, you know? I think that's -- if people really see your basis that says hey, look, here's the data, here's the numbers, here's the kind of margin that we put on it, for just common sense.

So this is an appropriate change. Is there that kind of a basis that, you know, could change people's views? Or is it a weak basis? Is it a strong basis that supports the change or is it kind of fuzzy?

MR. COOL: We believe that there is a pretty solid basis, and that's actually where I'd like to go to next. Thank you for the segue.

MEMBER ARMIJO: Yes, well I'd like -- unfortunately, I am going to have to bug out in a few minutes but I'll stay as long as I can and I'll come back as soon as I can.

MR. COOL: Because in fact, the very first question asked, is there any scientifically justified basis for considering the changes at all.

MEMBER SCHULTZ: In terms of the comments Don, were they specific to the areas that you proposed, or were discussing, I should say, in the workshops? Or were they mostly blanket statements about -- it's not a demonstrated need, that the risk is not demonstrating that we should change the limits. Were those blanket statements against all three, or specific to particular areas?

MR. COOL: We had both. We had both blanket statements and more specific statements related to one or other of the limits.

MEMBER SCHULTZ: Thank you.

MR. COOL: So, radiation risk. The current basis in the NRC regulations is actually a mixture of information that ranges from 1958 to 1990, depending on which regulation you are in, and even which portion of the regulation that you are in.

Part 20 has basically, for the most part, the risk basis of about 1.25 times 10 to the minus four and I realize that's too many significant figures, but that's the way it was being written back in those days, which was cancer mortality and the risk of heritable disease.

MEMBER SKILLMAN: So that is one in 8,000, is what that number is?

MR. COOL: One in 10,000. Ones times 10 to the minus four.

MEMBER SKILLMAN: Yes, the reciprocal is 1.25, to the minus four is 8,000.

MR. COOL: Yes.

CHAIR RYAN: 1.25 --

(Simultaneous speakers)

MR. COOL: Yes. So, when you start to dig a little bit deeper, which we'll talk about in a little bit, the values for public exposure are actually different from the underlying basis for

occupational exposure at this point, because in fact when the revision of Part 20 was done in the late '80s, we already knew, we already had ICRP's revised recommendation in a statement much like what they have done with the lens of the eye now, that the limit for the public should be a simple, straight, one millisievert, one hundred millirem in a year.

And in fact that was within the range of options that was in the proposed rule for Part 20 at that time. That proposed rule in fact had said the limit is 500 millirem with a reference level, or some other term, I don't remember exactly the term that was used, of 100 millirem, and much of the comment that was received at that time was 100 millirem is the limit, why make games about it not being the limit?

And so we actually had fairly substantial comment as well as the ICRP's recommendation and other statements that resulted in us making the public dose limit at the time of the revision 100 millirem, one millisievert.

CHAIR RYAN: Don, it's probably helpful to point out that this excludes yet recognizes the presence of background radiation --

MR. COOL: Correct.

CHAIR RYAN: in the three to five hundred

millirem per year range.

MR. COOL: Right, the dose limits --

CHAIR RYAN: in addition to any background. Forget, you know, your normal terrestrial background and radon and everything else.

MR. COOL: The limits exclude all the natural background. It excludes the contribution from -- atomic bomb testing and things.

CHAIR RYAN: Diagnostic and therapeutic radiology --

MR. COOL: And it excludes radiation received as a result of medical diagnosis and treatment, and if you are familiar with NCRP's report 160, which came out a couple of years ago now, which was a description of the average exposure of a member of the United States to different kinds of radiation, with a lovely little pie chart, medical now forms just about half of the average exposure of an average person in the United States, and that's only the diagnostic medical applications. It did not include therapy.

Radon is a couple of hundred millirem on average. The natural background's about 100 millirem. The various uses that are licensed by the NRC is a very thin little line along one edge and a fraction of

one percent of that total.

So there are a lot of contributions, most of which are not covered by these limits. The current radiation risk value is a value of around five times 10 to the minus four, a nominal value of five times 10 to the minus four.

It has more things wrapped into it nowadays, in consideration not only of mortality but the morbidity, some of the incidents of diseases, heritable effects and otherwise.

The values are actually quite consistent when you look at work that has been done by UNSCEAR, that's the United Nations Scientific Committee on the Effects of Atomic Radiation, ICRP, who did their own analysis, the National Academies of Sciences, Biological Effects of Ionizing Radiation, that's what BEIR is, the National Council on Radiation Protection and Measurements, NCRP here in the United States, all have put out values that are very similar to this on a rounded aggregate average, recognizing that as you dig into the details, you find differences. Children are more sensitive than adults. Females are more sensitive than males.

MEMBER ARMIJO: But, on this using that same around five times 10 to the minus four, what's

the spread of the radiation risk number? Is it one times 10 to the minus four, 10 to the minus three or --

CHAIR RYAN: That's a tougher question, I think, for a --

MEMBER ARMIJO: Well, I'm just looking for --

CHAIR RYAN: The reason it's a tough answer to give is you have to then get into what cancer, what organ, and there's a wide range of numbers around this --

MEMBER ARMIJO: So the bases for all the number are different?

CHAIR RYAN: They can be, based on end-point type or radiation.

MEMBER BLEY: This is cancer deaths per rem?

MR. COOL: This is cancer deaths --

MEMBER BLEY: And it just kind of is a homogenized view that says it doesn't matter if you get it in little bit or big bits, it's all the same?

MR. COOL: Correct.

MEMBER BLEY: Or, rather than it's all the same, this is an average?

MR. COOL: It's an average and it is all

1 based on the linear hypothesis that the -- for
2 regulatory purposes and ICRP I notice have been very
3 careful to say we are not saying that this is the
4 actual radiation response of the body. But for
5 regulatory purposes, it's prudent to assume that
6 that's a line that goes straight all the way down into
7 zero, and so you can add all of those increments up,
8 because if it wasn't linear, then the whole concept of
9 adding last year and this year, or today versus
10 yesterday, would all sort of fall apart.
11 So there are those sorts of assumptions in
12 it. It has built into it a component for cancer
13 incidence, not a complete addition to it. EPA, in
14 their Blue Book, which is actually -- the reference is
15 EPA402-R-11-001 April of 2011, with their update of
16 their radiation risk information. It was based on the
17 BEIR report from several years before, but went beyond
18 in several areas where they applied some additional
19 information. They are in fact today considering a yet
20 further addendum for lower-energy beta and gamma.
21 The Blue Book report from last year says
22 that at that point, they believed that there was a
23 higher risk from some of these very low energies
24 because all of the energy was essentially being
25 deposited earlier.

I understand that there is going to be a publication of some of the research and that that will result in an addendum to that Blue Book at some point in the not so distant future.

When you look at that --

MEMBER BLEY: And that's more pessimistic than LNT?

MR. COOL: It's LNT.

MEMBER BLEY: It's LNT but --

MR. COOL: It's LNT but their numbers would say four incidents, not quite 1.2 times 10 to the minus three per rem, for mortality, 5.8 times 10 to the minus four per rem, and there is a factor of two or three on each side.

I mean you asked the question -- and if you stand back far enough with all of the lots of variations, because there are huge variations, if you had six, the 5.8, it goes down to about two and a half and up to 1.2, 1.3 times 10 to the minus three.

So there is a spread -- it's probably close to an order of magnitude -- on that sort of generalized level within which they then send -- select the central tendency.

CHAIR RYAN: And my own view is I think part of the difficulty in setting any standard, by any

body, is that there is no absolute, very sharp number. It is a range.

MEMBER ARMIJO: Yes, I understand it would be a range, something like that. I just wondered how big.

CHAIR RYAN: Electron energies, I mean, if you look at electron interactions in tissue, the density of interactions, as the energy goes down, goes up. So if you're dealing with something that has come from some other part of the body and now hits the special tissue that you are interested in, at a lower energy, that linear deposition of energy is going to be higher so the risk is going to be higher, the damage is going to be higher. So it's a very difficult thing to kind of extrapolate with a very simple sentence. It's -- and I --

MEMBER ARMIJO: You've got to get very, very specific about what you are --

CHAIR RYAN: What it is you're doing, and I credit the staff with trying to do the best job that I think can be done to put at least some framework on that and then come up with a reasonable view of central tendency. Yes.

MR. COOL: Vince is our resident expert on this.

MEMBER ARMIJO: Yes he is.

MR. HOLOHAN: Just as another clarification, especially with the -- regards to the EPA numbers, these are population-dependent. The EPA number is for a U.S. population.

If you go back to ICRP report 60, you find that different populations have different sensitivities to radiation, and most of that is based on socio-economic type of factors.

For example, based on diet, the Japanese have a much higher risk of stomach cancer based on the type of things they eat and some of the viruses that are there.

At the same point, U.S. women have a much higher incidence of breast cancer because of the consumption of meat in this country. If you take that same individual from Japan, move them to the U.S., what you find is all of a sudden, they adopt the U.S. breast cancer rates and they have very reduced rates of stomach cancer.

So what you find in many of these composite reports, whether they be UNSCEAR or ICRP, they are combining Japanese populations with Chinese populations with U.S. populations with United Kingdom populations, they even threw, in ICRP 60, segregated

and brought in Puerto Rico, and they add all of that together, and that's where we come up with this number of five times 10 to the minus four, but in fact, in the U.S., it's really 12 times 10 to the minus four, and that's adjusted then for by a dose and dose rate reduction factor of two. That's what then brings that down to six or seven.

So, much of what you are seeing here is just trying to correct for the population basis, and that Blue Book number is based on U.S. Census information going back to the year 2000.

CHAIR RYAN: What fraction of the U.S. population, Vince, does of cancer?

MR. HOLOHAN: About 21 percent.

CHAIR RYAN: Twenty one percent dies of cancer and we are looking for a little tiny effect, in that 21 percent that does from cancer from all causes, and the -- probably on the teeny end of things is what is happening with ionizing radiation.

(Simultaneous speaking)

MR. HOLOHAN: I don't know if this is off topic or not, but I'm really curious, based on what you just said: is there a socio-economic group or an ethnic group --

MEMBER SKILLMAN: What was the last one?

MR. HOLOHAN: Is there a socio-economic group or an ethnic group where the cancer risks are shown to be very low across that entire control group?

MEMBER SKILLMAN: It is socio-economic and I want to say ethnic. What is the smoking rate, what's the alcohol consumption rate, what's the composition of the diet?

We find that there is differences based on economics for screening, the type of treatment that occurs. So you can have a similar, let's say, cancer incidence rates, but then cancer mortality is going to be based on the treatment that's received.

So it's a combination of many of these things and the epidemiologists have to look at those type of factors to try to segregate those type of things and have equal comparisons.

CHAIR RYAN: There is one ethnic example, which is melanoma. Based on the amount of melanin in your skin, you know, you have a very different susceptibility over the range of folks that have, you know, a range of melanoma. So --

MEMBER SKILLMAN: Thank you.

CHAIR RYAN: There's all sorts of variables like that.

MR. COOL: Just to quickly summarize this,

if you are looking at Part 50, Appendix I, the risk and scientific information supporting that is 1958. If you are looking generally at Part 20 and the occupational values, it's the one times seven to the minus four.

If you are looking at the public exposure limit, it's actually more reflective of the five times 10 to the minus number, because the information was available and could be adopted.

So within Part 20, you have different bases for the risk that is associated with those limits. But it's not -- it's not even that simple.

MEMBER SCHULTZ: One moment, Don.

MR. COOL: Okay.

MEMBER SCHULTZ: On your last bullet, LNT is adopted for practical purposes of radiation protection, and I think it's important to understand that, what we have just talked about in terms of cancer incidence and determining radiation risk, I don't think there's much data out there that in fact, where the data provides the cancer risk associated with low dose radiation.

MR. COOL: Correct, there isn't any. In the kinds of ranges that we are talking about, there is not direct, scientific studies, either

epidemiological, or the cellular, molecular or others.

You see bits of different things in individual systems and otherwise. That does not generalize to larger organizational systems, organs and tissues or individuals, because there are all sorts of additional things which come into play there, as Vince was just talking about.

So we are talking about a range in which we are working on an extrapolation, from data that is available to the ranges that we are dealing with.

MEMBER SCHULTZ: What continues to happen is that when publications come out that say well, we endorse the use of LNT, there's always the public view that that is based upon scientific evidence and therefore we cannot adopt anything but an LNT theory, or approach.

It's just very easy for the public to assume and adopt themselves that LNT is demonstrated by evidence. Happens all the time.

MR. COOL: Correct. So in addition to the risk itself is the mechanisms of calculating and the methodologies. So as I said, 10 CFR Part 50, Appendix I based on ICRP 1 and 2, maximal permissible concentrations for individual organs, there is on way to add the internal and the external exposure together

to get a risk.

Part 20 moved to the total effective dose equivalent concept, which allowed you to add together internal, external exposures, because it assigned relative weights for the induction of cancer in various organs and tissues so that you could sum it up into an equivalent sort of whole person.

As I said, the public exposure aligned to the new recommendation; where we had it available, the occupation exposure did not. We also have a situation where we have licensees who are in fact today using, by License Amendment, the internal dosimetry models from ICRP 60 and the supporting publications, 67, 68, and 72, which contains some of the details of the modeling.

We were requested for that by License Amendment Request. It actually was a Commission action that endorsed allowing that to take place, allowing them to use the updated models, with one primary condition, which was if you are going to move to the newer set of models, you have to use that newer set of models consistently for everything you do, as in no cherry-picking.

The licensees that we are talking about are principally uranium licensees, uranium fuel

fabricators, because the modeling at the time of ICRP 26 and 30 had one level. It actually had come up from these assumed radiation risks that was back known in the '50s and '60s.

By 1990, it had actually come down back down as there was additional information and studies that were available, so they were in fact taking advantage of a factor of about three in these uranium intake dosimetry systems.

So you have a number of folks who are using that. Now this next question of course would be so, what's the impact of the latest set of recommendations and all the calculations that are ongoing right now?

And I would love to be able to tell you firmly and unequivocally it is this, or whatever. We understand from the folks who are doing these calculations, most of which are being done by Dr. Keith Eckerman down at Oak Ridge, that for uranium, there is going to be very little change this time around.

Some things will go up a little, some things will go down some, because the set of tissues that are used in the calculation, and their associated tissue weighting factors, the percentage for the

cancer induction has been amended. You have got more tissues and a revision of the distribution, because in the end all the tissues have to end up to one, they have to sum up to one --

CHAIR RYAN: It's always been a little confounding to me that -- uranium is a good example of something that is chemically toxic. Radiotoxicity is an added feature so how do you sort that out? That's always a little headache.

MEMBER SKILLMAN: Yes, and sorting that out, I think, probably most of the folks who ware dealing with uranium are also dealing with hexafluoride, so there are chemicals --

CHAIR RYAN: With the hexafluoride, you are only -- a heavy metal poison.

MEMBER SKILLMAN: Oh yes, I got that. I got that.

MR. COOL: You have the HF issues associated with uranium hexafluoride if it gets itself with any moisture. That's quite true. But soluble uranium is in fact a greater concern from heavy metal kidney poisoning than it is from radiation exposure. And in fact the Part 20, Appendix B values have a quantity for the soluble uranium which is driven by the heavy metal component, not by the radiation dose.

If you have got an insoluble particle of uranium, that is going to be driven by the radiation dose because not as much of it is taken up and distributed through the body in deposits in the kidneys.

MEMBER SKILLMAN: Okay.

MR. COOL: In addition to that, at the time that Part 20 was revised in 1991, the total effective dose equivalent was the committed effective dose equivalent from internal exposures, from intakes, and the deep dose equivalent from exposures external to the body.

So that was the badge on the collar or the highest point of exposure. At that point in time, the modeling and calculations for being able to actually do a calculation of effective dose from an external exposure, were not refined enough for the staff to determine that it should be able to recognize that.

That has since changed. Part 20 was amended now four or five years ago, because it was a couple of years before we started this project, to explicitly allow the use of any of the several standard available methods for calculating effective dose from external exposure.

That becomes particularly important in

1 certain classes of occupational exposure, and in
2 particular our friends in the interventional
3 radiology, cardiology type things in the practice of
4 medicine.
5 Now, two points are important there. One,
6 it's actually radiation, so it's not NRC's
7 jurisdiction. Two, the states have consistently said,
8 as has been their practice in the past, that they will
9 move to adopt any changes in the state programs and
10 there will be a single state program. There will not
11 be a separate program for byproduct materials under
12 their agreement with the NRC and the machine-produced
13 radiations, which are only the jurisdiction of the
14 states.
15 So while, by legal mandate, we do not have
16 jurisdiction over things like the interventional
17 cardiology and radiology exposures, we are well aware
18 that the discussions of changes to the dose limits do
19 have potential impacts on those categories.
20 The third important point to that, is that
21 there had been a number of statements made by some
22 fairly reputable folks -- they are members of the NCRP
23 Council -- that if there was a consistent recognition
24 and use allowed of the effective dose calculation,
25 that those interventional radiologists and

cardiologist would have no problem meeting the lower dose limit, because in fact the difference obtained by the typical lead apron is more than enough to account for a difference between five and two. It could be more like 30 in many of the situations.

MEMBER BLEY: Don, there is one area that confuses me a bit because a few years ago I was involved in some risk work with folks in cancer treatment -- nothing associated with NRC -- but they were tending away from radiation because they were under the eye of the NRC and regulation, where, with everything else, nobody was regulating them and even though it wasn't byproduct, apparently the -- at least what they explained to me, was the argument that NRC used to be regulating what they were doing, was if the radiation was equivalent to what you would get from a byproduct, then NRC has the obligation to regulate.

Is that a real thing, or is that --

MR. COOL: No.

MEMBER BLEY: Okay.

MR. COOL: No. But there is a variation on that. The actual answer to the question in the regulations is if an individual is receiving exposure from a mixture of sources, that their total exposure has to be accounted for in compliance with the limit,

both that which is from the byproduct materials, and any exposure that might be received from other sources, as in the x-rays.

So if their techs were getting both x-ray exposure and byproduct material exposure, all of the dose had to be summed together and used in demonstration of compliance.

If they were only associated with the machine-produced radiation, the x-rays, the fluoroscopy, you didn't have any -- nowadays PET2 or a byproduct material of nuclear medicine, if none of the byproduct material is there, they are not under NRC jurisdiction.

CHAIR RYAN: They are only under the state if the state chooses to regulate.

MR. COOL: So, there is a variation on that, but it requires that they have exposure from both licensed and unlicensed.

MEMBER BLEY: And that's the other one they argue, was if they were implanting sources, and the sources were generated by some other approach, but they were identical isotopes to what you'd get from byproducts, then the regulation fell to the NRC again.

MR. COOL: Prior to 2005, that got to be a very sticky sort of question, because in fact the

1 original definition of byproduct material in the
2 Atomic Energy Act was material made radioactive in a
3 reactor.
4 So materials that were made radioactive in
5 an accelerator, were not actually a class of byproduct
6 material, and you could have the exact same isotope.
7 So that did pose a bit of an issue. Well, is was a
8 byproduct or is that not a byproduct?
9 All of that went away with the Energy
10 Policy Act in 2005, which created a new category of
11 byproduct material, which is anything that is made
12 radioactive in an accelerator or similar sorts of
13 device.
14 CHAIR RYAN: One thing that helps a lot to
15 understand this conundrum is that the original Atomic
16 Energy Act of 1948, not '54, but '48, really is where
17 you can see the clarity of this.
18 All these definitions were designed for
19 one sole purpose, maintaining control over what were
20 viewed to be militarily significant materials so they
21 were regulated not with regard to safety of the
22 public, of workers, or the environment or anything.
23 They were defined so that they could be very
24 thoroughly controlled by the military.
25 So it was '58 then of course nuclear power

and other questions came along, so the Atomic Energy Act of '48 -- so the Atomic Energy Act of '54, where it was kind of schmoozed into the -- well, we have got to have some public uses and we'll have all of our other stuff over here sort of buried in it, that kind of thing.

So it's very interesting to go back and read that Act, because in the '48 Act, it's crystal clear.

MEMBER BLEY: That is an interesting thing. Let me go back to where I was though, because this had really bothered me when I was working with these folks, because they were -- they were under pressure from their organizations, the medical organizations, to go to less effective treatments to avoid regulation.

And it was really disturbing to see that we were regulating one area and the net effect was we weren't helping people, we were driving them to lesser -- less good treatment.

And is there any kind of interplay among agencies, with NRC being a part, that is trying to avoid this kind of problem? Or is there a way to avoid it?

MR. COOL: I can't sit here and tell you

that there is an automatic way to avoid the issue. What I can tell you is that we work very closely with FDA, associated with the medical -- their medical device licensing and other things. We try to work very closely in cooperation with the different state organizations, both the Organization of Agreement States, which are those states that have entered into the agreement, and the Conference of Radiation Control Program Directors, which is everybody, all of the state organizations.

That doesn't guarantee that that sort of thing might not happen as a result of some particular management wishing to do that.

CHAIR RYAN: Don, I think it's a fair comment, to let the Committee know that there is a very wide range of capabilities in the states' programs, from, you know, larger states like California and others that would have a lot more wherewithal, and the smaller, very unpopulated states where they might have a, you know, satisfactory program but it's not going to be as broad-ranging or as well outfitted with personnel or capabilities. We have a lot of these states, so --

MEMBER BLEY: Okay, something to pursue elsewhere, I suppose. But we don't have an agency

like HSE in the UK that oversees everything so that they can get an integrated policy that works to the good, rather than perhaps to the --

CHAIR RYAN: Somebody many moons ago said that to get radioactive material, he had to get 17 authorities from 17 different organizations to sign something.

MEMBER BLEY: Gee, I wonder who that was. Okay, I'm sorry Don. Go ahead. This one has bothered me for a long time and I don't want to --

MR. COOL: And I can certainly understand that. There have been calls on any number of occasions, from states, from the Health Physics Society and others, to Congress, wishing that there could be a consolidation of use of -- there could be an organization that was responsible for radiation.

That hasn't ever gotten very far down on the Hill. Okay. I'm not going to go there. Okay, so I'm up to Slide 11. The basis for occupational limits. As I said, 1977, the comparison was then with the average annual accidental risk of death in what were considered to be relatively safe industries. In other words, had about a one times 10 to the minus four fatality risk for that kind of industrial use.

So that leaves out the farmers and some of

the other things that have much higher accident rates. The five-rem value was selected with the assumption that the average exposure would be one fifth of that, as in about one rem. It's actually the one rem that corresponded to the one times 10 to the minus four risk of generally considered safe industries.

In 1990, it is a much more complicated sort of process, and you can spend some several numbers of hours, I would guess, working through Appendix B or 2 of ICRP's Publication 60 that talks about the multi-attribute process that they put together looking at morbidity, mortality, years of life lost, and a variety of things that they built into their selection.

They then actually laid out a table of various levels of cumulated dose, and the associated risk that was associated with that, and reached the conclusion, the objective that they chose, to try and avoid an cumulated exposure of 100 rem or one sievert or more, because at that point, the aggregate increased risk to that individual was about five percent, and that was viewed as a place that they really didn't believe you should allow somebody to go, and if you make the assumption that somebody could be working for 50 years, it's a bit on the outside for

most people perhaps, but --

MEMBER BLEY: Yes, I don't know --

MR. COOL: Some of us just keeping going and going and going.

MEMBER BLEY: Yes.

MR. COOL: But if it's 50 years, and you didn't want somebody to get over 100 rem, that got them to two rem per year, and they said okay, but we know this isn't a precise science, so let's make it two rem per year, average it over five years or so for some flexibility, with a maximum of five in any one year, because they recognized that people would go, well, we don't know if we can get there.

So the recommendation that ICRP made in Publication 60, and reaffirmed in ICRP 103, was a limit which is actually an average number, sometimes written as 10 rem over five years, sometimes written as two rem as an average over a five-year period, with a maximum of five rem, 50 millisieverts, in any one year.

MEMBER BLEY: Now, you've left that as an option in your --

MR. COOL: That was one of the options that we discussed with stakeholders. We'll get to those in just a moment.

1 MEMBER BLEY: Okay.

2 MR. COOL: In fact, that same number, 100

3 rem or the one sievert cumulative value, was the value

4 that NCRP here in the United States also used as the

5 basis for their recommendation for an occupational

6 limit.

7 NCRP chose a slightly different approach,

8 which was to say 1N, where N is your age in years, so

9 your cumulative exposure shouldn't exceed your age in

10 years.

11 So people who start working at 18 or so,

12 could get up to 18 rem at a five rem per year sort of

13 clip. Now, you couldn't do that for very long and

14 then, but they both had an underlying approach of

15 reaching to a cumulative value which was a five

16 percent net incidence of harm to the individual.

17 The question of a lifetime occupational

18 exposure limit, has been talked about some many number

19 of times. In fact it was on the table at the time of

20 the revision that was published in 1991.

21 That statement of considerations says

22 amongst a variety of things that the staff in the

23 Commission did not accept an approach of a lifetime

24 limit.

25 There are significant difficulties

associated with trying to keep an accurate record of an individual and cumulation over all the time.

One of the things that we had heard on and on in that discussion was everybody very excited that they might not have to do the form 4s and 5s to keep records, and go back and have the dose histories over the last number of years that was necessary under Part 20 before that revision.

In fact, jumping ahead, the exact same sentiment expressed now, the idea of having an average value, was the worst of all possibilities because they would have to go back for additional record-keeping and tracking the individuals and going back to previous employers, so the whole question of transient workers and otherwise made that incredibly complicated. Of all the things they didn't like, they really didn't like that one.

MEMBER BLEY: They being the licensee?

MR. COOL: The licensees. So you have the ICRP's recommendation, which is an average and a maximum. That's what their recommendation is. That becomes --

MEMBER SKILLMAN: Just your 1N riddle, some of us in this room are probably at that point where 1N would be around 60 or so, a little more or

less. Does that mean we could get 12 per year for five years?

MR. COOL: NCRP wouldn't let you go -- NCRP's recommendation wouldn't let you go over five per year.

MEMBER SKILLMAN: I see.

MR. COOL: Up to a total to value.

MEMBER SKILLMAN: Thank you. Thanks.

MR. COOL: Yes. But in fact, when you are getting up in our age bracket, where you can have 55 or 60 rem or more, we were also up in the bracket where, unfortunately, the likelihood of living long enough for that to really start being expressed in another 25 to 30 years, is fairly rapidly going away.

MEMBER SKILLMAN: Okay, thank you.

MR. COOL: In fact, in an ideal situation, I suppose, from the radiobiologic standpoint, you'd try to minimize the exposures in early years, because those are the ones that have the greatest implications for the individual because they have the longest time for them to be expressed.

Contrary to that, the average occupational exposure, if you watch an individual, in any number of situations, medical, radiography and others, they get a heck of a lot more dose in the first few years where

they are getting smart, with the training in doing things, and it tends to taper off a bit, in some cases, because they have gotten over that learning curve.

In the medical, it stays right there or even goes up. The people with the highest occupational medical exposures, as far as we can tell, are probably the best, most experienced physicians there are in that category. Why? They get called for all of the really tough, long cases, so even though they can do it better and ought to know all the right technique, it's pure time factor associated with the exposure that goes along with it.

When you've got surgeries that are going seven, eight, nine hours, to try and fix somebody on the table, right then, there and now, you are going to get more exposure than a simple stent or something that only takes them an hour or two.

So there are a lot of differences that come into play there. There's also been work updating the dose assessment methods. So, this is actually now the first of the topics.

So we said to people okay, should we update the new information, the new tissue-weighting factors, the new radiation-weighting factors, the new

nuclear decay data that was published a year and a half or so ago, all the calculations, the new human alimentary tract model, the lung model, all those sorts of things, should we move to that information modeling?

The answer that came back, almost completely, was yes, that's a good idea. We really don't want you to do it in dribs and drabs. If you are going to do it, do it once, do it right.

There was actually the question on the table, should we tell people in an interim, use the ICRP 60 numbers until the ICRP 103 numbers were in place. That would take a rulemaking in essence.

People said no, because we'd go through all of the hullabaloo to use those, and in another couple of years we'll do it all again. No reason to do that, just wait and do it once at the right time and go ahead and do it.

So the staff's recommendation to the Commission in this paper is that we move to adopt the methodologies, the updated models, scientific information.

We recommend, although some of us wish it could not be so, as individuals, that we continue with Appendix B. There were lots of people who said can't

we get all those detailed numbers out of the regulation and make it a guidance document. And the answer is actually a legal answer: if Appendix B was just used as method for demonstrating compliance with Part 20, you could take it out. It would be a Reg Guide.

But those numbers are picked up as references in other portions of the regulations, triggering reporting requirements, some record-keeping requirements, response requirements.

That makes them regulatory. You cannot reference a Reg Guide for that sort of action. So the only way to take Appendix B out would be to find a mechanism for expressing all of those other triggers by something else.

And if you start to look at it for a second, you say okay, those were triggered basically because that would be the equivalent of five rem, or 25 rem, or whatever it was. If you wrote in the number, you would actually have a much less precise trigger, because everybody would have their own calculation, would have their own little variations on the theme and all of that, so --

MEMBER BLEY: So, all the other regulations referenced the appendix. They don't --

MR. COOL: they reference --

MEMBER BLEY: get the numbers from --

MR. COOL: They referenced the values of Appendix B, the appropriate value.

MEMBER BLEY: Okay, so changing that is the one place that takes care of all the regulation?

MR. COOL: So, and that will correspondingly be one of the things we will have to look at very closely, because all of the changes in the numbers, even if everything else stayed the same, updating the calculation, so some things go up a little bit, go down a little bit, all of those triggers change.

So that's part of the impact that we will have to look at in detail because the trigger number for that report is going to be slightly different for cobalt than it was before, or cesium or otherwise.

CHAIR RYAN: Don, I'm going to suggest that we take a five-minute break and let people take a --

MEMBER BLEY: Let me speak on one quick question.

CHAIR RYAN: Well, we can, but I just -- whenever you get a spot where you can stop, and answer that as his question, that would be great.

MEMBER BLEY: If you were adopting an ICRP 103 exactly, could Appendix B reduce to adopting 103 by reference?

MR. COOL: No. Much as I might like to, if the values are going to be used as triggers, it has to be in the regulation. First thing. The ICRP numbers themselves, ICRP doesn't actually calculate the ALIs and the DACs, the annual limits of derived air concentrations now. We actually go and do that as an aid for compliance to licensees.

So that's the second reason why you couldn't just say go adopt it there. The third would be that that would be an incorporation by reference of a document that was not subject to the public notice and comment processes under the Administrative Procedures Act, as in illegal.

So unlike my friends in the IAEA, who can say in the basic safety standards, use the latest ICRC stuff, and they're fine, we can't do that legally here.

CHAIR RYAN: They don't even say which one. They just say the latest one.

MR. COOL: The latest.

MEMBER SKILLMAN: And you figure it out.

CHAIR RYAN: Yes, you figure it out.

MEMBER BLEY: There are some other places in the regulation where the regulation has adopted by reference an outside document.

MR. COOL: Correct. There are methods to specifically reference by incorporation another document, another agency's regulation --

MEMBER BLEY: Maybe with exceptions --

MR. COOL: Or certainly it sets the standards where that -- and it's usually specific, by version, and date, because people could comment on that thing being incorporated, rather than just replicating it into the text.

But that thereby has the opportunity for notice and comment on the reference, because they had the opportunity to look at it. And I think this probably would be a good time to take a break if people want to --

CHAIR RYAN: All right. Five minute so and come back and continue. Is that okay with everybody?

MEMBER BLEY: Make it 10.

CHAIR RYAN: All right, 10. Fair enough.

(Whereupon, the meeting went off the record at 9:55 a.m. and resumed at 10:09 a.m.)

CHAIR RYAN: Okay, all right. I guess we will open the record and reconvene. Please, Dr. Cool.

MR. COOL: Thank you, Dr. Ryan. Let's go to the quite related category for the terminology itself. As the calculational approaches changed, so did the terms that they used to represent it.

In 1997, when radiation was being looked at with the quality factors, it was the effective dose -- it was the effective dose equivalent. We had dose equivalence of this and that.

By the time we got to 1990 they had moved to radiation weighting factors and the tissue weighting factors and the term that was used was simply effective dose, or the equivalent dose, for individual organs and tissues.

So one of the questions that we went and got public comment on was the question of aligning the methodology with aligning the terminology. Now, this is one, where again, stakeholders supported making the change, probably a good idea, slightly more grumpy probably because explaining to the folks, well, we used to call it total effective dose equivalent and now we're going to call it to call it total effective dose, and then I'm going to go, huh?

So there are some issues associated with that, with training, with records and other things, in order to move to the new terminology. But generally, I view that it probably was a good idea, certainly from a correctness standpoint, if you are going to recognize and use the calculational approach, then you should use the term that corresponds to that calculational approach.

Our recommendation is to go ahead and develop the details of the regulatory basis to update the terminology, look at those factors associated with people having to gradually change their records and things, look at the question of the degree to which we can allow some flexibility for folks, maybe even over a more extended period of time, so that instead of having to go through and change every procedure immediately, they could do them as they came to them in some cycle or otherwise to lessen the impacts that would be associated with a name change because that is in fact what this would be.

MEMBER SKILLMAN: So, what is the benefit in -- what is the perceived benefit in changing from TEDE to TED?

MR. COOL: The only benefit, quite frankly, is a qualitative benefit associated with

using the same calculation and the same term all the way across, and what you used in other countries, and we are using the term which was created to describe the calculation which is being required by the regulation.

If you said total effective dose equivalent, and used all the new tissue weighting factors and radiation weight factors, you would be using a term which did not apply to that calculation.

MEMBER BLEY: Creating confusion for some.

MEMBER SKILLMAN: So the terminology should go hand in hand with the methodology.

MR. COOL: We are recommending that the terminology go hand in hand with the methodology, while recognizing that for a lot of people this is a wide sort of approach.

MEMBER SKILLMAN: Yes, what are you getting for this --

MR. COOL: This is one where I am not going to suggest to you that I have got a safety benefit lined up that says that this is a safety thing to go ahead to go do.

CHAIR RYAN: I guess I would take a view that there could be a safety benefit, and probably is. By having consistent terminology, people in different

1 places are going to be informed in the same way, using
2 the same terminology, whereas there can be mistakes
3 made by the misuse of terminology.
4 So I think that you know, we have had some
5 people call it a rainbow of terminology. I call it a
6 rats' nest of terminology. It's very difficult and it
7 takes a lot of overhead to keep it sorted out, quite
8 frankly, to train subsequent generations of, you know,
9 what's the Rosetta Stone to sort this all out.
10 Fixing the terminology solves that problem.
11 MR. COOL: Okay, now for the fun one,
12 which we have already spent a fair bit of time talking
13 about in bits and pieces, the occupational dose limit.
14 I have continued to use the existing terminology
15 letters here. So, I -- instead of saying TED here I
16 still use TEDE, because that's the existing limit.
17 And we have already talked about the fact
18 that the limit does not reflect the current risk basis
19 or cumulated basis. Under the regulation today, you
20 could get background each and every year and therefore
21 you would have the potential for coming very close to
22 or exceeding the total cumulated level of dose which
23 would be a five percent change of harm.
24 We know that there are individuals who
25 received exposures above two rem per year. Now, how

large a number is that? Not terribly large. As in any dose distribution, you have got a whole bunch of people that didn't get any measurable dose at all. You've got a bunch that are getting just sort of the minimal and the first sort of things, and as you get out to higher dose, it drops off rather rapidly.

If you look at the databases that we have available to us, the REIRS database, the REMS database for the DOE workers, there are very few folks out there in the upper ranges.

The reactors don't have anybody above three or four. They have only got maybe 50 people or so above two, total.

MEMBER BLEY: For the whole country?

MR. COOL: For the whole country, right. They have very detailed programs and a very good handle and they have a methodology for tracking all the individuals, job to job, site to site. So they have actually got it tracked.

I have momentarily lost the acronym for the database -- PADS. I don't know what it actually stands for in terms of those letters.

MEMBER SKILLMAN: Personal Access Database.

MR. COOL: Which is the database that gets

used by a number of the utilities, so they have got everybody in. It facilitates not only the dose calculations, but knowing if they are trained and qualified in certain things, and a variety of other things.

That is not so much the case in some of the other types of licensed use.

CHAIR RYAN: Don, just for perspective, could you give us a quick just percentage cut, what number of employees, badged employees, are medical profession, nuclear power profession and other?

MR. COOL: Yes.

CHAIR RYAN: Okay.

MR. COOL: Medical -- this is numbers taken from NCRP Publication 60, where they went to the dosimetry process in order to try to get a handle in general. Medical had 735,000 or so folks. There are 3,000 people above two rem per year. They said there were 500 people above five rem. This was 2006, I think was the number.

Nuclear power had just about 60,000 people and in 2006 they had 149 above two rem. They didn't have anybody above five rem.

Industrial, commercial-type operations, 134,000 folks, 930 above two rem, 128 of those

supposedly above five rem.

Education and research, 83, almost 84,000, 263 folks above the two rem number, 65 above the five rem number.

Various governmental issues. Mostly that's DOE, 35,000 folks, 40 people above two, eight people above five.

CHAIR RYAN: DOE -- where's the Navy?

MR. COOL: NCRP did not say whether Navy was in there.

CHAIR RYAN: Okay.

MR. HOLOHAN: NAVSEA doesn't release that.

CHAIR RYAN: Pardon?

MR. HOLOHAN: NAVSEA won't release that.

CHAIR RYAN: Okay, just checking.

MR. COOL: And there's actually two components. You've got the certain component that is dealing with their propulsion units, which is outside. And then there's all of their routine uses of materials, so the radiography in the shipyards and otherwise, which is actually done under license. Those are NRC licensees.

CHAIR RYAN: I was thinking more the fleet.

MR. COOL: So, for those limited segments,

power reactor folks, industrial radiographers who are still NRC licensees, the other categories, 99.7 percent of the folks are underneath the two rem. We are talking a fraction of a percent. That percentage gets larger -- I didn't try to actually do the calculation -- when you wrap in some of the other types of users who do not report to us.

It's interesting, as a correlation, I have no idea whether there's causation, those types of licensees that have to report to us are the ones that have zeros about five. In ICRP's Report 160, every other category they say there are people who are getting greater than the dose limits today. That's an enforcement issue, and worrisome.

There's also significant additional numbers of individuals that are less than five but above two, for those categories which are not in our REIRS database and reporting.

MEMBER BLEY: For the above fives, is there any hint of what the maximums are?

MR. COOL: The NCRP report did not give those so I don't have a good idea. I can tell you that there has been what the epidemiologists would call a cluster. I think we have had five events in the past six or seven months in industrial radiography

and irradiators, for we have had situations where they have gone over five as a result of -- I should be careful and use the next term -- but it was an accident. It was not, certainly not intended.

The individual was up on the side of the scaffolding, took the guide tube, draped it over his shoulder, climbed down. He had not retracted the source, for example, and you can go over five real quick.

So you have those, and those accidental doses may have quite a large range going up, depending on the circumstances and how long he's actually there without realizing that he has got a source sitting on the back of his neck or something.

CHAIR RYAN: There's a fairly well documented series of these evaluated in what are called the medical basis for radiation action, accident preparedness, by Shirley Fry and Karl Hubner and it kind of gets into the question that you are asking.

But it's -- there is a record there. These things happen.

MR. COOL: The net result of that is that for most people, the question of meeting the dose limit, whether it's five or two, is not a question.

They are below it, the two rem, 20 millisieverts.

And for a number of the smaller licensed use, industrial gauge users and x-ray crystallography sorts of things, they never get anywhere close. In large measure they don't even necessarily get to the level, the fractional level that would require monitoring.

Much of the monitoring is done for legal and informational purposes, not because they actually believe the individuals are going to exceed some 10 percent of the dose limit or something like that.

So you've got categories, and in our meeting, said, "We don't have an issue with that. We don't ever get close to it, it's not a problem for us."

And of course you've got others who say, "We have got individuals that are over, it's going to be very difficult for us to do that." So a lot of the discussion we had throughout this was the question of what do you do with that group of individuals that are the tail of the distribution, that would be above the two rem, 20 millisievert level, average, or whatever it might be, but below the maximum five today, the maximum of five that would be in the ICRP recommendations?

And I'm going to go ahead and use this slide to talk about the connection this has with the ALARA program in radiation protection. We will get to that topic in a little bit.

But it's very relevant here, because one of the major pieces of discussion was what are the different mechanisms that might be available for reducing that high dose end of the distribution, because that's really the question. Those are the folks who, if they get it year after year, would be starting to challenge the cumulative exposure which is of concern.

And in meetings, down in Houston, radiographers sitting right about where Derek is from me, in that meeting, saying yes, I've been in the industry a long time, got like 30 years, I'm still out doing shots, I'm getting over two rem a year, still.

So there's clearly people who are getting those kinds of levels every single year for multiple years. Now, we don't have a notion of how many there are. This is again one of those reporting questions. There's either no reporting at all, or it may be a report to the Agreement State. That means it doesn't have to come into us. Some of those are voluntarily shared. Some of them aren't.

So, we don't have a good analytic way to add it up and say that person, be it Derek for the moment or anyone else, worked for X company and got two rem and three rem and three rem and two rem and 2.5 and -- and we are finally following them year after year, to see whether they are cumulated or not. We can do that with the folks in the reactor community and others because they were reported to the database on an annual level.

MEMBER BLEY: Do you have oversight on agreements states or are they independent?

MR. COOL: We have oversight of the programs. The programs have to be adequate and compatible. There are some things that have to be essentially identical, high degree of adequacy and compatibility like the limit itself. Reporting is not one of those. The states have some flexibility in terms of the reporting, and whether they actually have it submitted or whether they just expect -- inspect the licensee records.

MEMBER BLEY: You don't have any right to audit that or --

MR. COOL: We have no reason to go into state of whomever and say how come you didn't get all of this data. That's -- each state will have some

variations in their own requirements, and we -- one of the things that we did through the Office of Research was to go out and ask for a voluntary submission of information, and we did get some, to help try and get some idea.

But that really doesn't help you assemble a picture like this of potentials for year after year. You have to go by the statements of individuals and we have those statements on the record.

CHAIR RYAN: Just for Dennis, your benefit on that question, there's two organizations that help with that. One is the Organization of Agreement States and the other is the Conference of Radiation Control Program Directors.

And correct me if you don't agree, Don, but my view of those organizations is their tendency is to try and help bring things that are federal, whether it's OSHA or radiation protection or other relevant issues, through their organizations to the member states.

So there is some effort to look at consistency and looking at reporting and practice and other issues as well. I have worked personally in a bunch of agreement sates and I kind of found that there was consistency both with NRC and among the

Agreement Seetes.

Now, there will be larger programs, California is a large program, Massachusetts might be a larger one, and there will be smaller ones with some of the rural Midwestern and Western states where there won't be nearly as many licensees and subsequently not nearly as many resources put in that program; but I think the effort is to try and maintain consistency and quality across the program, just, and that comes from many of those experience with the states and the organizations themselves. That's my view.

MEMBER BLEY: Thanks.

CHAIR RYAN: Is that a fair summary?

MR. COOL: Yes, particularly for the CRCPD.

CHAIR RYAN: Yes.

MR. COOL: The Conference of Radiation Control Program Directors. They actually have a set of documents that are suggested state regulations, or SSRs.

One of the SSRs, I think it is D, the letter D, is the one that is the mimic of Part 20 and the radiation protection. They have different subparts for all the different -- so there will be a subpart for radiography and a subpart for medical. So

there is a lot of consistency there. The states will sometimes use almost exactly what's in the federal or the CRCPD, and then there will be some modifications for individual states. But there is --

MEMBER BLEY: The modifications the individual states make really are well, we've got to redo the numbering so it conforms to our state's requirement, something, it's not content-wise, it's more how do we make it look like our own.

MR. COOL: Right. So the issue really becomes how do we find a way to try and influence, as in reduce, the exposure of that relatively small group of individuals out there and in fact there was a lot of discussion about whether additions and modifications to the ALARA provisions, as low as reasonably achievable, would function to serve that purpose without having to change the legal limit.

And there were various proposals that got tossed back and forth and different things, and in the end, we concluded that it was possible to write such a thing, but that it would be very prescriptive because you would have to start laying out in detail what a radiation protection program would have to do and at what kind of dose levels, to increase investigation justification, find alternatives, do

another review, those sorts of things, that if you did that kind of prescriptive level and put in a boundary where certain actions had to happen that ICRP calls a constraint, a boundary on the ALARA process, that actually had teeth, it would be a limit because then there would be a requirement to get back underneath it.

MEMBER RAY: What would motivate doing such a thing?

MR. COOL: An alternative to changing the dose limit itself. We were basically weighing two options. Do you change the limit and let people figure out how do it, or do you prescribe at least to some extent a methodology which is known to work in larger, well-functioning programs, like the power reactors?

It's how they do business. They do it in an incredible level of detail, planning an activity, they have got virtually nobody over two rem anymore an they're in an advertised effort to have nobody below two in the next couple of years.

MEMBER RAY: Well, there is an unintended consequence to be concerned about there, just to refer to Davis-Besse as an example, in which you can drive things too far and particularly when the consequences are deferred, that will tend to happen.

And so I was just wondering whether the -- because there already is a somewhat -- a program, as you well know, in the power reactors, in which people compete basically to get their radiation exposures as low as possible, and as a result of that, they don't do the inspections and the maintenance sometimes that they should.

MR. COOL: That is an unintended consequence sometimes. For our considerations, more important was the fact that that kind of program works really nicely when you have got a larger, well-functioning, funded program, so it works pretty good for a power plant, a fuel cycle facility, not so good for a radiographer.

MEMBER RAY: I'd rather see the limit move down, if that's what you have to do, than use some other mechanism which has this more perverse result.

CHAIR RYAN: There has been some drift, to the phrase you used, which is low as possible. That's not what was intended in the regulations or guidance. It's as low as reasonably achievable. So the reasonable achievable part kind of got -- has been, by some, turned into an absolute must do. Everything, you know, within range of human, you know, activity.

MR. COOL: I would suggest to you that the

exposures in the reactor community are not driven by the dose limits and they are not driven by NRC's ALARA requirement in Part 20.

MEMBER RAY: That's right. They are driven by INPO --

MR. COOL: They are driven by, they are driven by license conditions where they have incorporated their protection program into their condition so they are held accountable to it.

They are driven by their competitive rank in the INPO rankings and otherwise. That influences their insurance, outage and otherwise and so they have a whole lot of factors that are driving them in the direction of lower and lower exposures.

From this perspective, we don't necessarily have the view of when they took it too far and didn't do something that was necessary, although certainly that event would be a situation where it shows up.

MEMBER RAY: I know, but for the agency, I think, which is what we are trying to talk about here, there is a concern about -- because you can drive that number way down, get a great score, and simply run the risk numbers, that but nobody is aware of, as a result of what you are not doing that you

should be doing.

MR. COOL: Correct.

CHAIR RYAN: Don, I don't mean to press you along but --

MR. COOL: Yes we have to keep going.

CHAIR RYAN: we are on slide 14 and we have got an hour and a half.

MR. COOL: Yes.

CHAIR RYAN: So we probably ought to push along.

MR. COOL: So we have in fact concluded that exploring -- we got some of the dose limit. It was a more straightforward and better approach than attempting to add specifications in the ALARA requirements.

Now, the stakeholders. Nobody wants to have their limit changed, okay? I guess we're not really surprised by that. There were a number of suggestions. There was suggestions of significant impact on the licensed activities, how many people would be needed to do the job. Under delivery of medical care is the doctor available, the things that we talked about a little bit earlier.

There were suggestions that this might increase the rate of non-compliance, which we also

talked about: they just decided to leave their badge somewhere else and not get any exposure.

And there were a number of statements particularly in the industrial radiography community, that the kinds of sources, the activity of the sources, 100-curie, 120-curie sources, was such that they should have different dose limits.

The staff in the Commission paper makes a very clear statement that we as the staff do not believe that a limit related to health and safety of individuals has any bearing on the kinds of sources in terms of justifying whether or not it goes down or not.

It equally applied to the dose whether you get it from a reactor, from a radiographer, from a portable gauge. So the staff has rejected the assertion that the changes -- that the types of uses and the types of sources that are used in the United States form any justification for not changing the dose limit if that is the appropriate direction to try and reduce that high dose end of the distribution, which is what we have recommended.

And as I said, adequate protection is independent of the source size. We are recommending to the Commission that they agree to us developing a

regulatory basis for reducing the limit to two rem. Notice that does not say average.

Stakeholder feedback was we really don't want to have to go back and average numbers and things. And when the staff looks at this, the staff believes that there is a mechanism, which we have had some discussion with the states already, to provide flexibility for those cases that need it.

It actually works on a model that is already in regulations today. You have provisions today for planned special exposures, only once ever been used.

You can apply for it, set out specific specifications for it, and get a larger dose if it was necessary, all approved in advance.

In public exposure, the limit is 100 millirem, one millisievert, but there is a provision that a licensee could apply for a public dose limit greater than that, up to 500 millirem, on an infrequent basis with justification, pre-approval.

The staff believes that it is appropriate to look at a single basic dose limit and the language that might provide a similar flexibility for a licensee should they need to do so over some period of time, to provide the justification for an alternative

value, with boundaries, like you've got to know what the dose history for your individuals are over the last five years. You can't be above five rem in any year. It doesn't matter anyway. You'd have to be at two rem average.

You'd have to have some planning or otherwise the kinds of details that might go along with that would have to be worked out. That's where the ink dots meet the road in terms of what would be looked at, but we believe that such an approach could provide flexibility in the industrial community, in the medical community, to work with the very small percentage of folks that are actually over the two rem value now.

We recognize that an individual dose less than two rem does not mean that a licensee would not have to change anything, because all licensees like to have some margin.

And so lowering the limit is likely going to result in people looking at more details of their program to make sure that they are not going to hit the new dose limit.

CHAIR RYAN: So allowing a limit doesn't mean ALARA goes away. It means you probably are going to focus on ALARA a little bit more to make sure you

are there?

MR. COOL: Correct.

CHAIR RYAN: Okay.

MR. COOL: So that's what we have recommended to explore and work the details of, with licensees, to actually develop what the regulation might look like, what the alternative provisions might look like, to provide the flexibility and what kind of cost and implications, the number of people that would use it, and the kinds of things that would be necessary to have the right script around that.

Let's go to the lens of the eye. This was the most recent one. The reduced limit recommendation was based on the radiation in cataracts. We have already talked about that.

And then we also talked about the fact that the effective dose and the lens dose are pretty similar if you don't have shielding or if you aren't running on lower-energy beta or gamma, where there's a significant difference in the dose at different depths.

We do know that there are potential implications in interventional radiology and cardiology. That's one of the cases where there is shielding for the body. If you calculate the

effective dose for those folks you actually calculate the effective dose, it's probably less than a rem.

You have done the calculation. If they aren't wearing eye protection, side shields, the lens dose is going to be significantly greater.

If the lens dose number were smaller than the whole body number, you could have a situation where the lens dose would in fact be driving protection, which you intimated earlier.

We also have a case here where the effect, induction of the cataract, has been challenged by a number of folks as to the equivalency of that to cancer mortality, with a number of people saying lots of people get cataracts, a huge percentage of the population is going to have cataract surgery irrespective of radiation exposure -- my wife has a cataract slowing growing in her eye, we'll face that one of these days -- so why are we equating that, the same severity with cancer induction?

MEMBER ARMIJO: It's a good question. What's the answer?

MR. COOL: There was mixed feedback. Our answer back is we think there is a basis for reducing the limit. We are not convinced that reducing it to two is the right number.

We actually think it's probably five, to maintain a relationship between the number for the body, the effective dose, and the number for the lens of the eye. It's still a reduction by a factor of three. In fact the data that we have today says that there's only a few people that have ever gotten over five lens dose equivalent, even under today's regulations.

CHAIR RYAN: I think there's an interesting question in the rate of cataracts in the U.S. population. Many people don't get any radiation exposure and have cataracts, like probably most.

So I would suggest to you that there's something to think about, in that those radiation -- I mean, is the epidemiology sound enough to say it's causal for somebody that gets, pick a number of rem, you know, over their occupational lifetime up to the diagnosis of a cataract? I don't know.

MR. COOL: There have been challenges to some of the underlying science.

CHAIR RYAN: So I think --

MR. COOL: It's actually more mixed in this case than in some of the others. We had at least one group --

CHAIR RYAN: That being said, I think this

is one where caution and perhaps waiting might not be a bad idea. That's my own personal view.

MR. COOL: Our recommendation to the Commission is that we explore the implications of reducing it, that we are not locked down to a particular number yet. In fact, the staff would probably lean towards five rather than two, and continue to watch the ongoing development of some of this information and otherwise in order to put together an adequate regulatory basis for a proposal at some point.

CHAIR RYAN: Okay. I especially liked the last part, waiting for an appropriate basis.

MEMBER BLEY: And not to be flip about this, but they certainly aren't equivalent issues, and 40 years ago, maybe, getting cataracts was a horror, I just had my operation last year --

(Simultaneous speaking).

MEMBER BLEY: I think this is one where the impact on the individual I think has to be taken into account. If you've got a stomach cancer, you really are facing a lot of questions.

If you are -- you have got something that is relatively easy to fix, and has a low frequency to begin with, I'd almost ask the question why are you

messing with it, when there's other things on the priority scale that need time and attention and resources by comparison.

MEMBER ARMIJO: Don, do all the European countries in the nuclear industry, do they comply with this new view from ICRP on the cataract?

MR. COOL: I believe they are headed that direction, because they only came out last year. It's not in the current draft of the European basic safety standard directive.

It is in the approved version of the International Atomic Energy Agency basic safety standards.

MEMBER ARMIJO: IAEA --

MR. COOL: IAEA has adopted it.

MEMBER ARMIJO: It's not surprising, they're all UN organizations, right? So it would be --

MR. COOL: The EC would bristle at that but IAEA certainly --

MEMBER ARMIJO: Well, you know, it's consistency within an organization. I don't see anything really bad about it.

MR. COOL: So that is one that is -- this one, the lens of the eye, is one where we are right in

the same sort of adoption string as everyone else.

CHAIR RYAN: Press on.

MR. COOL: The embryo/fetus for an employed pregnant worker. ICRP's recommendation is now 100 millirem, one millisievert applied after declaration.

MEMBER SKILLMAN: That's versus 500 which is presently being --

MR. COOL: That's versus 500 which we have presently in our regulation, which applies over the entire gestation period. Now, the statements to ICRP's 103 were more the general ambition of the exposure should be roughly the same as the expectation for a member of the public. That's how you get to the 100 millirem sorts of level.

Over time it ranged from 200 millirem on the surface abdomen of the woman, plus a fraction for any internal intake --

CHAIR RYAN: Don, let me ask you a more fundamental question. Is it still true on the -- I know it is currently -- but will is still be true that a woman does not have to declare her pregnancy?

MR. COOL: Yes.

CHAIR RYAN: So this is solely to the discretion of the employee at this point, whether they

are going to take advantage of the different regulation --

MEMBER SKILLMAN: In all the plants its optional and she has to declare to be protected.

MR. COOL: That is correct. By law, it is the individual's choice. This is the only limit that is optional based on her choosing to do so, and in fact, that factors into our thinking a little bit. If the individual wants to choose protection, basically why is it that the regulation shouldn't provide explicitly the protection that is equivalent to the level for a member of the public?

Now, there are a number of things associated with the implications. We know that there are programs -- some of the nuc medicine groups -- that routinely and only do 200 or 300 millirem a year for their workers under most circumstances if there is no abnormal situation.

They simply haven't ever worried about if one of their workers is pregnant, declares or not, because they are never approaching 500. One hundred would put them in a situation where they would have to think about it.

You have a variety of other things here because this was one of the ones where the ICRP's

recommendation is after declaration. Well if she declares at week two, it's very different than if she declares at month seven, a huge difference.

In fact, when you look at this and you sort of lay out a matrix of the possibilities, in some cases, NRC's existing regulation today would be more protective, because it requires the licensee to go back and look at all of the exposure up to that point and specifies what is allowable after that -- 50 millirem if they have already exceeded the 500 millirem level at the time of declaration.

The ICRP recommendation would actually allow 100 in that case --

CHAIR RYAN: Well and that kind of flies in the face of radiation biology, because the period of most risk is the period when the woman --

(Simultaneous speaking)

CHAIR RYAN: So, you know, and I think that -- and as you go into the pregnancy more and more, the risk to the unborn fetus and the radiation injury risk goes dramatically down so --

MEMBER SKILLMAN: Well, and the policy that the stations normally say is pregnant or intends to become pregnant, so it catches that --

CHAIR RYAN: Well no, it doesn't. That's

a policy decision so if somebody intends to become pregnant, no, let's not even explore that, that would take too long. But you know, the point is, is that if we are dealing with a biological risk, the biological risk very quickly goes down.

Do you know, I just -- and I guess, in a way, 100, 200, whatever, is splitting hairs a little bit on this, and I don't know that 100 versus 500 is a big deal at all in this case.

MR. COOL: This is one area where that question perhaps is still open. In fact, we know that there is an NCRP draft report circulating which might not necessarily support all of this.

Our recommendation to the Commission at this point is to develop a basis for lowering it. You have as much perceptual and public confidence issues, and the protection if she chooses to declare.

CHAIR RYAN: And I think you know, we would probably offer a view that -- and I would suggest to the full Committee -- that we offer the view that you know, the period of most risk is the period before conception is even recognized --

MR. COOL: She may or may not know. It's eight to 15 weeks, which means starting the third month, to about the fifth month.

CHAIR RYAN: So, you know, it's --

MR. COOL: Lots of people don't know.

CHAIR RYAN: it's difficult to say, are we really accomplishing the goal, or has the risk already flown by us when we are cognizant of doing something?

MEMBER SCHULTZ: So then what is the proposal? Does it line up with this or is it different?

CHAIR RYAN: Well, the answer to that question, Steve, I think, has to come from what's the evidence of harm and to pregnant workers being exposed and what does the database tell us? Is there any risk? Have there been any increases in birth defects or you know, I mean, we have got to sort of see is there something we are really trying to prevent, or obviate here, and my view is the answer is probably not, at least statistically discernible data that is available.

So I think this is a real open question for me.

MEMBER SKILLMAN: There is another piece of this that has intrigued me for years. I have been party to meetings where the woman will communicate this part of the regulation is --

PARTICIPANT: Discriminatory, right?

MEMBER SKILLMAN: Singles her out for a decision that her male counterparts are not required to make, and therefore this becomes somewhat exclusionary or becomes some form of a problem for them.

And so there is another piece of this that is very, very delicate, but you know, when you say to an individual, if you want to be protected, you have got to come forward, that person can feel discriminated against.

CHAIR RYAN: Well, in part that's why the act of declaration part is in there because you don't have to declare it. They can be just exactly the same all through the pregnancy right up to the day they leave for maternity leave.

MEMBER SCHULTZ: So that is what I wanted to clarify. What I'm hearing you say is that the current approach is --

CHAIR RYAN: If the pregnancy is not declared, it's not regulated -- the worker is not regulated any different.

MEMBER SCHULTZ: Understood. So the current approach is not attractive. These --

CHAIR RYAN: Wait a minute, whoa whoa whoa, I didn't say it was not attractive. I said

that's the way it is and I think you're going to have it the same, right? You are going to keep it the same way, that it has to be after declaration?

MR. COOL: That legal question is not up for discussion. It's -- the question is -- the first issue is, does she declare. There's no mandatory think on it.

What is open, what we are suggesting to the Commission that we don't have a recommendation yet, is whether we do it the way ICRP did it and just apply that for declaration, or --

CHAIR RYAN: Don't declare it doesn't apply.

MR. COOL: That doesn't apply.

CHAIR RYAN: So that would be the option.

MR. COOL: If they do declare, it could apply after the declaration, which is what ICRP has recommended. We have had a number of people who said it should be the whole gestation period, just like your 500 now. And we do not have a basis for looking at that in terms of the implications and otherwise. That needs some more exploration.

We certainly have had some people who have suggested that this sort of thing, and getting specifically to your point Dr. Skillman, that such a

provision might unintentionally cause bias in the selection of individuals for medical programs or internships or otherwise.

Now I think that would be illegal.

CHAIR RYAN: Or employment.

MR. COOL: Or employment. I think that would be illegal in terms of Equal Opportunity and otherwise, but there has been that suggestion, that this poses one possible way that would be an unintended consequence. So, Vince?

MR. HOLOHAN: Just as an additional point here, keep in mind the basic question is, is do we treat the embryo/fetus as a member of the public, or not? The 500 millirem number was the public dose limit prior to 1990. Keep in mind, with the change in our regulations of Part 20, we changed the public doses but not the occupational doses. So the fetal dose never was reduced from 500 to 100.

Also keep in mind that children and embryo/fetus are considered more sensitive to radiation carcinogenesis induction than adults. Therefore the international push has been to reduce that exposure to the same as the public dose limit, or 100.

Now, several years ago the question was

1 should it be 100 millirem a year or during the period
2 of gestation, which would actually say it would be the
3 less than what the recommendations have been.
4 But that is where the clarification has
5 been coming out. With regards to whether or they can
6 declare, that goes back to Union Carbide, in a vinyl
7 chloride decision, where basically the court said you
8 cannot make a woman declare, period, and that is the
9 catch that we are in.
10 MEMBER ARMIJO: She can put herself and
11 her baby in danger if she so chooses. And this
12 provides no protection for the earliest stage of
13 development of the fetus.
14 CHAIR RYAN: Well, and practically
15 speaking Sam, for that very earliest stage, she's not
16 going to know she is pregnant at all, period.
17 MEMBER ARMIJO: And to get right back to
18 the thing there's some jobs that women of childbearing
19 age shouldn't be engaged in, if you are really --- if
20 this is a real --
21 CHAIR RYAN: Well, I guess I wouldn't go
22 that far. I would say that how do you evaluate and
23 measure and assess risk --
24 MEMBER SKILLMAN: I think this is one
25 where wisdom might prevail and you might say for a

woman who chooses to declare, she may choose 500 or 100. It's her choice, when she chooses to declare. And that way you preserve your 100 but to the -- perhaps the young mother who has never been through this before, that may give her the --

CHAIR RYAN: Well, I sure hope that if we allow that, we have a requirement that they understand radiation risk and radiation protection decision-making at a much higher level than they have been trained to in their rad worker training program.

MEMBER SKILLMAN: My only point is if you go from 500 to 100, there will be that population that says --

(Simultaneous speaking)

CHAIR RYAN: radiation exposure limit under any circumstance. It should be something that is done by the professionals and the regulators. It is what it is. Pick your own number ain't going to work.

MEMBER SCHULTZ: Then you force the person to make two choices --

(Simultaneous speaking)

MR. COOL: Quite frankly we have not considered optional numbers for her to choose. Her choice is the question of whether or not she declares.

In the staff's discussion it was pretty much, if she chooses to declare --

CHAIR RYAN: I must suggest we move on, Don, because we could spend the next hour on this one.

MEMBER ARMIJO: This could get into Roe v. Wade before we are over.

MR. COOL: So let's move on. The next issue that we discussed was the question on ALARA planning and I have already told you most if what was in this slide.

ICRP's Publication 103 provides added emphasis to optimization of ALARA, the consistent use of planning values, constraints or reference levels if it's an emergency or existing exposure situation.

So it was explored in detail about what it would be. People didn't like the word constraint. They didn't like the idea of the numeric number because there would be a limit, didn't like much any of it. It would be incredibly difficult to figure out how to even apply it to large segments of the licensee community which don't have the kind of programs that have all of the resources and levels of ability to add things.

Staff's recommendation is at this point to not do anything significant to the requirements for

ALARA.

CHAIR RYAN: Right, but I must say, that when you look at INPO's data and NEI's data and the utility industry, for one segment, they have done a fabulous job of reducing occupational radiation exposure. So -- and I know of other examples outside of the nuclear industry that have done similar work, so --

MEMBER RAY: Just don't do any maintenance at all and it will go to zero.

(Laughter)

CHAIR RYAN: That would create a new problem.

MEMBER RAY: It already has created problems, but anyway.

MEMBER SKILLMAN: That is the Davis-Besse -- that's exactly what that is.

MEMBER RAY: That is an extreme example, but it's happening every day in every plant today. We are taking great credit and celebrating it as you did, and they don't have any idea what's happening as a result.

CHAIR RYAN: Well, they shouldn't let it get to that extent, that's --

MEMBER RAY: Well, it is.

MR. COOL: So, let me move on to Dr. Ryan's most favorite topic. Again, the protection of the environment was actually not an issue that we explicitly put on the table with stakeholders at the beginning of the process because we had already made the statement that we did not believe that new standards were necessary.

ICRP has been working for quite some time now, developing an assessment framework that would allow you to look at the potential for impacts to other than humans in the environment, referencing --

CHAIR RYAN: Flora and fauna.

MEMBER ARMIJO: Flora and fauna, yes. Do they ever have a practical assessment of what that would do to anybody working in this --

MR. COOL: Well, there actually have been a number of assessments in various estuarine and in other environments where there are no humans. I know of several in the UK and otherwise.

The staff recommendation continues to be that the application of the program of radiation protection with licensees is doing the job. I t is in fact providing adequate protection for the environment as well. An assessment framework that is consistent could be very useful to prove it to people who don't

want to just accept it because we say it is, and that in fact is maybe one of its greatest virtues, is in NEPA analysis and other things, as another tool to provide more explicit demonstrations, rather than a categorical statement.

CHAIR RYAN: And there counter-examples of ecosystems where, when humans are removed, the ecosystems becomes fabulously healthy.

MEMBER ARMIJO: Chernobyl. I don't want to waste your time, but I was just shocked, a couple of nights ago I saw a PBS special on Chernobyl and wolf population research around Chernobyl.

First of all, it's a wildlife paradise. Every animal in Russia has returned to the Chernobyl area and this guy did a study of wolf populations in the very heavily contaminated area, and out, way outside in Belarus and the other -- Ukraine, I guess.

And it was amazing and it was a wonderful environment, and it concluded there is no, no difference. Healthy ecosystems in both areas. So you know --

MEMBER BLEY: It has no people, that tends to --

MEMBER ARMIJO: Yes, but of course -- but there were no people in the other area too, so it was

-- the only big difference was the Chernobyl contamination in that particular area, and it, it just said hey, the ecosystems are pretty, pretty resilient.

And so I don't know what ICRP is after, but that part of their work sure doesn't resonate.

MR. COOL: It is to fill in -- their words -- it is to fill the conceptual gap, and allow you to make a demonstration, for people who want a demonstration, as part of a tool set.

The kinds of levels at which the RAPs numbers would derive consideration reference levels of dose rate for different animals and plants at which there is some effect, are several orders of magnitude higher than the kinds of dose rates and activities at which you would exercise control going through the pathways to humans, and that has been shown in most all of the studies that have been done thus far.

But you are quite right. The environment is impacted most severely when a human shows up.

So let's move on to the next one. The units of exposure and dose activity. This is the question of the extent to which we encourage, push people towards use of the SI units, becquerels, and grays and sieverts, rather than curies and rads and rems.

Part 20 today is written in dual units with the special units first, rads/rems, with the SI in parentheses. In fact, subsequent to that, the NRC's metrication policy was established which actually says that the standard protocol should be for the SI unit to be listed first, and the special unit in parentheses.

So question one is do we move to the existing metrication policy, and look at the implications of that? Do we move yet further? The Health Physics Society has a very strong position statement that it put out just a couple of months ago saying strict use of SI, let's -- you are never going to do it unless you just decide you are going to do it. I'm summarizing it overly much.

CHAIR RYAN: Well said. I agree with it.

MR. COOL: It's that sort of issue. There are clearly implications of communication on both sides of the street. There are many who have been around for too long. Some of us have managed to become bilingual. Others simply refuse to. The young folks, younger folks, not trying to be age- or gender-specific there, will much more easily pick it up because it generally is what they are going to be trained to, if we could ever get them to the point

where they are actually allowed to use it.

And so the staff's recommendation at this point is to explore the implications of at least moving to the SI first, other things in parentheses. This is one where the work with states and the other federal agencies is as much, or more important as anything else, because we are only one of many in this field, in radiation protection, and we know we have states that have clearly said we don't want to go there, so this will not work unless it happens in toto and completeness.

CHAIR RYAN: So it looks like from your recommendation that we are going to kind of explore and watch and listen and not do much.

MR. COOL: And see where we can get. Correct. As I said, in the latest publication of the policy statement, which was 96 I believe, the paper has all of the citations, the Commission at the end of that actually made a statement that it did not plan to reopen the policy unless there was significant impact, issues that had been identified.

The question is whether the HPS statement and others now form a basis where there are enough implications that we should in fact reopen that, or not.

CHAIR RYAN: Okay.

MR. COOL: Reporting. There are seven categories that are required to report. The licensees in Agreement States, as we have already discussed, report according to the state requirements, which means there are some differences. You don't have state data in the database except for a few that are providing voluntary submissions. In the byproduct world, outside of the reactors, 80 plus percent of all the licensees are in the states. They are not ours. The percentage is even higher for things like industrial radiography, where the vast majority of all of the actual licensees, Texas, Louisiana, they are all Agreement State licensees, not NRC licensees.

And we have got some categories as I said that do not have to provide individual exposure data at all, period, all of the medical exposures and otherwise.

There are uses of a database and a national database that go beyond just a question of can we make an assessment of implications for some Part 30 revision. That certainly would not provide an adequate justification to go tossing on a requirement that wouldn't go into place until after the rule was done. But in fact being able to look at the

information, being able to go validate the question of whether the doctor in Fairfax might also be getting exposure in GW in D.C., a different licensee, different jurisdiction -- happens to be NRC in that case -- and who might also have practice privileges at the University of Maryland or something. Now, individuals are supposed to be providing their licensees with indications of other exposure that they maybe received, but there's nothing that necessarily provides you an independent way to verify things like that.

So there are a number of places where this could potentially be useful in inspection and enforcement and cooperation. So the staff is recommending that we look at the implications, impact f requiring a different -- additional categories. I didn't say everybody: we still don't think it makes sense for very small source users to have to provide reports -- and at the same time to explore would the states' mechanisms to increase the sharing of data so that action can be useful across jurisdictions for inspection, enforcement, validation purposes.

The states were actually quite supportive of that. I will tell you quite frankly, this is the place where I expect there to be an enormous uproar

raised. There is a reason that there is no reporting of medical.

I fully expect there to be a lot of pushback, and while the cost of providing a report is now very small -- it's all electronic transfer; it gets sent from the dosimetry processor to the licensee in electronic file, you push a couple of buttons and it can be automatically sent to the database, all electronic reporting, all of the record-keeping, all the systems are in place for protection of privacy data and otherwise -- even though that's a very small increment, when you add it over lots and lots of people, it still ends up being a rather large chunk of expended dollars associated with it.

MEMBER ARMIJO: Let's assume they started reporting, Don. What would you do with it or what would the NRC do with it, or the states do with that information? Is it for research, historical, for analysis or is it for some sort of an enforcement action, or what?

MR. COOL: All of the above. We would certainly be using it in research and reporting. Today we have a NUREG, I think Vince Holohan represented it a little bit earlier, where we provide the information out there.

As I noted, those groups that report are the groups that don't have that high tail. Now, that's an interesting correlation. I do not want to suggest it's actually causation. But in fact people don't like to have their categories to just show up in things like that, so there might be some forcing function there.

But there are also more routine uses in terms of backtracking and validating individuals who may be working in more than one facility, just as we talked about in the reactor community, who have their own system, and we can validate that because we can independently compare that data with the data that we have in REIRs, because they report to us. We don't have any way of going and doing that for other types of licensees, and we have no way of doing that across jurisdictions.

And industrial radiographers hop across state borders just as fast as everybody less. They can have temporary job sites in three states in two days. Not any difficult at all. So there are --

MEMBER RAY: Well, at least in the area of health care you are also coming in at a time when there's lots of pressure on healthcare reimbursement rates and things like that. So even though this

doesn't directly intersect with those things, if you are a practitioner, you see this is one --

MR. COOL: It's another cost.

MEMBER RAY: Well, cost, also it's one more constraint on your ability to generate revenue presumably.

MR. COOL: Correct. As I said, I expect this to receive a lot of external stakeholder feedback. Okay. Part 50, Appendix I. As I said, this is still based on ICRP 1 and 2. Licensees today have to file a set of reports related to Part 20 with one set of calculations. They have to file another report related to their effluents with an entirely different set of calculations.

The nuclear industry, NEI and others, have been asking us for some time to align them, to bring it up so they didn't have to go back and training HPs that they were getting out of college on how to do an MPC calculation for an environmental release.

So we are recommending that there be an effort in parallel, moved forward with Part 50 Appendix I, and that it be aligned methodologically with the basis for Part 20 so the demonstrations of compliance can use the exact same set of calculations.

You've only got one set of numbers and you

can explain that set of numbers, not why is this something different and otherwise, and that it run on on parallel tracks, because there are a bunch of other things, as I suspect you are well aware, related to Part 50 Appendix I, that do not actually hinge directly on the dose calculation methodology, which certainly warrant looking at, including the question of, well, that has a whole series of dose numbers. Do we simply make those effective dose numbers, or do we change them? Do we need them all, since you're now moving to effective dose, instead of individual organ doses? What do you do about multiple reactor sites, multiple reactors at a site, different sites?

There's been some issues that have been raised in various licensing hearings and adjudications related to that and a number of other things which do warrant looking at but which are not connected to the dose methodology, and it's for that reason that we are recommending that they run in parallel -- we want to keep them synchronized -- but that we don't try to do them as a single rule and encumber those discussions with Part 20 discussions or vice versa, because this is a whole set of things talking about radioactive material in the environment and it does very much engage a different segment of stakeholders.

So, the reactors and a bunch of other people are subject to protection under the backfit requirements. Part 20 applies to everybody. This will have to go through a backfit analysis and justification.

Some of these provisions, depending on what actually would become proposed, could be considered as redefinitions of adequate protection. If you change the dose limits, that probably qualifies.

At some point, I have even heard suggestions that changing the numbers of ALIs and DACs, the demonstration, could be considered as a redefinition. It wasn't changing the underlying basis but it reestablished the connection of what constitutes compliance at that particular point.

There are other things that we have talked about this morning that clearly are not adequate protection issues. Both quantitative and qualitative arguments will need to be examined in determining whether or not it can pass a backfit analysis.

In fact that is the same as the revision that was published in 1991 where the Commission in the end concluded that there was a substantial increase in the overall protection, based on both quantitative and

qualitative grounds. This is not one of those where you are going to be able to rack up dollars saved from dose against dollars expended for changes of procedures and otherwise and have them match out in some respect. There's a lot more considerations that have to play into this, and we have talked about a number of those.

Impact assessments. As I have mentioned several times, so now you have actually covered a lot of these sorts of things, we went out and looked for additional data. We got some, not a huge amount. I have already told you some of these statistics -- overexposure vents, the little blip that we have just had recently, which wouldn't be in that data --

CHAIR RYAN: Am I reading that right, Don, that you are going to update 6112?

MR. COOL: Yes.

CHAIR RYAN: Okay. Have you any idea on its appearance, when is it due or coming out or --

MR. COOL: Tony?

CHAIR RYAN: Roughly.

MR. HUFFERT: Hi, Tony Huffert, Office of Research. Our contract, we plan to have a report December 2012. We continue to get data and do a bunch of analysis on several fronts and we keep on getting

interim reports from them but the final will be ready, we hope, December 2012.

CHAIR RYAN: It might be helpful to think about -- not today -- but when the time comes to the Subcommittee, would be to maybe update a little bit, probably a little ahead of the final report, but somewhere later in the game, I'm guessing. Thank you.

MEMBER SKILLMAN: Hey, Don. For this spate of overexposures, the recent spate of overexposures, by chance was there a study or some examination made to find out what is the root cause? What comes to my mind is are we seeing a younger group of radiological protection workers who have not been as deeply steeped in some of the cardinal rules that the older rad protection people have been steeped in, and so in a way, we are losing our grip. Is there something like that playing in here?

MR. COOL: There, I believe, are some assessments to try and figure out what is going on, to look at the specifics of each case, because most of them are in Texas, and it's being done in the state, I can't -- I'm not in a position to comment at the moment.

I will note that I know that there has been research done by various groups that have looked

at the data, the number of events, the number of exposures over time, and that it does appear to be very cyclic with the level of activity in the industry and the number of new individuals in the industry.

The extent to which that is playing in these particular cases, I don't know. I know at least one of the cases was a person who was still a radiographer trainee. They had only been on the job a couple of months.

MEMBER SKILLMAN: Thank you.

CHAIR RYAN: Dick there is a very specific study on one industry segment in Texas, where new entrants' arrival for work has really resulted in a clear pattern. The younger the workforce, and the more cyclic the workforce, the more you end up with these kind of events, so --

MEMBER SKILLMAN: That makes you wonder, is it the new worker or the oversight of the new worker, to be in the control of the radiological controls program to prevent the exposure.

CHAIR RYAN: My reading of the article that was published on it was that it was basically the training of the new worker, because the oversight is about the same.

MEMBER SKILLMAN: Okay. Thank you.

CHAIR RYAN: In that particular case. So I mean It could be both, but there is a clear example there that I think that might have been the Texas one that you are referring to.

MEMBER SKILLMAN: There was a time when RadPro just absolutely laid down the law and you didn't get beyond the boundaries until you --

CHAIR RYAN: That's a power plant. This is not a power plant circumstance. Don't forget, this is over all licensees, this is a power plant.

MR. COOL: Radiographers are actually probably safer when they are up -- when they are working at a power plant than any other time because they have got the plant HP staff looking over their shoulder.

MEMBER SKILLMAN: Looking over their shoulder, yes.

MR. COOL: And I will also tell you that NEI and the various groups have been looking really closely because they have more problems associated when those radiographers come on site than they do have at any other time also.

MEMBER SKILLMAN: Yes, they are rule-benders, often.

MR. COOL: So, moving on, in addition to

1 looking at stuff here with another piece of contract
2 with the Nuclear Energy Agency in Paris, trying to get
3 some historical information on costs associated with
4 implementing ICRP 60, trying to take advantage of
5 anything we can learn from what other countries have
6 already done.
7 It's kind of interesting and a little bit
8 sad in one sense, there is little to none of real
9 quantitative data that is out there. Most of the
10 country did not have, at that time, may or may not
11 have now, the kinds of requirements for regulatory
12 analysis that we have here in terms of the
13 justification of the rules.
14 If you are a member of the European Union,
15 when the revision was made to the directive for the
16 basic safety standards, that became mandatory upon
17 each of the countries that are in the European Union
18 for transposition, as they put it.
19 It's not a question of whether or not they
20 are going to do it and whether it makes sense. It has
21 to be complied with. So a no action alternative was
22 essentially never looked at.
23 You get the general view back, do we think
24 it's been a good idea, most people have been able to
25 comply, it's worked pretty well for us. The most data

I think came from -- that had numerical dollar signs in it was associated with Canada and the UK.

What I found interesting there was at least half of the costs that they were talking about in that implementation was actually driven by post-September 11, 2001 security issues, and changes in cost of their regulation and licensees. It was a huge adder that came in at about the time that they were in fact bringing in an implementation of the 1990 recommendations.

Having gone through all of the technical issues, there are three policy directions that we have suggested to the Commission. Obviously the first one is status quo, no action. Beside that what we have got here is sufficient, it's adequately protective, there's no reason for us to worry about being on the current level of science and otherwise, we should just simply stay the course and do what we are doing today. People are being protected. The regulations in total are doing the job. No changes.

The second option is to develop the regulatory basis for a more limited revision that would look at the dosimetry methodology and terminology which a large percentage of the stakeholder population thought was something that we

should be doing. And in parallel, put that in when looking at a process to look at Part 50 Appendix I.

The third approach is to do that and to also go ahead and look at the regulatory basis for possible reductions of the limits, looking at the SI units reporting and another set of factors, which is sort of a third category.

Now, in theory, you could pick and choose amongst each of the technical issues, and in fact when we get all said and done, if we were to pursue option 3, it would be a picking and choosing of specifics that might actually come forward as you develop the technical basis and the regulatory analysis and all of those things.

That makes for a very unwieldy set of possibilities for the Commission so we have tried to keep it more straightforward: this do nothing; the set of things that all the stakeholders suggested; or the additional set, which is justified by the changes in risk level and that consistency and the additional consistency with other countries.

I will note that the staff's recommendation, while nothing that there are certainly qualitative benefits associated with aligning with the other countries and all the other things that they

have been doing and the movement of workers and otherwise, that we believe that there is a scientific risk basis for taking a look at further exploration of the technical basis of each of these areas. This is not simply a, we should do this because everybody else did. That is there, but that is not the reason for the recommendation.

We did have a discussion of resources. We are pumping not quite four FTEs right now into the Part 20 process that would continue over the next couple of years. If it moved to exploring the detailed options, that would require a lot of exploration and eventually rulemaking; not quite that much related to Part 50 at the moment, but that would also have to ramp up.

CHAIR RYAN: Taking the message that Part 60 -- 50 is out of scope today, you need money in addition to what you have now?

MR. COOL: The rest of Part 50 or just Part 50 Appendix I?

CHAIR RYAN: Well I mean you have got no dollar values for 20 rulemaking and you have got 60 and 60 for Part 50.

MR. COOL: Yes, and that is actually an artifact of the way we constructed the table. If you

look at the paper in its form, which has a -- this is taken from that enclosure, which is a couple of pages, we laid out the resources that were associated with the rulemaking itself. Separately, we have, from the materials users program, and the operating reactor program, 400,000 right now which is currently being pumped into work associated with the revision, much of that associated with funding Keith Eckerman --

CHAIR RYAN: Do you have a resource issue or not?

MR. COOL: Not at the moment.

CHAIR RYAN: Okay, good. That's what I needed to know.

MR. COOL: We have the resources budgeted to do that which we have suggested for the Commission over the next couple of years.

CHAIR RYAN: Okay.

MR. COOL: So, conclusions. We do have an inconsistent technical basis. The basis does not, in some cases, reflect our current estimates of risk. We do have some occupational exposures that are close to the existing limits and we have statements that indicate that may be the same set of people every single year. We do not have the data to be able to lay that out on a chart and show you exactly how many

and who is what.

We do believe that we have an appropriate and scientifically justified basis to make changes in a number of specific areas. If you are wondering why that little phrase, that is the phrase from the SRM where the Commission asked us to go make that determination.

We do believe that there is value in alignment with the international recommendations. It doesn't necessarily mean that that is the only reason for doing it. As I said, there are some qualitative benefits but each of the issues is justified on a technical and scientific rationale, as well as noting the alignment issues.

I think you asked a little bit earlier are you doing exactly what ICRP recommended, and the answer to that question is no on all three of them. In the case of the overall occupation exposure, we are suggesting a single value and a separate way of providing flexibility rather than an average.

With the lens of the eye, probably not even down to the two rem average value, perhaps a five, if that's where it turns up, on those issues associated with the comparability of the actions.

With embryo/fetus, the number is the same,

maybe it is after declaration, maybe not, there's still another set of things that has to be done there. So the staff is not recommending just go do what ICRP said. There are specifics associated with each one with what we believe should be explored in greater detail.

We believe that changing the limit is a much more straightforward approach than trying to write a very prescriptive ALARA program which wouldn't change the reactors one whit and would result in radiographers completely being unable to do such a thing because there are just not the kind of infrastructure resources and the sorts of approvals.

For just an aside at the moment, the Department of Energy, in the last couple of years, has completed rulemaking on their occupational exposure, 10 CFR 835. They chose to leave the dose limit at five rem.

Associated with that is their radiation control manual which is mandatory on all of their program. That has an administrative control level at two rem.

For anyone to be allowed an exposure greater than two rem, they have got to go to a headquarters deputy under secretary at least to

approve it. They don't have anybody over two rem but the dose limit itself is five.

That works okay in a program like that. It doesn't work in the commercial sector for small licensees. We looked at that. It just -- the model just doesn't make sense to us.

MEMBER RAY: Yes, ALARA is very hard to enforce also.

MR. COOL: What's really interesting is the citations on ALARA are not against Part 50. They are against the license conditions and the licensee commitments. They are not against the Part 20 regulations themselves, which was one of the reasons we looked at whether there should be some teeth so that the regulation was something that you would actually be able to cite against. We have decided that we don't believe you should go there at this time.

CHAIR RYAN: That is a tough way to go, too.

MR. COOL: It's a tough way to go.

CHAIR RYAN: In essence what you would be saying is by these measures or evidences, we have decided your program isn't working, which is -- that's a personal observation as much as it is --

MEMBER RAY: And you'd just fight endlessly.

CHAIR RYAN: Yes, it's a fight. That's right. I agree with Harold completely.

MR. COOL: And when it boiled down to it, when I asked myself the question, if I were standing out on the plaza and somebody said, "So, Dr. Cool, how do you know that that detail of the ALARA program that you just talked about is going to make sure that nobody gets over two rem?"

The answer is, "I don't."

Unless you make it a limit, you don't have any guarantee that the exposures would be less than the value. Just as simple as that.

There are a number of things that we would need to do, if the Commission approves, in order to develop the regulatory basis. This would be the point where we would start to look at specifics of what rule text might look like, and we all know that until you see it in writing, it's nice to write generalities and all of that, and you don't really get to the details of the -- exactly what it means.

What goes along with that is okay, that might be what the rule says, what are we going to expect in terms of the guidance? How would that be

implemented? And how would that be implemented for different categories of licensee?

Part of that is what we are proposing would be done over the next couple of years to develop the regulatory basis.

CHAIR RYAN: And as you have said well, the regulated community here is not just NRC licensees, but quite frankly in numbers it's the agreement states, which adds a whole other dimension to it all.

MR. COOL: That's correct. This would be the point where, within the rulemaking process, as we often do in rulemakings, there would actually start to be a working group which would actually explicitly include one or more members from state programs to help us work with that area.

The timing of this is -- driven is not the right word; held up might be the better word I suppose -- by the availability of the information of the dose coefficient to make any revision of Appendix B.

ICRP's information is going to come out in a total of five volumes, to be done by roughly the end of 2015. Volume 1 of their OI or Occupational Intake of radionuclides set of volumes is currently in public consultation now. It's a description methodology. It

doesn't have any of the numbers yet.

Two, three, four, five will be the sets of volumes that have all the different numbers. Volume 1 will have the most common ones.

CHAIR RYAN: Is Dr. Eckerman the one doing the work on all of that? Yes.

MR. COOL: Dr. Eckerman and others.

CHAIR RYAN: And others.

MR. COOL: Yes. So we are recommending that we use that time between now and the end of 2015 to continue to engage and really to be able to develop that detailed technical basis, so that we would actually have, at the end of 2015, a regulatory basis for a formal set of proposals with all the documentation that would be necessary, and to do the backfit that is associated with it.

We are recommending that the Commission approves the third option, which is to look at the technical basis for both the scientific information and the exploration of the regulatory basis for the reduction in limits, additional reporting and other activities, without -- or with clearly recognizing that this is not a final decision on a particular number, that all of that still hinges on developing the costs and impacts and specifics of regulatory

language and guidance which the staff would conduct.

We believe that this has to continue to involve all the stakeholders, just as we have to, up until this point, and yet more so, because now we'd be getting to the details.

As I said, it's all very easy in these sorts of meetings to talk in generalities. It gets much more interesting when you have a specific text on the screen or something like that.

And we have recommended that we move forward in the parallel effort which would be actually run by our Office of New Reactors to do an update on Part 50 Appendix I and we keep them connected in terms of the scientific underpinnings and deal with the individual issues on each site, keep them running along and saying that they would be driven by some of the same timing of the availability of dose coefficients, but could work all of their other issues.

With that, Mr. Chairman, I have done my set of slides and --

CHAIR RYAN: Well done I might say. I guess I'd like to go around, maybe start with Stephen Schultz.

MEMBER SCHULTZ: Just I guess an

administrative comment on that last slide where you were presenting the recommendation of the staff, the first bullet, "Staff recommends approval of option," it doesn't say option 3, and the rest of the text would apply to either option 2 or 3 so you may want to clarify that going forward.

MR. COOL: It's true, we didn't actually --

MEMBER SCHULTZ: But --

CHAIR RYAN: So just for the record, here, it is three.

MEMBER SCHULTZ: Okay. And it is on the record. I heard him say it. I thank you for the presentation. It was at a very good level, and quite detailed and very comprehensive to bring forward a number of points that you have been considering for some time and certainly worthy of our consideration as well.

And my only comment here would be I really appreciate what you said as -- and you have interacted with the stakeholders, so this leads you to it, I'm sure, the need for supporting the overall approaches that have been taken and will be taken with regard to being very clear with respect to communicating the why of these changes, why would the changes be made, what

is the basis for them, how are they developed, and so forth.

And in that regard, I would again come back to what I think is a very strong need to identify that the occupational limits utilized, linear no-threshold, to develop conservative occupational exposure limits, and that's how it's applied.

Below the occupational exposure limits, there has always been a tendency, and it goes to what Harold was saying, there has always been a tendency to say, well, since LNT was applied to derive the limits, it must certainly therefore be applicable below the limits. That is not true. We don't have scientific evidence to demonstrate that. And it would be very nice to be able to clarify that distinctly so that we have occupational limits that are conservatively developed on a basis of LNT.

But below that, we don't have evidence to do the types of things that have happened, drive the doses to zero or be concerned about the doses to drive them to zero, and as Mike said, the appropriate approach to take, is ALARA, as clearly defined as low as reasonably achievable. And so --

CHAIR RYAN: Emphasis on the R.

MEMBER SCHULTZ: if that could be just

.presented over and over and over again, I think it would help the case and would certainly help the understanding going forward, for the reasons you have described. Modifying the limits is a very practical approach to take moving forward.

MR. COOL: In fact, the individual limits, occupational or public, for any single year, are at ranges of dose where you do not have explicit demonstrations of what the harm is. You cannot detect it.

MEMBER SCHULTZ: That's right.

MR. COOL: The cumulative number, getting up to the 100, you are getting up to the cumulation where you then have some correlation of the radiation risk and effects. But the individual extrapolation is just that, an extrapolation, for the both the limits on occupational, embryo/fetus, public, all of those other sorts of things.

And what's interesting, and what many people, I'm not sure sort of fully grasp, ALARA really only works if you have a linearly based regulatory system such that there is some validity of the underlying assumption that you can add up each of those individual bits and pieces.

If you were to run -- let me make a

digression just a moment -- if you were to run a thing that said oh, well, perhaps there's a threshold down at one rem or two rem or something, the immediate implication of that in a regulatory program is that the total exposure for anybody on our control, has to be kept below the threshold. Period. End of discussion. All there is to it. And we would be immediately in a rather difficult situation because that would me that to do it right you would have to deal with all of your occupational exposure, you'd have to deal with the public exposure that the person gets when they go home, you'd have to know whether or not they had radon in their house or not and you'd have to know if they went to the doctor and got an x-ray.

CHAIR RYAN: Don't forget what location they live at.

MR. COOL: Because the total would have to be less than the threshold. That, if anything, would probably result in a more restrictive system, and it would be really complicated. But I agree with you completely, that underlying rationale, are we setting a regulation on a known effect? Absolutely not.

MEMBER SCHULTZ: Thank you. Good presentation.

CHAIR RYAN: Dick.

MEMBER SKILLMAN: Yes, thank you Don, for a very informative presentation. I have two comments . I believe that the benefit of transitioning to the SI units may be much greater than you have communicated here.

We have all been bathed in the Fukushima units. It's alive in everyones mind. Most of us have a chart that shows sieverts and rem or millirem or whatever it is. Most of us have now memorized the conversion so we are becoming bilingual as you and Mike Ryan speak. Bilingual.

But it seems to me that implementing and going to the SI units won't be a whole lot more difficult or will be equally as difficult as going to the Maintenance Rule. You simply say here it is, we are going to do it and here's the time frame.

And there will be some chatter and some pushback but you know what? That will fade quite quickly, and it probably brings to the table this notion that this international data, with these international units, and international science, now means something. As long as we stick with rem and rad and dose conversion factors and that type of thing, we are going to be stuck with what we have today.

So I am a proponent of going with the SI units. The second thing is the value of developing this regulatory basis to get 10 CFR 20, Appendix B and Appendix I to 10 CFR 50, on the same plane.

I think that has real benefit for the power users, for the 104 or 108 licenses that we are now dealing with. So I think that there is some real benefit to that. Thank you.

CHAIR RYAN: Thank you, Dick. Dennis

MEMBER BLEY: Don, I had a lot of questions when I came in, after reading this, and you have addressed essentially all of them. I think this is long overdue and I agree with what Dick said about the SI units. It's just time to stop the confusion and maybe buried in there somewhere must be a safety implication, but it's hard to hang on to, but once somebody makes a bad decision based on getting things mixed up, then we will have it, and I hate to wait for that. Thanks.

MEMBER RAY: I would, I think I have said all that I need to. I agree with the focus on the limits and not on programmatic rigor and efforts to impose -- use ALARA as a means of achieving what needs to be done, but rather the changing of the limits.

I hope what you are doing doesn't get hung

1 up in this area where you said there is going to be a
2 lot of pushback, because I believe there will be, and
3 that is from the effort to aggregate information that
4 is presently diffuse and not presently available, and
5 I think there is going to be a lot of reaction to
6 that. That doesn't involve anybody in the power
7 reactor community of course, it doesn't affect the,
8 but the people how you are going to be affecting will
9 see it as something to be opposed to, for a number of
10 reasons, and the balance should go on, if it has to,
11 without that being fully resolved I would think.
12 That's my two cents' worth. In other
13 words, I wouldn't want to see the value here held up
14 by some huge fight on Capitol Hill about whether --
15 because it is going to go to Capitol Hill, I would
16 guess, before it's done, and people will do their best
17 to try and prevent you from doing what you are
18 striving to do in that area.
19 CHAIR RYAN: Thanks, Hal. Don, thank you
20 very much and thanks to the other staff who are here
21 today for their participation and I think it has been
22 an excellent briefing to at least get the Subcommittee
23 started on thinking about this.
24 In thinking ahead to the full Committee I
25 guess the briefing will need to be a little bit

shorter because we will probably have no more than an hour, I would guess, for presentation and questions, so I would say 20 minutes/20 minutes isn't a bad split, but I think you will have no trouble getting the essence of what you have got here cut down to, you know really focus on the four or five key messages and the facts that support that.

Having some of the Subcommittee hear all of the details I think has been very helpful to allow us to then maybe chime in and offer our views while we are in the full Committee session.

MR. WIDMAYER: I think we asked for an hour and a half.

CHAIR RYAN: An hour and half, okay, well that's great. That should work pretty well, then. We have got an amount of time. And I would say no more than an hour for the presentation or maybe even a little bit less, and then the rest of the time for the questions because we will have all 15 of us there for that session.

I would also add my compliments to all of you, Don, for your work, and Tony and Vince as well for putting together what I think is a really good radiation protection strategy.

And I say that in the broad spectrum of

that kind of thinking, that you really are moving the ball forward here. We -- it seems like since I joined the health physics profession that there has always been an evolution of terms and terminology and units and everything else, and does anybody know what a REP is? A roentgen equivalent physical?

(No response)

But, so there's all sorts of evolution going on and I think Steve, you summarized it well, that we have got an opportunity to straighten out a lot of stuff, and we really ought to emphasize that success, because if we get this clarified and uniform, I think, then, the radiation protection practice not only in nuclear power but across the board, gets a little bit better and easier and clearer to do, and it's better for Agreement States ultimately, when they get it done, so there is a lot of advantages of moving the ball forward in the way we have talked about today.

So any other closing comments from staff or?

(No response)

CHAIR RYAN: All right. With that, any other comments from members or anything else?

(No response)

CHAIR RYAN: With that, I am going to adjourn the meeting and close the record here. Thank you all very much for your time and attention.

(Whereupon, at 11:41 a.m., the meeting was adjourned.)

SECY-12-XXXX

Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance

ACRS
April 27, 2012

Donald A. Cool, Ph.D.
Senior Advisor Radiation Safety and International Liaison

Outline of Paper

- SECY Paper
  - Background
  - Discussion of Stakeholder feedback and technical issues
  - Policy Options
  - Recommendations
- Enclosures
  1. Radiation Risk
  2. Summary of Stakeholder Interactions
  3. Assessment of Technical Issues and Feedback
  4. Examination of National and International Impacts
  5. Resource Estimates

Purpose

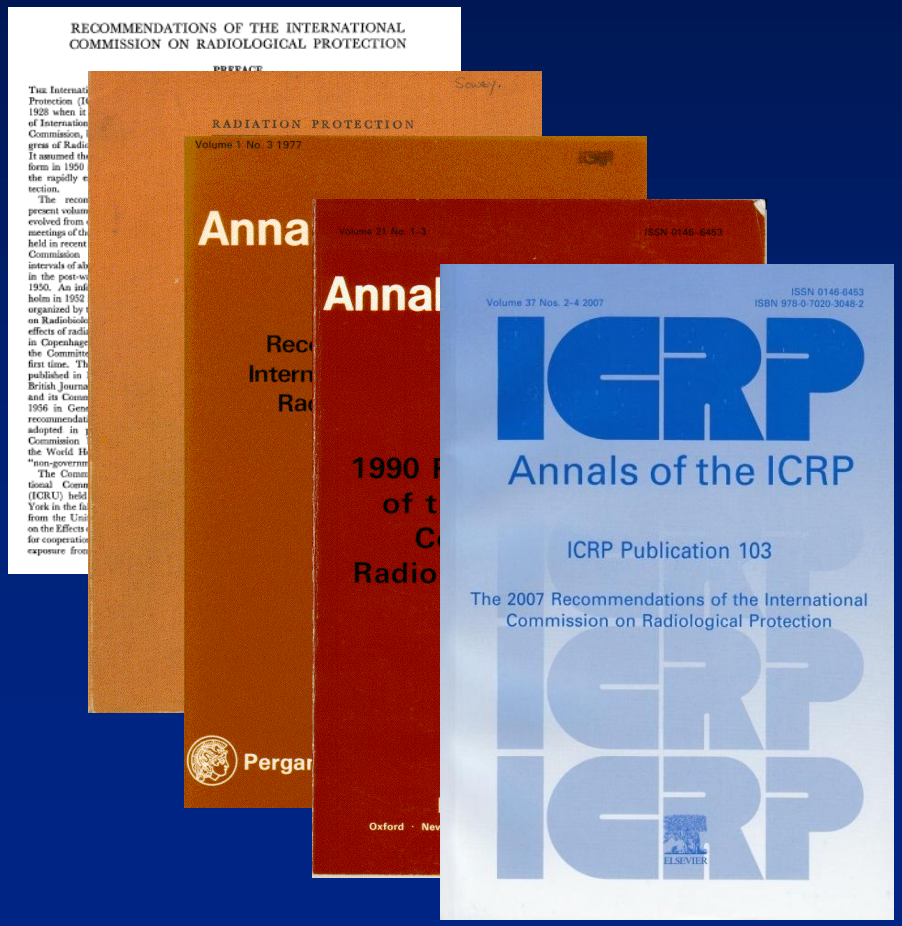
- Summarize staff's interactions with stakeholders
- Request approval of recommendations for policy and technical directions for further development of a detailed regulatory basis
- Request approval to develop regulatory basis for 10 CFR Part 50, Appendix I in parallel with 10 CFR Part 20

Summary of Recommendations

- Update scientific information and models
- Update terminology
- Reduce Occupational TEDE limit
- Reduce Occupational LDE limit
- Reduce Occupational Embryo/Fetus limit
- Explore increased use of SI
- Explore adding categories of licensees reporting annual occupational exposures
- Align 10 CFR Part 50, Appendix I to updated scientific and terminology

History of ICRP Recommendations

- International Commission on Radiological Protection (ICRP) Recommendations
  - Earlier recommendations: 1928, 1934, 1937, 1950, 1954
  - 1959 Publication 2
  - 1977 Publication 26
  - 1990 Publication 60
  - 2007 Publication 103



U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

Background

- ICRP revised recommendations announced in December, 2007
- NRC staff analysis indicated areas warranting consideration for revisions – SECY-08-0197, December, 2008
- Commission approved staff recommendation to engage stakeholders and initiate development of technical basis materials on April 2, 2009

Outreach Activities

- Phase I of outreach included:
  - Presentations to numerous organizations and groups
  - FRN published inviting inputs (72 FR 32198)
- Phase II Workshops
  - FRN published with issues and questions (75 FR 59160)
  - Workshops in Washington, Los Angeles, and Houston
  - Comments accepted through January 31, 2011
- Phase III
  - FRN published for lens of the eye (76 FR 53847)
  - FRN closed October 31, 2011
- Still accepting comments if submitted

Stakeholder Dialogue

- Total of 59 comments docketed
- General support for changes to reflect current dose calculation methodology and terminology
- Opposition to changes to dose limits and ALARA provisions
  - View that risk did not warrant changes
  - View that impacts would be unacceptable
  - View that sources and uses in US are different, and justify different limits

Radiation Risk

- Current basis supporting NRC regulations is a mixture of risk information ranging from 1958 to 1990
- 10 CFR Part 20 based on assumed risk of 1.25×10^{-4} per rem cancer mortality and risk of heritable disease
- Current radiation risk ≈ 5×10^{-4} per rem
  - Considered mortality, morbidity and hereditary effects
  - Comparable results from UNSCEAR, ICRP, BEIR, NCRP
  - EPA "Blue Book" values even higher
- LNT for practical purposes of radiation protection

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Methodology Basis

- 10 CFR Part 50, Appendix I based on ICRP 1 and 2 MPC critical organ approach
- 10 CFR Part 20
  - Generally based on ICRP 26 and 30 TEDE approach
  - Public Exposure aligned to newer recommendations and increased risk in final rule
  - Occupational Exposure not aligned in final rule
- Licensees granted use of ICRP 60+ approach on case by case basis for internal dosimetry
- Effective dose recognized for external exposure

Basis for Occupational Limits

- 1977
  - average annual risk of accidental death in industries generally accepted as safe working environment – 1×10^{-4}
  - 5 rem value based on expectation that most individuals would be unlikely to exceed 1 rem
- 1990
  - Multi-attribute approach
  - Objective to prevent cumulative exposure to less than 100 rem
  - Average and maximum values to provide flexibility for implementation

Update Dose Assessment Methods

- General support for moving to consistently incorporate latest scientific information and modeling.
- Stakeholders supported delaying rulemaking until ICRP completes work on dose coefficients
- Staff Recommendation:
  - Adopt updated methodologies and models
  - Continue with Appendix B in rule for ALI and DAC
  - Use updated methods for 10 CFR Part 50, Appendix I, and other portions of the regulations to establish new consistent basis

Revise Terminology

- Changes in methodology resulted in changes in Terminology in 1990
- Stakeholders supported changes, but noted impacts in updating procedures, records, reports, and training
- Staff Recommendation:
  - Develop Regulatory Basis to incorporate updated terminology.
  - Explore options to provide flexibility during implementation

Occupational TEDE Limit

- Limit does not reflect current risk basis
- Individuals continue to receive exposure above 2 rem (20 mSv/yr)
- Exposures near limit could exceed recommended cumulative total
- Flexibility only needed for some licensees and small groups of individuals
- Differences present complications to trans-boundary movement of workers
- Changing limit is most straight forward performance based approach for elimination individual exposures that are above recommended values

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Occupational TEDE Limit

- **Stakeholder Feedback:**
  - **Little support for change to regulation**
  - **Suggestions of significant impact on licensed activities and delivery of health care**
  - **Suggestions that there could be an increase in the rate of non-compliance**
  - **Statements that sources and uses in U.S. are basis for having different dose limits**

Occupational TEDE Limit

- **Staff Recommendation:**
  - **Level of adequate protection is independent of source size or types of uses**
  - **Develop regulatory basis for reducing limit to 2 rem (20 mSv/yr)**
  - **Explore mechanism for flexibility for those licensees who need it through specified approval process**

Lens of the Eye

- ICRP recommendation issued April, 2011
- Reduced limit based on evidence that radiation induces cataracts at lower cumulative levels than previously estimated (≈ 50 rem (500 mSv)).
- TEDE and LDE similar in many situations except
  - Shielding of body
  - Lower energy β/γ
- Significant impacts in interventional radiology and cardiology

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Lens of the Eye

- **Mixed Stakeholder Feedback:**
  - **Scientific information questioned**
  - **Concern about values less than TEDE**
  - **Concern about type of effect**
- **Staff Recommendation:**
  - **Develop regulatory basis for reducing limit**
  - **Consider single values of 5 rem (50 mSv) or 2 rem (20 mSv)**
  - **Continue dialogue on how prevention of cataracts should be viewed in comparison with the potential induction of cancer**

Embryo/Fetus

- ICRP recommendation of 100 mrem (1 mSv) applied after declaration
- Mixed feedback from stakeholders
- In many cases, accommodation results in no additional exposure after declaration
- Potential concern (medical) that lower value might result in decision to not declare
- Staff Recommendation:
  - Develop regulatory basis for reducing limit to 100 mrem
  - Consider options of applying over entire gestation period, or only after declaration

ALARA Planning

- ICRP added emphasis to consistent use of optimization and use of constraints
- Proposals to add requirements for ALARA planning to reduce highest individual exposures, instead of changing limits
- Opposition to term constraints
- Opposition to numeric value because it would be perceived to be a limit
- Staff Recommendation:
  - No significant change in rule text
  - Explore guidance to provide additional examples of acceptable mechanisms and programs

Protection of the Environment

- ICRP work continues on framework for assessment of exposures in the environment
- Staff Recommendation:
  - No additional requirements needed
  - Assessment framework may be useful to provide validated approaches for use within NEPA
  - Continue to monitor international developments

Units of Exposure and Dose

- Issue raised by stakeholders to move to SI units (Becquerel, Gray, Sievert)
- HPS position statement in February, 2012
- Current metrication policy states preference for SI units first, with special units in parenthetical
- Staff Recommendation:
  - Explore implications, benefits, and costs of aligning with metrication policy
  - Close interactions needed with other Federal Agencies and States

Reporting of Occupational Dose

- Seven categories required to report individual occupational doses
- Licensees in Agreement States report as required by the State
- State data not in NRC database except for some voluntary submissions
- Some categories of licensed use (e.g. medical) do not report
- Database useful for assessment of impacts, inspection and enforcement, dose to an individual from multiple licensees.

Reporting of Occupational Dose

- **Staff Recommendation:**
  - **Explore implications, benefits, and costs of requiring additional categories to report**
  - **Explore mechanisms to increase sharing of data between NRC and States to move towards national database**

10 CFR Part 50, Appendix I

- Methodology still based on ICRP 1 and 2
- Compliance calculations different for 10 CFR Part 20 and 10 CFR part 50
- Stakeholder encouragement to update and align dose calculation methodologies
- Staff Recommendation:
  - Initiate development of Regulatory basis for revision using updated methodology
  - Pursue rulemaking on parallel track with changes to 10 CFR Part 20

Backfit Considerations

- 10 CFR Part 20 applies to all licensees, including those protected by various backfitting provisions
- Some provisions could be considered as redefinitions of adequate protection
- Other provisions would require assessment of benefits and impacts
- Both Quantitative and Qualitative arguments will be important in analysis
- Previous revision in 1991 concluded final rule provided a substantial increase in overall protection of public health and safety based on both quantitative and qualitative grounds

Impacts Assessments

- Solicitation of voluntary data to assess impacts for various industrial and medical uses
  - Limited additional data
  - 21 TEDE overexposure events 1994 – 2010
  - 99.7% of individuals were below 2 rem in 2010
  - 75% of individuals exceeding 2 rem were reported from industrial radiography licensees
- Staff work to update NUREG/CR-6112

Impacts Assessments

- **Staff work with NEA for historical information on costs and impacts of implementing ICRP 60**
  - **Little quantitative data available**
  - **No survey participants evaluated a no action alternative**
  - **Survey participants believes move to adopt ICRP recommendations was generally beneficial**

Policy Direction Options

- No Action
- Develop Regulatory Basis for Limited Revision of 10 CFR Part 20 dosimetry methodology and terminology, with parallel alignment for 10 CFR Part 50, Appendix I
- Develop Regulatory Basis for dosimetry methodology, terminology, reduction in dose limits, with parallel alignment for 10 CFR Part 50, Appendix I

Rulemaking Resources

Business Line	Part 20 Rulemaking				Part 50 Rulemaking			
	FY 2012		FY 2013		FY 2012		FY 2013	
	FTE	$k	FTE	$k	FTE	$k	FTE	$k
Materials Users	1.0	0	1.0	0	0	0	0	0
D&LLW	0.4	0	0.4	0	0	0	0	0
New Reactors	0	0	0	0	1.6	60	1.5	60
Operating Reactors	2.1	0	2.1	0	0.2	0	0.2	0
Corporate Support	0.3	0	0.1	0	0.2	0	0.2	0
TOTAL	3.8	0	3.6	0	2.0	60	1.9	60

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Conclusions

- Current regulations have inconsistent technical basis, and do not, in part, reflect current assessment of radiation risk
- Occupational exposures at levels close to existing limits could result in accumulated exposures that may pose a potential to exceed recommended cumulative dose recommendations
- Appropriate and scientifically justified changes should be made in a number of specific areas

Conclusions

- Increased alignment with international recommendations, and the standards used in other countries, have qualitative benefits, but each technical issue is justified by technical and scientific rationale
- A change to limits is a more straight forward, performance based approach than additions to ALARA program requirements

Conclusions

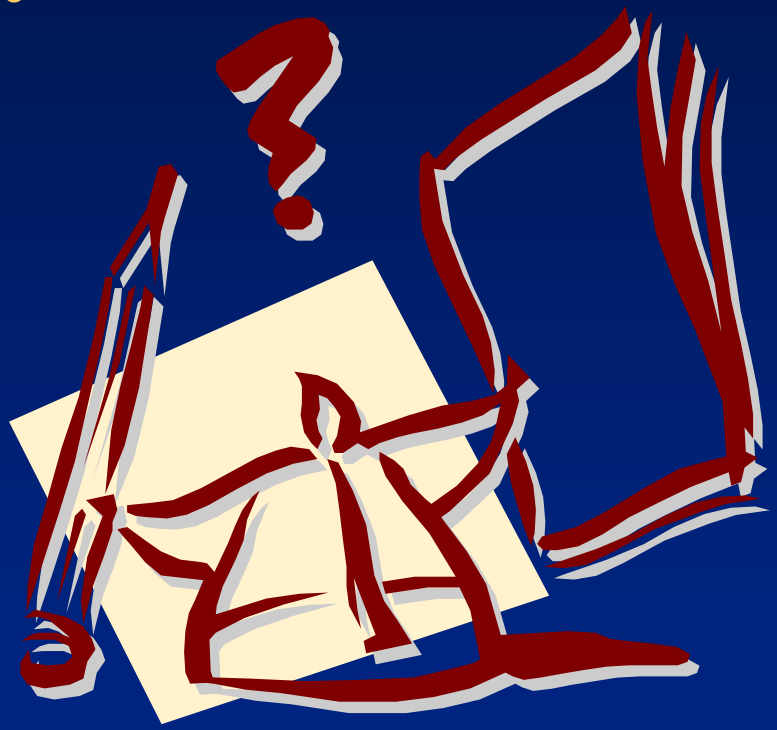
- Additional efforts needed to develop regulatory basis for a proposed rule
  - Explore possible draft rule text
  - Explore possible guidance for implementation
  - Dose coefficients needed before Appendix B values can be revised
  - Detailed cost-benefit information needed for specific proposals
- Rulemaking would require backfit justification on both quantitative and qualitative grounds

Staff Recommendation

- Staff recommends approval of option to continue development of regulatory basis using recommended direction for each technical issue
- Staff recommends stakeholder outreach and participation on possible rule text, guidance, benefits, and impacts
- Staff recommends parallel regulatory basis development for proposed rules for 10 CFR Part 20 and 10 CFR Part 50, Appendix I

Questions?

Questions?



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